ACCU-CHEK Aviva Combo

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ACCU-CHEK®
Aviva Combo

BLOOD SUGAR METER

Standard Owner's Booklet

Roche

Aspects of the ACCU-CHEK Aviva Combo system, including the meter, code key, and test strips, and their use, are covered by one or more of the following United States patents: 5,352,351; 4,999,582; 5,997,817; 5,053,199; Re. 36,268; 5,438,271; 5,366,609; 6,645,368; 6,662,439; 5,122,244; 7,073,246; 7,276,146; 7,276,147; 7,338,639; 7,386,937; 7,407,811; 7,452,457; 7,488,601; 7,494,816; 7,556,723; 7,569,126. Additional United States Patents pending.

The ACCU-CHEK Multiclix device and its use are covered by the following U.S. patents: 4,924,879; Re. 35,803; 6,419,661. Additional U.S. patents pending.

LAST UPDATE: 2009-08

Before You Start Testing

About the meter and test strips

- Carefully read and follow the instructions in the Getting Started Guide, the Standard Owner's Booklet, the Advanced Owner's Booklet, and Package Inserts for the test strips and control solutions. Not following the instructions may lead to a wrong result or improper treatment, causing you health problems.
- Set the time and date on your meter before you begin testing.
- Inspect the test strip container before using the test strips for the first time. If you see any damage to the container cap or if anything prevents the cap from closing properly, do not use the test strips. Contact ACCU-CHEK Pump Support at 1-800-688-4578. Damaged test strips can cause inaccurate results, which could lead to improper treatment.
- Carefully dispose of used test strips and lancets.
- Home use of the ACCU-CHEK Aviva Combo system is limited to capillary whole blood testing.

About Your New Meter

- The meter is designed and can be used for testing fresh capillary whole blood samples (for example, blood from a fingertip or forearm).
- Only use ACCU-CHEK Aviva test strips. Other test strips will give inaccurate results.
- Although you always apply whole blood to the test strip, the system has been calibrated to deliver plasma-like values for easier comparison to lab results.
- The meter, test strips, and control solution are only for use outside the body (in vitro). Do not eat the test strips. Do not swallow or inject the control solution, or use the control solution for any purpose other than testing the ACCU-CHEK Aviva Combo system.

About Testing Yourself or Others

⚠ WARNING:

Certain substances can interfere with the ACCU-CHEK Aviva Combo blood glucose system and cause falsely high results. For example, peritoneal dialysis solutions containing icodextrin (such as Extraneal) or certain immunoglobulin therapies that contain maltose (such as Octagam 5 %) cause inaccurate results. For more information, refer to the Test Strip Package Insert or ask your healthcare professional.

- If you are very dehydrated or urinating frequently, you may get an inaccurate test result. If you think you are dehydrated, call your healthcare professional right away.
- Some people with diabetes do not experience symptoms of low blood sugar (hypoglycemia). Others, such as children or people who are unconscious or have certain disabilities, may not be able to communicate their symptoms to caregivers. For these reasons, do not change any treatment without first talking to a healthcare professional.
- Run a control test when you open a new box of test strips or if you think that your test result is incorrect. Running a control test lets you know that the meter and test strips are working properly.

- Refer to the Test Strip and Control Solution Package Inserts for additional health-related information.
- It is always a good idea to have a back-up testing method available. Failure to test could cause a delay in treatment decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter or testing by a lab. Ask your healthcare professional or pharmacist about other possible back-up methods.

DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.

If your blood sugar result doesn't match how you feel and you have followed the instructions in your owner's booklets, follow your healthcare professional's instructions or call your healthcare professional.

Special Information to Consider When Using This Meter

- Do not use this device to measure blood sugar if you or a person to whom you are providing care is experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Consult your healthcare professional to determine if it is appropriate for your child to be taught how to use the meter system or any other medical products.

Contents

Introduction

Whether the ACCU-CHEK Aviva Combo meter is your first blood sugar meter or you have used a meter for some time, please take the time to read the Getting Started Guide, the Standard Owner's Booklet, and the Advanced Owner's Booklet carefully before you use your new meter. To use it correctly and dependably, you need to understand its operation, screen displays, and all individual features.

Your new meter includes three booklets:

- Getting Started Guide:
  Use this booklet to set up the meter.
- Standard Owner's Booklet:
  Use this booklet for instructions on how to operate the standard features of the meter.
- Advanced Owner's Booklet:
  Use this booklet for instructions on how to operate the advanced features of the meter.

Should you have any questions, please contact one of our customer support and service centers. A listing is at the back of this booklet.

This booklet includes information about:

- Understanding your new ACCU-CHEK Aviva Combo system
- Coding the meter
- Testing your blood sugar
- Control testing
- Managing your data
- Changing the meter settings
- Understanding the icons, reminders, warnings, and errors
- Care and maintenance
- Troubleshooting
- Technical information

If you have questions, we are here to help. Just call ACCU-CHEK Pump Support at 1-800-688-4578. You can also visit www.ACCU-CHEK.com for diabetes management tools.

The ACCU-CHEK Aviva Combo System

The ACCU-CHEK Aviva Combo meter is for quantitative blood sugar testing using ACCU-CHEK Aviva test strips. The meter has many features including:

- Controlling your ACCU-CHEK Spirit Combo pump
- Administering a bolus
- Bolus advice
- Daily time blocks that can be adjusted to fit your lifestyle
- Data management
- Data transfer
- Date reminders
- bG test reminders: Alarm clock, Target bG levels, and Health events
- An electronic diary that allows you to enter meal time, carbs, health, and bolus information with your blood sugar test results

For detailed information about the features of the meter, see Chapter 1, “Understanding Your New System.”

NOTE:

Blood sugar and bG are interchangeable and mean the same thing.

Intended Use

The ACCU-CHEK Aviva Combo blood glucose monitoring system is intended for the quantitative measurement of blood glucose. The ACCU-CHEK Aviva Combo system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes and/or by professionals in a clinical setting as an aid to effective diabetes management. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

The ACCU-CHEK Aviva Combo meter can also be used to interface with and remotely control compatible ACCU-CHEK insulin infusion pumps via *Bluetooth* wireless technology (radio frequency communication).

The ACCU-CHEK Aviva Combo meter is also indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data.

The system includes:

- **ACCU-CHEK Aviva Combo meter with three AAA batteries (already inserted)**
- **ACCU-CHEK Aviva test strips and code key**
- **ACCU-CHEK Aviva control solution**

> ⚠ **WARNING:**
>
> 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 – Third Edition; CLSI document M29-A3, 2005).

Why Regular Blood Sugar Testing Is Important

Testing your blood sugar regularly can make a big difference in how you manage your diabetes every day. Discussing your results with your healthcare professionals and following their advice about medicine, exercise, and food plans can help you better control your diabetes.

Important Information About Your New Meter

- The meter is designed for testing fresh whole blood samples (for example, blood from your fingertip or forearm). The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- This meter requires ACCU-CHEK Aviva test strips. Other test strips will give inaccurate results.
- The meter comes with the time and date preset. You may need to change the time to your time zone.
- If you have followed the steps in this booklet but still have symptoms that do not seem to match your test results, or if you have questions, talk to your healthcare professional.

1 Understanding Your New System

1.1 Overview

Your new meter has several features to assist you in managing your diabetes. It is important you understand the features and how to operate the meter correctly.

NOTES:

- This booklet shows sample screens. The screens in this booklet may look slightly different from the screens on the meter. If you have any questions about the meter screens, contact ACCU-CHEK Pump Support at 1-800-688-4578.
- On the meter display, the code chip is referred to as a code key. Code key and code chip are interchangeable and mean the same thing.
- Blood sugar and bG are interchangeable and mean the same thing.

1.2 The ACCU-CHEK Aviva Combo Meter at a Glance

Display
Shows menus, results, messages, and data stored in the diary.

Buttons
Press to enter menus or the diary, adjust settings, and scroll through results.

Left/Right Soft Keys
Press to select the menu or option above the key.

Power On/Off Button
Turns the meter on or off.

Test Strip Slot
Insert golden end of test strip here.

Backlight Button
Press to adjust the backlight level.

Infrared (IR) Window
Transfers data from the meter to a computer.

Code Key Slot
Insert code key here with code number facing away from you.

Battery Door
Remove the battery door by pushing the tab and pulling the door up.

Top View
Infrared (IR) Window

Code Key
(for example)

Batteries
Insert batteries according to the + and - symbols in the battery compartment.

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

Golden End - Insert this end of the test strip into the meter.

Test Strip Container
(for example)

Control Solution Bottle
(for example)

The meter has seven buttons and two soft keys.

NOTES:

- You hear a sound every time an active button/soft key is pressed unless you turned off the key sound.
- Press ⏻ or insert a test strip to turn on the meter. If the meter displays the Time/Date screen, make the necessary changes and press ↵.

Table of Buttons and Soft Keys

Button	Name	Function
	Left Arrow	▸ Move or scroll to the left in a screen.
	Right Arrow	▸ Move or scroll to the right in a screen.
	Up Arrow	▸ Move or scroll up in a screen.
	Down Arrow	▸ Move or scroll down in a screen.
	Left Soft Key	▸ Select the option above the key on the display.
	Right Soft Key	▸ Select the option above the key on the display.
	Enter	▸ Select a menu or option. ▸ Save changes and exit the entry field.
	Backlight	▸ Adjust the backlight level (low, medium, high). ▸ From the Bluetooth screen, press and hold ☼ to turn *Bluetooth* wireless technology on and off.
	Power On/Off	▸ Turn the meter on and off.

Table of Button Combinations

Button Combination	Name	Function
When the buttons are locked, press and hold and until the Main Menu appears.	Unlock Keys	▸ Unlocks the buttons.
With the meter turned off, press and hold and then press .	Meter/Pump Pairing	▸ Begins meter and pump pairing.

1.3 The ACCU-CHEK Spirit Combo Insulin Pump at a Glance

Menu Key
Cycles through menus, functions, and information screens.

OK Key
Selects current settings displayed on screen, saves changes, exits a screen, and allows the user to view the QUICK INFO screen.

Display
Shows menus, messages, and data stored in the pump memory.

Cartridge
Holds insulin.

Adapter
Connects the cartridge to the infusion set.

Up Key
Moves forward in an information screen, increases a setting, turns on the backlight, programs a Quick Bolus, cancels a Quick Bolus, and turns off the STOP-Warning.

Down Key
Moves backward in an information screen, decreases a setting, programs a Quick Bolus, cancels a Quick Bolus, and turns off the STOP-Warning.

Infusion Set
Connects the pump to your body to deliver insulin.

For information about the pump, see the ACCU-CHEK Spirit Combo Insulin Pump User Guide.

1.4 Summary of Features

Display

The meter has a full-color graphic LCD (Liquid Crystal Display) that displays current and historical information.

Backlight

- The backlight helps you read the information on the meter display under different lighting conditions.
- When the meter is turned on, the backlight is set to the medium level.
- Adjust the backlight level by pressing and releasing the backlight button.
- The backlight adjusts from low, to medium, to high, and back to low again.
- If set to the medium or high level and the buttons are not pressed for about 15 seconds, the backlight returns to the low level to save power.
- When the meter returns to the low level, pressing any button restores the previous backlight level.
- For more information about backlight settings, see Chapter 5, “Changing Meter Settings.”
- For more about power-saving tips, see Chapter 7, “Care and Maintenance.”

Key Lock

- The key lock feature allows you to lock all of the buttons on the meter, except for the power on/off button.
- The key lock serves as a safety measure against unintentional activation of meter functions.
- For more information, see Chapter 5, “Changing Meter Settings.”

Signal Settings

- The meter communicates reminders, warnings, and errors using sounds and vibrations.
- For more information, see Chapter 6, “Icons, Reminders, Warnings, and Errors.”

Blood Sugar Test

Your new meter allows you to enter detailed information for each blood sugar test to include:

- Meal time (pre-meal, post-meal, bedtime, or other)
- Carbs (the amount of carbohydrates you are intending to eat)
- Health events (fasting, exercise 1, stress, illness, exercise 2, or premenstrual).

If bolus advice is set up on the meter and the meter recently communicated with the pump, the amount of active insulin is displayed on the detailed bG Result screen.

Bolus Advice (Optional)

- The term “bolus” refers to the delivery of insulin all at once rather than slowly throughout the day, usually used to compensate for meals or high blood sugar.
- Bolus advice calculates a bolus for you that is adapted to the time of day and your changing situations.
- This function is activated only if you set up bolus advice on the meter.
- For instructions on how to set up bolus advice, see Chapter 5, “Changing Meter Settings.”

> ⚠ **WARNING:**
>
> Before setting up bolus advice, it is very important to read all of the safety information in the Advanced Owner’s Booklet and talk to your healthcare professional.

Using the Meter with the Pump

- The meter can communicate with and remotely control your pump.
- Pump information is automatically downloaded to the meter when *Bluetooth* wireless technology is activated.
- The meter must be paired with the pump.
- For more information, see the Advanced Owner’s Booklet.

Administering a Bolus

Using your new meter, you can deliver a bolus:

- Remotely on your pump using *Bluetooth* wireless technology
- Using the bolus advice feature of the meter
- Independently on your pump
- Using an insulin pen or syringe

My Data

- Your new meter stores 1,000 records in the diary.
- You can view, modify, or add information to your diary.
- You can view blood sugar test averages, trends, standard day, standard week, and target tables and graphs of the data in the diary.
- You can view the data in graph or table format for the last 7, 14, 30, 60, or 90 days.
- For more information, see Chapter 4, “Managing Your Data.”

Data Transfer

- You can transfer your data stored on the meter to a computer.
- For more information, see Chapter 4, “Managing Your Data.”

Warning Limits for Hypo and Hyper Blood Sugar Levels

- You can select hypo (low) and hyper (high) blood sugar limits that best fit your needs. Whenever a blood sugar test result is above or below this range, the meter displays a warning.
- In addition, Trend Graph screens indicate the hypo warning limit when displaying your blood sugar test results. For more information, see Chapter 4, “Managing Your Data.”
- The meter has default warning limits that can be adjusted. For more information, see Chapter 5, “Changing Meter Settings.”

Time Blocks

- Time blocks allow you to divide a day into different time periods.
- Setting time blocks to fit your own schedule helps you and your healthcare professional see how patterns in your blood sugar are affected by your daily activities and lifestyle.
- Time blocks can be set up with or without bolus advice.
- Talk to your healthcare professional about the best way to set up your time blocks to assist you in managing your diabetes.
- The meter has five default time blocks.
- You may set up to eight time blocks.
- For more information, see Chapter 5, “Changing Meter Settings.”

Without bolus advice, you need to consider the following when setting up time blocks:

- Determine the appropriate time range by reviewing the end time for each time block.
- Review the acceptable blood sugar target range (low and high) for each time block.

With bolus advice, you need to consider the following when setting up time blocks:

- Determine the appropriate time range by reviewing the end time for each time block.
- Review the acceptable blood sugar target range (low and high) for each time block.
- Determine your carb ratio (the amount of insulin needed to cover a given amount of carbohydrates) for each time block.
- Determine your insulin sensitivity (the amount of insulin needed to lower your blood sugar by a given amount) for each time block.

Health Events

Health events can be selected to indicate how you are feeling or what you are doing that might affect your diabetes. The meter allows you the option of setting a percentage for each health event if you set up bolus advice.

Health events available on the meter are:

- Fasting
- Exercise 1
- Stress
- Illness
- Exercise 2
- Premenstrual

Fasting does not scale bolus advice calculations and is not adjustable. Discuss the appropriate percentage for each health event with your healthcare professional. For instructions on how to set up bolus advice, see Chapter 5, “Changing Meter Settings.”

Blood Sugar Test Reminders (Optional)

The meter can be set up to remind you to retest your blood sugar after a high blood sugar test result, after a low blood sugar test result, or after a meal.

An after high blood sugar test reminder example:

- The meter is set up with a high bG threshold level of 240 mg/dL and with a reminder time of 60 minutes.
- You have a blood sugar test result higher than 240 mg/dL, perhaps 270 mg/dL.
- In 60 minutes, the meter reminds you to perform another blood sugar test.

The after meal bG test reminder is set up with a carb value and occurs when the carb value exceeds the snack size. Any of these blood sugar test reminders can be turned on or off individually, as needed. For more information, see Chapter 5, “Changing Meter Settings.”

Date Reminders

- The meter can be set up to remind you of upcoming appointments or dates, such as a "Dr. Visit," a "Lab Test," or an "Infusion Set Change."
- For more information, see Chapter 5, "Changing Meter Settings."

Alarm Clock Reminders

- The meter has alarm clock reminders which can be used as a helpful way to remind you when to test throughout the day.
- In addition to "bG Test," you can set reminders for "Other" for any other daily reminder.
- You can set up to eight reminders per day.
- For more information, see Chapter 5, "Changing Meter Settings."

1.5 Screen Content and Navigation

This section provides an explanation of how to understand and navigate the screens on the meter.

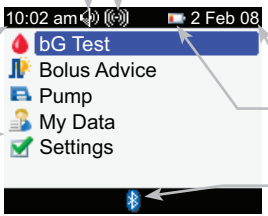
Each time the meter is turned on, this splash screen (ACCU-CHEK logo screen) is displayed for a short period of time.

Features on the Main Menu:

Sound Icon
Appears when the beeper is turned on.

Time

Menu Options



Vibrate Icon
Appears when vibrate is turned on.

Date

Low Battery Icon
Appears when the meter batteries are low.

***Bluetooth* Wireless Technology Icon**
Indicates whether the *Bluetooth* wireless technology is on, off, or connecting.

NOTES:

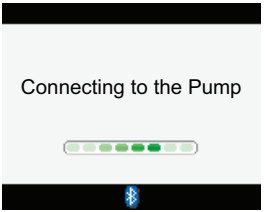
- To select an item on a menu, press ▲ or ▼ to highlight (blue) the menu item and then press ⬭.
- When remotely controlling your pump, the buttons of your meter have differing functions. For more information, see the Advanced Owner's Booklet.

Bluetooth Wireless Technology Icon Communication States

You may turn *Bluetooth* wireless technology on or off at any time using the meter.

Icon	Communication State
	*Bluetooth* wireless technology is on. The meter and pump are communicating.
	Bluetooth wireless technology is off. The meter and pump are not communicating.
	*Bluetooth* wireless technology is on. However, the meter and pump are not communicating.

Connecting to the Pump screen during pairing:



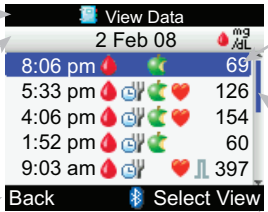
This screen appears when *Bluetooth* wireless technology is on and the meter is connecting to the pump.

Features on a screen:

Title Bar
Primary menu title is displayed here.

Secondary Title Bar
When necessary, a secondary title bar appears. Secondary menu text is displayed here.

Left Soft Key Option
Press to select the option above the button on the screen.



Highlighted Option
When a menu choice or item is selected, it is highlighted in blue.

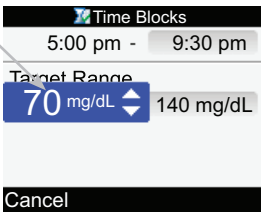
Scroll Bar
If there is more information available than fits on the screen, a vertical scroll bar appears on the right side of the screen.

Right Soft Key Option
Press to select the option above the button on the screen.

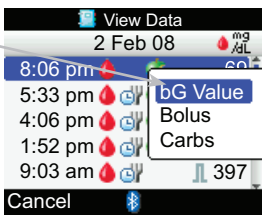
Information can be entered on some screens. Numerical entry fields appear as pop-up entry fields. When an option must be selected, it appears as a pop-up menu.

- To open a pop-up menu or entry field, press ⬭.
- Press ▲ or ▼ to select the appropriate pop-up menu option or until the correct numerical entry is present, and then press ⬭.
- Press and hold ▲ or ▼ to scroll faster.

Pop-Up Entry Field



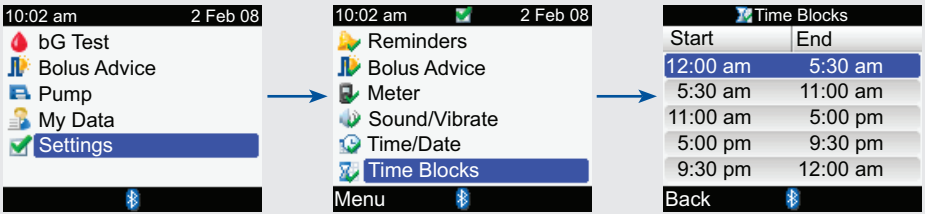
Pop-Up Menu



General Navigation Steps

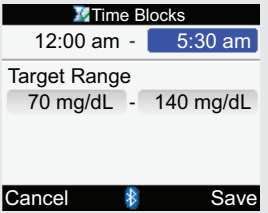
To change the settings or enter information into the meter:

1.



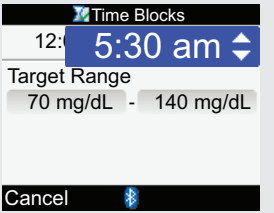
- Press ▲ or ▼ to select a menu option and press ⬭.
- Repeat the previous step as necessary.

2.



- Press ▲ or ▼ or ◀ or ▶ to select an option or a desired entry field and press ⬭.

3.



- Press ▲ or ▼ to select the desired entry and press ⬭.
- Repeat Steps 2 and 3, as necessary.

4.

- Select Save by pressing ⬭ to save changes and return to the previous screen.

7 Care and Maintenance

7.1 Overview

It is important to properly care for and maintain your ACCU-CHEK Aviva Combo meter. If you have any questions about the care and maintenance of your meter, contact ACCU-CHEK Pump Support at 1-800-688-4578.

7.2 Changing the Batteries

1.

- Remove the battery door from 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 from the meter.
- Insert three AAA batteries with the + and - ends matching the marks in the battery compartment.

3.

- Put the battery door back in place and snap it closed.

CAUTIONS:

- Using batteries other than those supplied or recommended for use with the meter may significantly reduce the life of the batteries. Batteries other than those recommended may leak and corrode the battery contacts within the meter. Using batteries not supplied or recommended may void the warranty.
- Replace all batteries of a set at the same time. Newly purchased batteries should not be mixed with partially exhausted ones. Batteries of different electrochemical systems, grades, or brands should not be mixed. Failure to observe these precautions may result in some batteries in a set being driven beyond their normal exhaustion point and thus increase the probability of leakage.

NOTES:

- Alkaline batteries are recommended for use with the meter.
- After you change the batteries, the meter prompts you to confirm the time and date settings.
- It is a good idea to have spare, packaged batteries available.
- All test results, diary information, and settings are saved in the meter memory when the batteries are replaced.
- The meter remains paired with the pump when you remove and replace the batteries.
- Rechargeable batteries may be used in the meter. However, rechargeable batteries may not maintain the same battery life as non-rechargeable batteries.
- When the Low Battery warning appears:
  - *Bluetooth* wireless technology communication is disabled.
  - If vibrate is set to On, it is disabled until the batteries are replaced.
  - If the backlight level is set to high, the medium backlight level is used until the batteries are replaced.
  - If the beeper level is set to high, the medium beeper level is used until the batteries are replaced.

7.3 Power-Saving Tips

To conserve battery life:

- Use the low beeper setting
- Only turn on the vibration feature when it is needed
- Turn off the meter when you are finished rather than utilizing the auto power off feature

7.4 Cleaning the Meter

Caring for the meter is easy: just keep it free of dust. If you need to clean it, follow these guidelines carefully to help you get the best performance possible:

DO

- Ensure the meter is off
- Gently wipe the meter's surface with a soft cloth slightly dampened with one of these cleaning solutions:
  - 70 % isopropyl alcohol
  - Mild dishwashing liquid mixed with water
  - 10 % household bleach solution (1 part bleach plus 9 parts water) made the same day
- Squeeze out any excess liquid from the cloth before you wipe the meter surface

DO NOT

- Get any moisture in the code key slot or test strip slot
- Spray any cleaning solution directly onto the meter
- Put the meter under water or liquid
- Pour liquid into the meter

For instructions on how to clean the pump, see the ACCU-CHEK Spirit Combo Insulin Pump User Guide.

7.5 Maintenance and Testing

- The meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. For detailed information on troubleshooting the meter, see Chapter 8, “Troubleshooting.”
- If you drop the meter or think it is not giving accurate results, ensure your test strips and control solution have not expired, and then perform a control test.
- Perform a control test with each new vial of test strips.
- To test the meter display, turn off the meter, and then press and hold the ⏻ button. The display cycles through colors (red, blue, green, and white). If any part of the display does not change colors, contact ACCU-CHEK Pump Support at 1-800-688-4578.
- If the meter is not working properly, contact ACCU-CHEK Pump Support at 1-800-688-4578.

8 Troubleshooting

8.1 Overview

For most problems, the meter displays a message with a short description of the symptom and, along with it, a proposed solution. This chapter goes into more detail by describing the symptom, the possible cause, and the possible solution. If the possible solutions do not fix the problem, contact ACCU-CHEK Pump Support at 1-800-688-4578.

⚠ WARNING:

Never make treatment decisions based on a warning or error message. If you have any concerns, contact ACCU-CHEK Pump Support at 1-800-688-4578.

NOTES:

- If you drop the meter or think it is not giving accurate results, make sure your test strips and control solution have not expired, and then perform a control test. For further assistance, contact ACCU-CHEK Pump Support at 1-800-688-4578.
- Blood sugar and bG are interchangeable and mean the same thing.

8.2 Troubleshooting the ACCU-CHEK Aviva Combo Meter

Display Shows	Possible Cause(s)	Possible Solution(s)
The display is blank or the meter will not turn on.	▸ Batteries are dead.	▸ Install new batteries. See Chapter 7, “Care and Maintenance.”
	▸ Display is damaged.	▸ Contact ACCU-CHEK Pump Support at 1-800-688-4578.
	▸ Meter is defective.	▸ Contact ACCU-CHEK Pump Support at 1-800-688-4578.
	▸ Extreme temperature – the temperature is outside the meter operating range.	▸ Move the meter to an area with proper temperature. Wait five minutes before turning on the meter. Do not artificially heat or cool the meter.
 *Bluetooth* icon flashing	▸ Communication ended due to a button press on the pump.	▸ Check the pump and continue operation of the pump manually. ▸ Ensure the pump has *Bluetooth* wireless technology turned on.
	▸ Meter and pump are outside of communication range.	▸ Ensure pump is within communication range.

Display Shows	Possible Cause(s)	Possible Solution(s)
Above Hyper Warning Limit	▸ Your test result is above the hyper warning limit set in the meter.	▸ Treat your high blood sugar as recommended by your healthcare professional. ▸ Consider checking bG, ketones, and insulin. ▸ See the pump User Guide for additional solutions.
Beep/Vibrate Off	▸ Beep and Vibrate settings cannot be turned off at the same time.	▸ Ensure that either the Beep or Vibrate setting is turned on. See Chapter 5, “Changing Meter Settings.”
Below Hypo Warning Limit	▸ Your test result is below the hypo warning limit set in the meter.	▸ Treat your low blood sugar as recommended by your healthcare professional. ▸ The meter displays a recommended number of carbohydrates for you to eat, and then retest your blood sugar.

Display Shows	Possible Cause(s)	Possible Solution(s)
Bolus Advice Bolus Advice data deleted	▸ Bolus advice data integrity cannot be confirmed.	▸ Wait 8 hours for accurate bolus advice.
	IMPORTANT: • Insulin doses and meals taken before the Bolus Advice warning are no longer reflected in the bolus advice calculation. • The meter may not reflect the pump bolus history, however the bolus history is available on the pump.	
Bolus Advice Not Setup	▸ Advice is not provided unless it is set up through Bolus Advice in Settings Menu.	▸ You can continue to use the meter without bolus advice or see Chapter 5, “Changing Meter Settings” for instructions on how to set up bolus advice.
Bolus Advice Timeout	▸ Bolus advice is no longer available for this bG result.	▸ Review data that was saved in My Data. Then, decide to modify data, add data, or begin a new bolus advice session.

Display Shows	Possible Cause(s)	Possible Solution(s)
Bolus Delivery Unavailable	▸ The meter cannot communicate with the pump.	▸ Retry or set to Manual Pump. ▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ Ensure the meter and pump are within communication range. ▸ If the low battery icon is displayed on the meter, the meter cannot communicate with the pump. Replace the batteries.
	▸ The pump is currently in Stop mode.	▸ Take the pump out of Stop mode.
	▸ The pump is currently delivering a bolus.	▸ Allow the current bolus delivery to complete before delivering the next bolus.
Bolus Too High	▸ The bolus is above the allowed amount. The bolus was set to 50 Units.	▸ Check the accuracy of all entries. If necessary, contact your healthcare professional.
Bolus Too Low	▸ The insulin pump cannot deliver a 0.1 Unit of multiwave bolus.	▸ The pump will adjust the bolus to 0.2 Units.

Display Shows	Possible Cause(s)	Possible Solution(s)
Carbohydrate Ratio	▸ Carbohydrate ratio is outside of the acceptable meter range.	▸ Check your entries and contact your healthcare professional to determine the appropriate settings.
Code Key Missing	▸ The meter is not coded or the code key is not inserted.	▸ Turn off the meter and recode it. See Chapter 2, “Testing Your Blood Sugar.”
Communication Lost	▸ Pump is out of range of the meter.	▸ Bolus delivery continuing, see pump screen. ▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ Ensure the meter and pump are within communication range. ▸ If the low battery icon is displayed on the meter, the meter cannot communicate with the pump. Replace the batteries. ▸ Use the pump to monitor or cancel a bolus which is in the process of being delivered.

Display Shows	Possible Cause(s)	Possible Solution(s)
Communication Warning	▸ Communication of bolus data from the pump was not successful. Therefore, pump data are not available and the bolus data may not be accurate. ▸ Communication of bolus data from the pump was not successful. Therefore, pump data are not available and the active insulin amount may not be accurate.	▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ Ensure the meter and pump are within communication range. ▸ If the low battery icon is displayed on the meter, the meter cannot communicate with the pump. Replace the batteries.

Display Shows	Possible Cause(s)	Possible Solution(s)
Connection Lost	▸ The connection was lost between the meter and the pump during the pairing process. Therefore, the attempt to pair the meter and pump was unsuccessful.	▸ Restart the pairing process. See the Advanced Owner's Booklet. ▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ If the low battery icon is displayed on the meter, the meter cannot communicate with the pump. Replace the batteries.
	▸ Pump is out of range of the meter.	▸ Ensure the meter and pump are within communication range.
Diary Entry Used For Advice	▸ The diary entry selected has been used for bolus advice and modifications are not allowed.	▸ Carefully confirm all information involving bolus advice. You cannot modify bolus advice-related entries on the meter.
Diary Results Expired	▸ Bolus advice is no longer available for this result.	▸ Review data that was saved in My Data. Then, decide to modify data, add data, or begin a new bolus advice session.

Display Shows	Possible Cause(s)	Possible Solution(s)
E-51 Bad Strip Error	▸ Your blood sugar may be extremely low.	▸ If you see this error message **after** you applied blood to the test strip, see Chapter 2, “Testing Your Blood Sugar.”
	▸ The test strip is damaged. ▸ The test strip is not properly inserted into the meter.	▸ If you see this error message **before** you applied blood to the test strip, remove the test strip and reinsert it, or replace it if damaged. Verify that the code number printed on the test strip container matches the code number printed on the code key currently inserted in the meter. If the message reappears, contact ACCU-CHEK Pump Support at 1-800-688-4578.
E-52 Code Key Error	▸ The code key is incorrect.	▸ Turn off the meter, remove the code key, and reinsert the code key into the meter. If you continue to receive this error message, turn off the meter, remove the code key, and insert a new code key into the meter. If this does not fix the problem, contact ACCU-CHEK Pump Support at 1-800-688-4578.

Display Shows	Possible Cause(s)	Possible Solution(s)
E-53 Bad Test Error	▸ A meter or test strip error has occurred.	▸ Discard the test strip and repeat the test.
	▸ Your blood sugar may be extremely high.	▸ If this confirms how you feel, contact your healthcare professional immediately. If it does not confirm how you feel, repeat the test and see Chapter 2, “Testing Your Blood Sugar.” If this still does not confirm the way you feel, run a control test with your control solution and a new test strip. If the control result is within the acceptable range, review the proper testing procedure and repeat your blood sugar test with a new test strip. If the E-53 error still appears for your blood sugar test, your blood sugar result may be extremely high and above the system’s reading range. **Contact your healthcare professional immediately.** If the control result is not within the acceptable range, see Chapter 3, “Control Testing.”

Display Shows	Possible Cause(s)	Possible Solution(s)
E-54 Not Enough Sample	▸ Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test has started.	▸ Discard the test strip and repeat the test.
E-55 Code Key Expired	▸ The code key is from an expired lot of test strips.	▸ Ensure the code key number matches the code number on the test strip container. Remove and reinsert the code key and ensure the time and date in the meter are correct. If this does not fix the problem, turn off the meter, remove the expired code key, and insert a new, valid code key into the meter.
E-56 Sample Applied Early	▸ Blood or control solution was applied to the test strip before the Apply Sample screen appeared on the display.	▸ Discard the test strip and repeat the test with a new test strip.

Display Shows	Possible Cause(s)	Possible Solution(s)
E-57 Electronic Error	▸ An electronic error has occurred or, in rare cases, a used test strip was removed and reinserted.	▸ Turn off the meter and remove the batteries. Wait at least 30 seconds prior to reinserting the batteries. Turn on the meter and perform a blood sugar or control test. If the problem persists, contact ACCU-CHEK Pump Support at 1-800-688-4578.
E-58 Temp. Error	▸ The temperature is above or below the proper range for the meter.	▸ Move the meter to an area within the proper temperature range indicated for test strip use in the test strip package insert. Wait five minutes before turning on the meter. Repeat the test. Do not artificially heat or cool the meter.
E-59 Battery Empty	▸ The batteries are extremely low.	▸ Insert new batteries. See Chapter 7, “Care and Maintenance.”
E-60 Time/Date Error	▸ The time and date settings may be incorrect. ▸ You have changed the batteries.	▸ Ensure the time and date are correct and adjust, if necessary. See Chapter 5, “Changing Meter Settings.”

Display Shows	Possible Cause(s)	Possible Solution(s)
HI bG Warning	▸ Your blood sugar may be higher than the measuring range of the system.	▸ If you are experiencing any of the common symptoms of high blood sugar, contact your healthcare professional immediately. ▸ Treat your high blood sugar as recommended by your healthcare professional. ▸ Consider checking bG, ketones, and insulin. ▸ See the pump User Guide for additional solutions.
Incorrect Pump Time/Date	▸ Pump time/date incorrect.	▸ Set time/date on the pump (see pump User Guide).
Infrequent Pump Communication	▸ At least two weeks have passed since the meter and pump have communicated.	▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ Ensure the meter and pump are within communication range. ▸ If the low battery icon is displayed on the meter, the meter cannot communicate with the pump. Replace the batteries. ▸ It is important to use *Bluetooth* wireless technology communication between the meter and pump regularly if you utilize bolus advice.

Display Shows	Possible Cause(s)	Possible Solution(s)
Insulin Sensitivity	▸ Insulin sensitivity is outside of the acceptable meter range.	▸ Check your entries and contact your healthcare professional to determine the appropriate settings.
Invalid Bolus Advice Times	▸ The acting time value is less than the offset time.	▸ The acting time value must be set equal to or greater than the offset time. Reset the acting time value or revise the offset time.
Invalid Date	▸ The date entered is invalid (dates for reminders cannot be set to occur in the past).	▸ Re-enter date.
Invalid Hyper Values	▸ The hyper warning limit value must be greater than all of your target ranges in the time block settings.	▸ Reset the hyper warning limit or revise the target ranges in time blocks and re-enter the hyper warning limit. ▸ Enter a hyper warning limit that is above the target ranges of your time blocks. See Chapter 5, “Changing Meter Settings.”

Display Shows	Possible Cause(s)	Possible Solution(s)
Invalid Hypo Values	▸ The hypo warning limit value must be less than all of your target ranges in the time block settings.	▸ Reset the hypo warning limit or revise the target ranges in time blocks and re-enter the hypo warning limit. ▸ Enter a hypo warning limit that is below the target ranges of your time blocks. See Chapter 5, “Changing Meter Settings.”
Invalid PIN	▸ The wrong PIN was entered.	▸ Select OK and re-enter the PIN shown on the pump display.
Invalid Record Time/Date	▸ The time/date entered is invalid (Add Data entries cannot be set to occur in the future).	▸ Re-enter time/date.

Display Shows	Possible Cause(s)	Possible Solution(s)
Invalid Target Range	▸ The lower target range value is above the upper target range value.	▸ Reset the target range values. ▸ Enter the correct lower target range value and upper target range value. See Chapter 5, “Changing Meter Settings.”
	▸ The range selected conflicts with your hyper and/or hypo warning limit settings.	▸ Reset range or revise warning limit settings and re-enter range. ▸ Enter the correct lower target range value and upper target range value. See Chapter 5, “Changing Meter Settings.”
LO bG Warning	▸ Your blood sugar may be lower than the measuring range of the system.	▸ If you are experiencing any of the common symptoms of low blood sugar, contact your healthcare professional immediately. ▸ Treat your low blood sugar as recommended by your healthcare professional.

Display Shows	Possible Cause(s)	Possible Solution(s)
Meter and Pump Not Paired	▸ Meter and pump have not been paired. You cannot use the pump functions without pairing the meter and the pump.	▸ You must pair the meter and pump to use these features. ▸ For instructions on how to pair the meter and pump, see the Advanced Owner's Booklet.
Meter Battery Low	▸ Battery power is low.	▸ Install new batteries. See Chapter 7, "Care and Maintenance."
No bG with Bolus	▸ You have not tested your bG and are attempting to deliver a bolus.	▸ It is recommended to test bG before delivering insulin.
Pairing Failed	▸ The attempt to pair the meter and pump was unsuccessful.	▸ Restart the pairing process. See the Advanced Owner's Booklet.

Display Shows	Possible Cause(s)	Possible Solution(s)
Pump Not Available	▸ The pump is out of the communication range of the meter.	▸ Ensure the meter and pump have *Bluetooth* wireless technology turned on. ▸ Ensure the meter and pump are within communication range. ▸ If the low battery icon is displayed, the meter cannot communicate with the pump. Replace the batteries.
Test Strips Expiring	▸ The test strips expire at the end of the current month.	▸ Before the end of the month, insert a new code key from a new box of test strips (dispose of expiring test strips) and ensure the code key number matches the code number on the test strip container. ▸ Ensure the time and date are correct and adjust, if necessary. See Chapter 5, “Changing Meter Settings.”

Display Shows	Possible Cause(s)	Possible Solution(s)
Time Mismatch	▸ The time or date on the meter is more than five minutes different than the time or date on the pump.	▸ The meter time and date were changed to match the pump time. Ensure the time and date are correct. If the time or date are not correct, change the time and date on the pump.

NOTES:

- For additional information on errors and warnings, see Chapter 6, “Icons, Reminders, Warnings, and Errors.”
- If you have a question or if you see any other error screen, please contact ACCU-CHEK Pump Support at 1-800-688-4578.

9 Technical Information

9.1 Overview

This chapter provides you with important performance information regarding the meter.

9.2 Product Limitations

Please read the literature packaged with your test strips to find the latest information on product specifications and limitations.

9.3 Specifications

Blood volume	▸ Refer to the test strip package insert.
Sample type	▸ Fresh whole blood
Measuring time	▸ Refer to the test strip package insert.
Measuring range	▸ Refer to the test strip package insert.
Test strip storage conditions	▸ Refer to the test strip package insert.
Meter storage conditions (with batteries inserted)	▸ -4 °F to 122 °F
System operating conditions	▸ Refer to the test strip package insert.
Relative humidity operating range	▸ Refer to the test strip package insert.
Memory capacity	▸ 1,000 diary records
Automatic power off	▸ 2 minutes

Power supply	▸ Three AAA batteries (recommended: alkaline)
Display	▸ LCD
Dimensions	▸ 3.7 x 2.1 x 1 inches (LWH)
Weight	▸ Approximately 3.6 oz with batteries inserted
Construction	▸ Hand-held
Protection class	▸ III
Meter type	▸ The ACCU-CHEK Aviva Combo meter is suitable for continuous operation.
Control solution storage conditions	▸ 36 °F to 90 °F
Interface	▸ IR; LED/IRED – Class 1

9.4 Product Safety Information

***Bluetooth* Wireless Technology**

The meter and the pump utilize *Bluetooth* wireless technology to communicate and transfer information. *Bluetooth* wireless technology is a form of 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 the pump is not an open channel. The meter can only communicate with the pump it is paired with; therefore, other *Bluetooth* wireless technology devices (e.g., cell phone, printer, etc.) cannot be paired with, communicate with, or access your personal information on the meter or the pump.

Radio Frequency Communication

FCC ID: WX3-361

The device complies with the United States Federal Communications Commission (FCC) standards. The device complies with FCC Part 15 Rules. Operation of the device 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.

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 distance between meter and that device. You may also turn off the interfering device. In addition, you may turn off *Bluetooth* wireless technology on the meter and deliver insulin directly using the pump.

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.

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.

Electromagnetic Compatibility

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

Performance Analysis

The performance data for the ACCU-CHEK Aviva Combo system (ACCU-CHEK Aviva Combo meter with ACCU-CHEK Aviva test strips) were obtained using capillary blood from diabetic patients (method comparison, accuracy), venous blood (repeatability), and control solution (reproducibility). The system is calibrated with venous blood containing various levels of sugar. The reference values are obtained using the hexokinase method. For method comparison, the results were compared with results obtained using the hexokinase method with deproteinization (automatic analyzer). The hexokinase method is traceable to an NIST standard.

Measuring Principle

Refer to your test strip package insert for more information.

⚠ WARNINGS:

- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this 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.

9.5 Disposing of the Meter, Strips, Lancets, and Batteries

⚠ WARNINGS:

- Any product coming in contact with blood is considered contaminated (potentially infectious).*
- During normal testing any blood sugar 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 a 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, e-scrap, and batteries.

*29 CFR 1910.1030-Bloodborne pathogens

**Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE)

9.6 Warranty

ACCU-CHEK Aviva Combo Meter Limited 4-Year Warranty

Disetronic Medical Systems Inc., a member of the Roche Group warrants to the original purchaser of the meter that your ACCU-CHEK Aviva Combo meter will be free from defects in materials and workmanship for 4 years from the date of purchase. If during this 4-year period, the meter does not work properly because of a defect in materials or workmanship, Disetronic Medical Systems will replace it with a new ACCU-CHEK Aviva Combo 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 Combo meter shall be replacement.

This warranty does not apply to the performance of an ACCU-CHEK Aviva Combo meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way.

THE PRECEDING WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND DISETRONIC MEDICAL SYSTEMS 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 DISETRONIC MEDICAL SYSTEMS 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.

Warranty Instructions

All requests for return of ACCU-CHEK Aviva Combo meters under the preceding warranty must be made to ACCU-CHEK Pump Support. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Disetronic Medical Systems. Cartons received without this label will be returned to you at your expense.

Customers experiencing difficulties should review the troubleshooting information in Chapter 8 of this booklet. Further inquiries should be directed to ACCU-CHEK Pump Support at 1-800-688-4578.

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

Limited License

CAUTION:

A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK AVIVA COMBO SYSTEM—READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK Aviva Combo system (meter, including the code key, and test strips) and its use are protected by U.S. Patent Nos. 6,645,368; 5,366,609; 5,352,351; 5,053,199; 5,122,244; 7,276,146; 7,276,147; and Re. 36,268. A license to use the ACCU-CHEK Aviva Combo system is only granted when the ACCU-CHEK Aviva Combo meter is used with the ACCU-CHEK Aviva test strips and ACCU-CHEK Aviva code keys.

ACCU-CHEK Aviva test strips are provided with a specifically matched ACCU-CHEK Aviva code key. These test strips and code keys are specifically manufactured for operation with the ACCU-CHEK Aviva Combo meter. Use of other test strips with an unmatched code key or even with the matched code key supplied by another manufacturer may prevent or impair the proper function of the ACCU-CHEK Aviva Combo system.

Using the ACCU-CHEK Aviva Combo system indicates your acceptance of the restricted license to use the ACCU-CHEK Aviva Combo system only with ACCU-CHEK Aviva test strips and the ACCU-CHEK Aviva code key. Further, if you have purchased an ACCU-CHEK Aviva Combo monitoring kit or an ACCU-CHEK Aviva Combo meter that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK Aviva test strip 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 Aviva Combo system for a full refund. If you have any questions, please call ACCU-CHEK Pump Support at 1-800-688-4578.

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

Patent Information

Aspects of the ACCU-CHEK Aviva Combo system, including the meter, code key, and test strips, and their use are covered by one or more of the following United States patents: 5,352,351; 4,999,582; 5,997,817; 5,053,199; Re. 36,268; 5,438,271; 5,366,609; 6,645,368; 6,662,439; 5,122,244; 7,073,246; 7,276,146; 7,276,147; 7,338,639; 7,386,937; 7,407,811; 7,452,457; 7,488,601; 7,494,816; 7,556,723; 7,569,126. Additional United States Patents pending.

The ACCU-CHEK Multiclix device and its use are covered by the following U.S. patents: 4,924,879; Re. 35,803; 6,419,661. Additional U.S. patents pending.

CAUTION:

A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK MULTICLIX DEVICE (lancet driver and lancets). READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK Multiclix device and its use are protected by U.S. Patent Nos. 4,924,879; Re. 35,803; 6,419,661. A license to use the ACCU-CHEK Multiclix device is only granted when ACCU-CHEK Multiclix lancet drums are used with the ACCU-CHEK Multiclix device.

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

Using the ACCU-CHEK Multiclix device indicates your acceptance of the restricted license to use the ACCU-CHEK Multiclix device only with ACCU-CHEK Multiclix lancet drums. Further, if you have purchased an ACCU-CHEK Multiclix device that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK Multiclix 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 Multiclix device for a full refund. If you have any questions, please call ACCU-CHEK Pump Support at 1-800-688-4578.

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

Patent Information

The ACCU-CHEK Multiclix device and its use are protected by U.S. Patent Nos. 4,924,879; Re. 35,803; 6,419,661.

9.7 Additional Supplies

The following supplies and accessories are available from your authorized Roche Diabetes Healthcare Center, pharmacies, or your medical/surgical supply dealer:

Test Strips

ACCU-CHEK Aviva test strips

Control Solutions

ACCU-CHEK Aviva control solutions

9.8 Information for Healthcare Professionals

⚠ WARNING:

Healthcare Professionals: Follow the infection control procedures appropriate for your facility.

A drop of fresh, whole blood is required to perform a blood sugar test. Refer to the test strip package insert for additional healthcare professional information.

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 and alternative site blood sugar test results. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in blood sugar 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 AST of adults with diabetes show that most persons will find their sugar level changes more quickly in the fingers' blood than the alternative sites' blood.[1] This is especially important when sugar levels are falling or rising rapidly. If your patient is used to making treatment decisions based upon fingertip readings, he or she should consider the delay, or lag-time, affecting the results obtained from an alternative site.

[1]Data on file.

Appendices

Appendix A: Abbreviations

Abbreviation	Definition
AM	▸ Ante Meridiem (12-hour clock notation for “before noon”)
AST	▸ Alternative Site Testing
BE	▸ Bread Equivalent (equal to 12 grams of carbohydrates)
bG	▸ Blood Sugar
Carbs	▸ Carbohydrates
CC	▸ Carbohydrate Choice (equal to 15 grams of carbohydrates)
°F	▸ Degrees Fahrenheit
FCC	▸ Federal Communications Commission (United States)
g	▸ Grams
GHz	▸ Gigahertz

Abbreviation	Definition
Hyper	▸ Hyperglycemia (high blood sugar)
Hypo	▸ Hypoglycemia (low blood sugar)
IR	▸ Infrared
ISO	▸ International Organization for Standardization
KE	▸ Kohlenhydrateinheit (equal to 10 grams of carbohydrates)
LCD	▸ Liquid Crystal Display
mg/dL	▸ Milligrams per Deciliter
N/A	▸ Not Applicable
NIST	▸ National Institute of Standards and Technology (United States)
PIN	▸ Personal Identification Number
PM	▸ Post Meridiem (12-hour clock notation for “after noon”)
RF	▸ Radio Frequency

Abbreviation	Definition
SD	▸ Standard Deviation
U	▸ Units (bolus insulin units)

Appendix B: Carb Units

For carbohydrates, the following units of measure are available on the meter.

Abbreviation	Unit of Measurement	Gram Equivalent
g	▸ Grams*	▸ 1 gram
KE	▸ Kohlenhydrateinheit	▸ 10 grams
BE	▸ Bread Equivalent	▸ 12 grams
CC	▸ Carbohydrate Choice	▸ 15 grams

*Standard unit of measure in the U.S.

Appendix C: Explanation of Symbols

You may encounter the following symbols on the packaging, on the type plate, and in the instructions for the meter, shown here with their meaning.

	▸ Warning (refer to accompanying documents). Please refer to safety-related notes in the owner's booklets accompanying this instrument.
	▸ Caution (refer to accompanying documents). Please refer to safety-related notes in the owner's booklets accompanying this instrument.
	▸ Note (additional information)
	▸ Store at
	▸ 1.5V AAA

Appendix D: Meter Settings and Range Limits

mg/dL

Data Type	Unit of Measurement	MIN	MAX	Increments	Default Setting
Acting Time	hours:minutes	1:30	8:00	0:15	4:00
Active Insulin	Units	0	99.9	0.1	No entry (“--- u”)
bG Threshold (High)	mg/dL	120	350	1	Hyper Warning Limit
bG Threshold (Low)	mg/dL	50	100	1	Hypo Warning Limit
Carb Ratio (carbs)	grams BE KE CC	1 0.1 0.1 0.1	240 20 24 16	1 0.1 0.1 0.1	No entry (“--- g”) No entry (“--- BE”) No entry (“--- KE”) No entry (“--- CC”)
Carb Ratio (insulin)	Units	0.1	50	0.1	1
Carbohydrates	grams BE KE CC	0 0 0 0	240 20 24 16	1 0.1 0.1 0.1	No entry (“--- g”) No entry (“--- BE”) No entry (“--- KE”) No entry (“--- CC”)

Data Type	Unit of Measurement	MIN	MAX	Increments	Default Setting
Exercise 1 (health event)	%	-50	50	1	0
Exercise 2 (health event)	%	-50	50	1	0
Extended Bolus (insulin)	Units	0	50[1]	0.1	No entry (“--- u”)
Hyper Warning Limit	mg/dL	180	350	1	300
Hypo Warning Limit	mg/dL	50	90	1	70
Illness (health event)	%	-50	50	1	0
Insulin Sensitivity (bG)	mg/dL	1	999	1	No entry (“---mg/dL”)
Insulin Sensitivity (insulin)	Units	0.1	50	0.1	1
Meal Rise (bG)	mg/dL	50	200	1	50
Multiwave Bolus (insulin)	Units	0.2	50[1]	0.1	No entry (“--- u”)

Data Type	Unit of Measurement	MIN	MAX	Increments	Default Setting
Offset Time	hours:minutes	0:45	Acting Time	0:15	1:00
Premenstrual (health event)	%	-50	50	1	0
Snack Size (carbs)	grams BE KE CC	0 0 0 0	24 2 2.4 1.6	1 0.1 0.1 0.1	No entry (“--- g”) No entry (“--- BE”) No entry (“--- KE”) No entry (“--- CC”)
Standard Bolus (insulin)	Units	0	50[1]	0.1	No entry (“--- u”)
Stress (health event)	%	-50	50	1	0
Target Range Upper Value	mg/dL	100	300	1	140
Target Range Lower Value	mg/dL	50	140	1	70

[1]The maximum that can actually be delivered may be less due to the ACCU-CHEK Spirit Combo pump’s maximum insulin amount.

The following are the default settings for bG test reminders. To turn on a bG test reminder, see “Setting Alarm Clock Reminders: bG Test, Other” in Chapter 5, “Changing Meter Settings.”

Test Reminder	Default Time of Day
1	7:00 am
2	9:00 am
3	11:00 am
4	12:00 pm
5	2:00 pm
6	4:00 pm
7	7:00 pm
8	10:00 pm

The following are the default settings for the time blocks. Talk to your healthcare professional about setting up time blocks to help you manage your diabetes. To adjust the time blocks, see Chapter 5, “Changing Meter Settings.”

Time Block	12-Hour Format
1	12:00 am–5:30 am
2	5:30 am–11:00 am
3	11:00 am–5:00 pm
4	5:00 pm–9:30 pm
5	9:30 pm–12:00 am

Glossary

Term	Definition
7-day average	▸ Includes results generated today and the previous 6 days.
Acting Time	▸ The period of time from the start of the meal rise or the delivery of a correction bolus until your blood sugar level is expected to return to the target level.
Active Insulin	▸ Bolus insulin that has been given to lower your blood sugar but has not yet been fully used.
Advice Options	▸ Factors that influence bolus advice calculations including meal rise, snack size, acting time, and offset time.
After High bG Reminder	▸ A reminder to retest your blood sugar. When enabled, this reminder occurs after a high blood sugar test result.
After Low bG Reminder	▸ A reminder to retest your blood sugar. When enabled, this reminder occurs after a low blood sugar test result.

Term	Definition
After Meal Reminder	▸ A reminder to retest your blood sugar. When enabled, this reminder occurs after a meal. For this reminder to occur, you must enter carbohydrate data greater than the snack size amount.
Alarm	▸ Audible or vibrating (silent) notification indicating a reminder, warning, or error.
Alternative Site Testing (AST)	▸ Blood sugar test from another place on your body besides the fingertip.
bG Test Reminders	▸ Reminders to retest your blood sugar after a high blood sugar test result, after a low blood sugar test result, or after a meal.
bG Threshold	▸ A bG test reminder setting. The upper limit for your blood sugar for a high bG test reminder and the lower limit for your blood sugar for a low bG test reminder.
Blood Sugar (bG)	▸ The level of sugar in blood.
Bluetooth Wireless Technology	▸ Wireless short-range communications technology which connects devices (such as meter and pump) in order to exchange information.
Bolus	▸ The delivery of insulin all at once rather than slowly throughout the day, usually used to compensate for meals or high blood sugar.

Term	Definition
Bolus Advice	▸ When enabled, bolus advice provides recommendations on the amount of insulin for food intake and for correcting blood sugar levels that are not within your target range.
Bolus Advice Options	▸ See Advice Options.
Bolus Delivery Start Delay	▸ The Standard Bolus icon blinks for five seconds and then the meter communicates to the pump to begin delivery of the bolus amount. During this delay you are able to cancel the bolus delivery by pressing △ or ▽. The meter beeps and returns to the Pump Run screen.
Carb Ratio	▸ The amount of insulin necessary to account for a certain number of carbohydrates.
Carbohydrates (or Carbs)	▸ Carbohydrate foods include sugars and starches. Carbohydrates can raise blood sugar levels slowly or rapidly. Carbohydrates are generally counted to calculate a bolus insulin dose.
Caution	▸ Provides information that, if not followed, could result in material hazards (damage to or destruction of equipment or materials).

Term	Definition
Control Result	▸ Value displayed on meter as the result of a control test. When the Control Result is within the range shown on the label of the test strip container, then the test strips and the meter are working properly.
Control Test	▸ A meter test using control solution which lets you know that the meter and test strips are working properly.
Corrupt Result	▸ bG test result that had an error.
Current Date	▸ Refers to the date you set through the menu Settings and then in the Time/Date screen.
Current Time	▸ Refers to the time you set through the menu Settings and then in the Time/Date screen.
Day	▸ Period of time starting at 12:00 am and ending at 11:59 pm.

Term	Definition
End Time	▸ The end time of a time block.
Extended Bolus	▸ A bolus delivered over a period of time. It can be helpful during long meals or when you have meals that are digested slowly. The Extended Bolus may also be appropriate for people who have gastroparesis (delayed digestion). This option is available only when *Bluetooth* wireless technology is turned on and the meter and pump are communicating.
Health Events	▸ A pop-up menu selection (fasting, exercise 1, stress, illness, exercise 2, or premenstrual) that allows information to be stored with a blood sugar test result or in a diary record and percentages that could adjust bolus advice recommendations for your current health status or activities.
HI	▸ The test result is above the meter's measurement range.
Hyper	▸ Hyperglycemia: an abnormally high level of sugar in the blood.
Hyper Warning Limit	▸ When your blood sugar test result is above the hyper warning limit, a warning is displayed.

Term	Definition
Hypo	▸ Hypoglycemia: an abnormally low level of sugar in the blood.
Hypo Warning Limit	▸ When your blood sugar test result is below the hypo warning limit, a warning is displayed.
Insulin Pump	▸ A device that delivers a continuous supply of insulin into the body.
Insulin Sensitivity	▸ The amount of insulin necessary to lower your blood sugar by a certain amount.
Ketones	▸ A by-product or waste product when your body burns stored fat for energy. Ketones are produced when there is not enough insulin to help your body use sugar for energy. Without enough insulin, sugar builds up in the blood.
Key Lock	▸ A meter function which disables the keys (buttons) in order to prevent its unintended use.

Term	Definition
LO	▸ The test result is below the meter's measurement range.
Meal Rise	▸ During or after meals, an increase in blood sugar levels is considered normal within a certain range, even though a meal bolus has been delivered. A meal rise is in effect for a specified time period.
Meal Time	▸ A pop-up menu selection (pre-meal, post-meal, bedtime, or other) that allows information to be stored with a blood sugar test or in a diary record.
Meter	▸ Blood sugar meter.
Multiwave Bolus	▸ A bolus designed to better simulate the body's insulin delivery. It combines an immediate bolus delivery followed by an Extended Bolus delivery. A Multiwave Bolus can be helpful when you have meals that include both rapidly and slowly absorbed carbohydrates. This option is available only when *Bluetooth* wireless technology is turned on and the meter and pump are communicating.
Note	▸ Additional information.

Term	Definition
Offset Time	▸ Offset time takes into account the expected delay for the blood sugar level to actually fall during the acting time of insulin in the body. It describes the first time period within the acting time.
Paired	▸ A pump and meter exclusively communicating and transferring information with each other.
Pump	▸ See Insulin Pump.
Quick Bolus	▸ A bolus delivery on the pump using the pump UP and DOWN keys. One key press equals one bolus increment (i.e., 0.1, 0.2, 0.5, 1.0, 2.0). See the pump User Guide for more information.
Remind After	▸ A bG test reminder setting. The amount of time after a high blood sugar test result, after a low blood sugar test result, or after a meal you want the reminder to occur.
Reminder	▸ When enabled, reminders occur to remind you to test your blood sugar, to retest your blood sugar or of an event or activity.

Term	Definition
Snack Size	▸ The amount of carbohydrates that is not to be counted as a regular meal with the expected meal rise.
Snooze	▸ Delay of some reminders for a defined time period.
Soft Keys	▸ Two buttons under the meter display used to navigate through the user interface. Just above each soft key, the meter display shows the selection (i.e., Save, Cancel, Back, etc.).
Standard Bolus	▸ A bolus that is immediately delivered to cover a food or a blood sugar correction. When Standard is selected, the bolus is delivered by the pump. This option is available only when *Bluetooth* wireless technology is turned on and the meter and pump are communicating.
Standard Deviation	▸ As it is used in this owner's booklet, standard deviation measures how widely spread the bG test results are (e.g., if the bG test results are close to the bG average, then the standard deviation is small).
Start Time	▸ The start time of a time block.

Term	Definition
Target Range	▸ The range of your blood sugar results considered acceptable when you are fasting.
Time Blocks	▸ Up to eight time periods within one day to facilitate your changing insulin needs throughout the day.
Time Range	▸ The user sets the duration of time. There is a start and end time.
User	▸ A person using the meter or pump.
Warning	▸ Describes items and conditions that present hazards and may cause personal injury.
Warning Limits	▸ See Hyper Warning Limit or Hypo Warning Limit.

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