



User's Manual Blood Glucose Meter





# Contents

ntroduction	1
Chapter 1: Your New System	3
Chapter 2: Blood Glucose Tests	7
Chapter 3: Meter Memory, Setup, and Data Transfer	. 15
Chapter 4: Control Tests	. 25
Chapter 5: Maintenance and Troubleshooting	. 29
Chapter 6: Technical Information	. 35
Chapter 7: The Accu-Chek FastClix Finger Pricker	. 41
ndex	. 48

## The Accu-Chek Aviva System

The Accu-Chek Aviva meter is designed to be used with the Accu-Chek Aviva test strip to quantitatively measure glucose in fresh venous, arterial, neonatal, and capillary whole blood as an aid in monitoring the effectiveness of glucose control. Capillary whole blood for testing of blood glucose can be obtained from fingertip and approved alternative sites (for example, forearm). Refer to the Alternative Site Testing (AST) section of this manual for approved alternative sites and associated limitations. The Accu-Chek Aviva meter with the Accu-Chek Aviva test strips provide a complete test system that is meant for in vitro diagnostic use by people with diabetes at home. The system is not for use in diagnosis or screening of diabetes mellitus. Healthcare professional blood sample collection and preparation is described in the test strip package insert. For use only with the Accu-Chek Aviva test strips and control solutions.

The system includes:

- · Accu-Chek Aviva meter with battery
- Accu-Chek Aviva test strips\*
- Accu-Chek Aviva control solutions\*

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

# Introduction

# 🕂 WARNING

The Accu-Chek FastClix finger pricker is intended for patient self-monitoring by an individual person only. It must not be used to collect blood from more than one person as it does not incorporate any features to guard against cross-infection.

## \land WARNING



- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Keep new and used batteries away from children. Ingestion or insertion into the body
  may cause chemical burns, perforation of soft tissues and death. Severe burns may occur
  within 2 hours of swallowing. If you think a battery might have been swallowed or placed
  inside any part of the body, seek medical attention immediately.
- If the battery compartment does not close securely, stop using the product and keep it away from children. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).
- 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 Glucose Testing Is Important

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We have made it as simple as possible.

### **Important Information About Your New Meter**

- The meter comes with a preset time and date. You may need to change the time to your time zone.
- If you follow the steps in this manual but still have symptoms that do not seem to match your test results, or if you have guestions, talk to your healthcare professional.

### The Accu-Chek Aviva Meter



1. Power/Set Button 🖲

Turns meter on or off and sets options.

2. Display

Shows results, messages, and test results stored in memory.

- 3. Right Arrow and Left Arrow Buttons Press to enter memory, adjust settings, and scroll through test results.
- 4. Test Strip Slot Insert test strip here.

- 5. Battery Door
- 6. Infrared (IR) Window Transfers data from meter to computer.



7. Test Strip Container\*

11. Battery

- 8. Insert this end into meter.
- 9. Yellow Window Touch blood drop or control solution here.
- 10. Control Solution Bottle\*

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

### Using the Accu-Chek Aviva System

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

# \land WARNING

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

### **Button Functions**

1

Here are the functions of the power/set and arrow buttons on the meter. These functions are used throughout this manual. For more information on using these buttons during meter setup, see Chapter 3, Meter Memory, Setup, and Data Transfer.

Button	Function	Action
Turn the meter on or off. (power/set		Press and release .
button) Enter the set-up mode.	Turn the meter on. Press and <b>hold</b> (1) until <b>set-up</b> appears on the display.	
	Set the chosen feature.	Press and release .
	Exit the set-up mode at any time.	Press and <b>hold</b> (a) until the flashing test strip symbol appears on the display.
	Check the display segments.	Turn the meter off. Press and <b>hold</b> (1) to see the complete display.
		If one of the segments is missing or looks different from the picture, do not use the meter. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).
	Adjust settings for time and date,	Press and release < or <b>&gt;</b> .
(right arrow and left arrow buttons)	beeper, test reminders, and hypoglycaemic alert.	Press and <b>hold</b> I or I to scroll faster.
	Enter memory.	Press and release ◀ or ▶.
	Mark a blood glucose result.	Press and release d or <b>D</b> .

2

### Performing a Blood Glucose Test with Blood from Your Fingertip

#### NOTE

Blood samples taken from the palm are equivalent to blood samples taken from the fingertip. To receive Alternative Site Testing (AST) instructions and an AST cap for obtaining blood from the palm, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

### \land WARNING

Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. If the meter shows the wrong unit, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI). If you do not know which unit of measurement is correct for you, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.



# 2 Blood Glucose Tests

Before you perform your first blood glucose test, set up the meter correctly. You need the meter, a test strip, a finger pricker, and a lancet.



Wash and dry your hands.



Prepare the finger pricker. See Chapter 7, The Accu-Chek FastClix Finger Pricker.



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



Insert the test strip into the meter in the direction of the arrows. The meter turns on and beeps.



When the blood drop symbol flashes, obtain a blood sample with the aid of a finger pricker.

With your hand facing downwards, gently squeeze your finger to assist the blood flow. This helps you get a blood drop.



Touch the blood drop to the **front edge** of the yellow window of the test strip.

Do not put blood on top of the test strip.

The meter beeps and  $\overline{\mathbb{Z}}$  flashes when there is enough blood in the test strip.

2



The test result appears on the display.

To assign a marker to the test result, leave the test strip in the meter. See Chapter 2, Marking Blood Glucose Results and Setting the Post-Meal Test Reminder.

Otherwise, remove and discard the used test strip. After a successful test, the meter turns itself off 5 seconds after the test strip is removed.

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

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

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

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

2

# \land WARNING

Do not change your therapy because of just one blood glucose result.

NEVER ignore symptoms of low or high blood glucose.

If your blood glucose result does not match how you feel, perform a fingertip or palm\* test to confirm your test result. If the fingertip or palm test result still does not match how you feel, contact your healthcare professional.

You may perform a palm, forearm, or upper arm test	<ul><li>immediately before a meal.</li><li>while fasting.</li></ul>
You may NOT perform a palm, forearm, or upper arm test	<ul> <li>up to 2 hours following a meal, when blood glucose values can rise quickly.</li> <li>after injecting bolus insulin, when blood glucose values can decrease rapidly.</li> <li>after exercise.</li> <li>if you are sick.</li> <li>if you are sick.</li> <li>if you think your blood glucose is low (hypoglycaemia).</li> <li>if you are sometimes unaware of your blood glucose being low.</li> </ul>

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

\*For samples from the palm you will need an AST converter cap, which can be obtained by contacting the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

### Marking Blood Glucose Results and Setting the Post-Meal Test Reminder

You can mark a blood glucose result to indicate a special event. If you select a test result marker, it is automatically stored in memory. When you review the test results in memory, these markers can help you remember what was different about the test result.

Symbol	Function
Ŭ	<b>Pre-Meal Marker</b> Marking blood glucose results with a pre-meal marker provides more information about your test results to help you and your healthcare professional in the management of your diabetes.
<b>è 4</b>	<b>Pre-Meal Marker with Post-Meal Test Reminder</b> When a pre-meal result is marked with a post-meal test reminder, the meter beeps 1 or 2 hours after you test to remind you to do a post-meal test.
Ť	<b>Post-Meal Marker</b> Marking blood glucose results with a post-meal marker provides more information about your test results to help you and your healthcare professional in the management of your diabetes. The post-meal marker automatically appears with the test result if a test is performed 15 minutes before or after the post-meal test reminder is programmed to beep. Set the post-meal test reminder time to 1 or 2 hours in the set-up mode. The meter will beep 1 or 2 hours after the pre-meal test to remind you to do a post-meal test.
*	<b>General Marker</b> You might want to use the general marker to mark an event such as an AST result or exercise.

2

#### Here is how to mark a test result and initiate a post-meal test reminder:

- 1. Perform a blood glucose test. The blood glucose result appears on the display.
- 2. Leave the test strip in the meter. Press and release d or b to toggle through the test result markers and post-meal test reminder.
- 3. When the marker or test reminder that you wish to select appears on the display, remove the test strip from the meter.

### **Unusual Blood Glucose Results**

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

Tro	ubleshooting Checks	Action
1.	Have the test strips expired?	Discard the test strips if they are past the use by date. Repeat the blood glucose test with an unexpired test strip.
2.	Was the cap on the test strip container closed tightly?	Replace the test strips if you think the test strip container was uncapped for some time. Repeat the blood glucose test.
3.	Was the test strip used immediately after it was removed from the test strip container?	Repeat the blood glucose test with a new test strip.
4.	Were the test strips stored in a cool, dry place?	Repeat the blood glucose test with a properly stored test strip.
5.	Did you follow the directions?	See Chapter 2, Blood Glucose Tests, and repeat the blood glucose test. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI) if you still have problems.
6.	Are the meter and test strips working properly?	Perform a control test. See Chapter 4, Performing a Control Test, for instructions.
7.	Are you still unsure of the problem?	Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

### Symptoms of Low or High Blood Glucose

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

Low blood glucose (hypoglycaemia): Symptoms of hypoglycaemia may include, but are not limited to: anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin colour, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion. High blood glucose (hyperglycaemia): Symptoms of hyperglycaemia may include, but are not limited to: increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

# \land WARNING

If you are experiencing any of these symptoms, or other unusual symptoms, test your blood glucose from the fingertip or palm. If your blood glucose result is displayed as L0 or HI, contact your healthcare professional immediately.

### Memory

### Storing Blood Glucose and Control Results

The meter automatically stores up to 500 blood glucose results and up to 20 control results with the time and date of the result and any test result marker which you can review at any time. Test results are stored from the newest to the oldest, so set the time and date correctly in the meter. Having the correct time and date setting helps ensure appropriate interpretation of stored blood glucose results by you and your healthcare team.

### NOTE

- The memory is not lost when the battery is replaced; however, confirm that the time and date are still correct. See Chapter 3, Setting the Time and Date.
- Once 500 blood glucose results are in memory, adding a new test result causes the oldest one to be deleted.
- If more than 500 blood glucose tests are performed within a 90 day period, only the most recent 500 test results are included in the 90 day average.
- Control results are stored in memory, but cannot be reviewed on the meter. To view stored control
  results, first transfer them to a compatible software application. Contact the Accu-Chek Customer
  Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI) for product availability.
- Control results are not included in the 7, 14, 30, and 90 day averages.
- Only test results that have been assigned a pre-meal or post-meal marker are included in pre-meal and post-meal averages. All blood glucose results are included in the general 7, 14, 30, and 90 day averages.

3

### Memory

#### **Viewing Test Results in Memory**

With the meter on or off, press and release  $\blacksquare$  or  $\blacktriangleright$  to enter memory. The most recent test result appears on the display.

Button	Function	Action
(left arrow button)	Previous test results	Press I to view previous test results from newest to oldest.
(right arrow button)	General averages	Press $\blacktriangleright$ to view 7, 14, 30, and 90 day averages. n = number of test results in the average $\begin{array}{c c} memory \\ n & 2 & 1 \\ \hline n & 42 & 14 \\ \hline n & 82 & 30 \\ \hline n & 83 & 10 \\ \hline n $
(right arrow button)	Pre-meal averages Post-meal averages	Continue to press 🗩 to view 7, 14, 30, and 90 day pre-meal and post-meal averages.

# \land WARNING

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

### Setup Using the Set-Up Mode

The following features can be customised as required.

Symbol	Function	Action	Factory Pre-set
	Time and date	Set the time and date.	
٣	Beeper	Select <b>On</b> or <b>OFF</b> . Setting the beeper to <b>OFF</b> does not affect test results. The beeper must be <b>On</b> to use the test reminders feature.	0n
è 🖡	Post-meal test reminder	Select 1 hour or 2 hours. The meter will beep 1 or 2 hours after the pre-meal test to remind you to do a post-meal test.	2Hr
÷	Test reminders	Select <b>On</b> or <b>OFF</b> . You can set up to 4 test reminders per day.	A-1 8:00 A-2 12:00 A-3 18:00 A-4 22:00
()	Hypoglycaemic alert	Select <b>On</b> or <b>OFF</b> . The hypoglycaemic alert can be set to a level between 2.8 and 5.0 mmol/L to let you know when your blood glucose is possibly too low.	OFF

3

### Setup Setting the Time and Date



Press and release (\*) (power/set button) to turn the meter on. The flashing test strip symbol appears on the display.



Press and **hold** (1) until **set-up** appears on the display.

The hour flashes.



Press and release ◀ or ► to decrease or increase the hour. Press and release ● to set the hour. The minutes flash.



Repeat step 3 to set minutes, day, month, and year.

To set up more options, press and release **(e)**. To exit, press and **hold ((e)** until the flashing test strip symbol appears on the display.

#### Setup Setting the Beeper On or OFF

#### NOTE

#### The beeper prompts you:

- to apply blood or control solution to the test strip.
- when enough blood or control solution is drawn into the test strip.
- when the blood glucose or control test is complete.
- when a button is pressed.
- when it is time to perform a test (if you set the test reminders or post-meal test reminder).
- if an error occurred while performing a blood glucose or control test (even if the beeper is off, it still beeps for an error).



Press and release (1) to turn the meter on. The flashing test strip symbol appears on the display.

Press and **hold** (1) until **set-up** appears on the display.



Press and release (1) repeatedly until the flashing beeper symbol and **On** or **OFF** appear on the display.

# 3

Press and release  $\blacksquare$  or  $\blacktriangleright$  to switch between **On** and **OFF**.

To set up more options, press and release **(e)**. To exit, press and **hold (e)** until the flashing test strip symbol appears on the display. 3

### Setup

### Setting the Post-Meal Test Reminder

### NOTE

#### The post-meal test reminder:

- beeps 1 or 2 hours after the blood glucose test to remind you to do a post-meal test.
- beeps every 2 minutes up to 3 times.
- turns off by inserting a test strip or pressing any button.
- If a test was performed within 15 minutes of a test reminder, the test reminder does not beep.
- If the meter is on at the test reminder time, the test reminder does not beep.
- Exposure to cold conditions may disable test reminders until the meter is turned on.



Press and release (1) to turn the meter on. The flashing test strip symbol appears on the display.

Press and **hold** (1) until **set-up** appears on the display.



Press and release () repeatedly until **set-up** and the flashing **1Hr** or **2Hr** appear on the display.

# 3

Press and release I or to select **1Hr** or **2Hr**. Press and release I to set the option. To set up more options, press and release I. To exit, press and **hold** I until the flashing test strip symbol appears on the display.

This display appears when a post-meal test reminder occurs.



### Setup Setting the Test Reminders

### NOTE

#### Test reminders:

- beep at the same time each day.
- beep every 2 minutes up to 3 times.
- turn off by inserting a test strip or pressing any button.
- If a test was performed within 15 minutes of a test reminder, the test reminder does not beep.
- If the meter is on at the test reminder time, the test reminder does not beep.
- Exposure to cold conditions may disable test reminders until the meter is turned on.
- If a test reminder is off in set-up mode, any subsequent test reminders are also off. For example, if you set A-1 but turn off A-2, then A-3 and A-4 will automatically be off.



Press and release (1) to turn the meter on. The flashing test strip symbol appears on the display.

Press and **hold** (1) until **set-up** appears on the display.



Press and release repeatedly until the bell symbol, **OFF**, **set-up**, and the flashing **A-1** appear on the display.





Press and release  $\blacksquare$  or  $\blacktriangleright$  to switch between **On** and **OFF**.

Press and release (1) to set your choice. If **On** is selected, the hour flashes. Press and release ◀ or ► to adjust the hour. Press and release ● to set the hour. The minutes flash.

# **3** Meter Memory, Setup, and Data Transfer



Press and release I or to select 00, 15, 30, or 45. These are the only choices.

Press and release (1) to set the minutes. The bell symbol, **OFF**, and the flashing **A-2** appear on the display.

### 6

Either set the **A-2** test reminder or press and release **()** to set up more options.

To exit, press and **hold** (1) until the flashing test strip symbol appears on the display.

### Setup Setting the Hypoglycaemic Alert

# \land WARNING

- This function is no substitute for hypoglycaemia training by your healthcare professional.
- Before you set the hypoglycaemic alert, talk to your healthcare professional to help you decide what blood glucose level is your hypoglycaemic level.



Press and release (1) to turn the meter on. The flashing test strip symbol appears on the display.

Press and **hold** (1) until **set-up** appears on the display.



Press and release **•** repeatedly until **set-up**, **OFF**, and the flashing **①** appear on the display.

# 3

Press and release  $\blacksquare$  or  $\blacktriangleright$  to switch between **On** and **OFF**.

Press and release (1) to set your choice.

If you select **On**, **set-up** appears and <sup>①</sup> flashes.



3

Press and release I or to adjust the level. Press and release I to set the level.

To exit, press and **hold** (1) until the flashing test strip symbol appears on the display. The set-up mode is

complete.

#### Data Transfer Transferring Results to a Computer

We offer software to help you transfer your results. For information on Accu-Chek software, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

You can transfer your stored results to a computer to track, identify patterns, and print.

# 🕂 WARNING

Transferring data to a computer from meters used for multiple-patient testing is NOT recommended since individual patient results cannot be identified.

#### Transferring Data Directly to a Computer Using Specialised Software and an Infrared Cable

- 1. Install the software according to the instructions.
- 2. To transfer the results to a computer, connect the infrared cable according to the instructions.
- 3. Run the software program and follow the instructions for data transfer. Make sure the software is ready to accept data from the meter.
- 4. With the meter off, press and **hold** both **I** and **D** until 2 arrows on the display alternately flash.
- 5. Locate the infrared (IR) window on the top of the meter.
- 6. Locate the IR window on the infrared cable.
- 7. Place the meter on a flat surface. Point the 2 IR windows toward each other. They should be 3-10 cm apart.
- 8. Do not move the infrared cable or meter during the data transfer.
- 9. Follow the prompts on the software.
- 10. The software program may shut off the meter automatically when the data transfer is complete. Should this occur, follow the prompts on the computer screen.





- If the data did not transfer successfully, try again. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI) if you still have problems.
- To make the most of the transfer feature, make sure the meter is set to the correct time and date.
- To find out about transferring results to a computer and what tools are available, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

### When to Perform a Control Test

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

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

#### About the Control Solution

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

# Performing a Control Test

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



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



Insert the test strip into the meter in the direction of the arrows. Place the meter on a flat surface.



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



Remove the cap from the control solution bottle. Wipe the tip of the bottle with a tissue.

Squeeze the bottle until a tiny drop forms at the tip.



# 6

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

Touch the drop to the front edge of the yellow window of the test strip until you see 素 flash. Do not put control solution on top of the When you see  $\mathbb{Z}$  flash, there is enough control solution in the test strip.

test strip.

# **Control Tests**



The control result, the bottle symbol, and a flashing L appear on the display. Do not remove the test strip yet. Press to mark the control result as a Level 1. Press a second time to mark the control result as a Level 2.



Press and release  $\ensuremath{\textcircled{}}$  to set the control level in the meter.

**OK** and the control result alternate on the display if the control result is in range.

**Err** and the control result alternate on the display if the control result is not in range.

Remove and discard the used test strip.

After a successful test, the meter turns off 5 seconds after the test strip is removed.

Δ

## **Understanding Out-of-Range Control Results**

### \land WARNING

4

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

Tro	ubleshooting Checks	Action
1.	Have the test strips or control solutions expired?	Discard the test strips or control solution if either is past the use by date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
2.	Did you wipe the tip of the control solution bottle before use?	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
3.	Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
4.	Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
5.	Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
6.	Did you follow the directions?	Read Chapter 4, Control Tests, and repeat the control test. If you still have problems, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).
7.	Did you choose the correct control solution level, either 1 or 2, when you performed the control test?	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
8.	Are you still unsure of the problem?	Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

### Meter Maintenance

The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See Chapter 5, Display and Error Messages.

If you drop the meter or think the results are not accurate, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

## \land WARNING

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

### **Changing the Battery**







Remove the old battery. Insert the new battery with the (+) side facing up.



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

#### NOTE

- The meter uses one 3-volt lithium battery, coin cell type CR2032. This type of battery can be found in many stores. It is a good idea to have a spare battery available. Batteries can also be obtained by contacting the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).
- All results remain saved in the memory.

5

#### **Cleaning the Meter**

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

### \land WARNING

- Do not allow liquid to enter any openings in the meter.
- Do not spray a cleaning solution directly onto the meter.
- Do not immerse the meter in liquid.
- 1. Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened (wring out any excess liquid) 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.

# **Display and Error Messages**

### \land WARNING

- Never make therapy decisions based on an error message.
- If you have any concerns or see any other error display, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (R0I).

Display	Action
The meter will not turn on or the display is blank.	<ul> <li>Battery is dead. Insert new battery.</li> <li>Display is damaged. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).</li> <li>Meter is defective. Contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).</li> <li>Extreme temperatures. Move the meter to a more temperate area.</li> </ul>
<b>i +</b> •	Battery power is low. Change the battery soon.
	The meter is in set-up mode, waiting for you to change or confirm settings.
	The meter is ready for you to insert a test strip.
	The meter is ready for a drop of blood or control solution.
HI	Blood glucose may be higher than the measurement range of the system. See Chapter 2, Unusual Blood Glucose Results.
LO	Blood glucose may be lower than the measurement range of the system. See Chapter 2, Unusual Blood Glucose Results.

5

# 5 Maintenance and Troubleshooting

Display	Action	
()	Blood glucose is below the defined hypoglycaemic (low blood glucose) level. See Chapter 2, Unusual Blood Glucose Results.	
*	A general marker was assigned to this test result.	
Ŭ	A pre-meal marker was assigned to this test result.	
Ť	A post-meal marker was assigned to this test result.	
<b>è</b> 🖡	A pre-meal marker was assigned to this test result and the post-meal test reminder has been activated.	
E-1	The test strip may be damaged or not properly inserted. Remove and reinsert the test strip, or replace it if damaged.	
E-3	<ul> <li>Your blood glucose may be extremely high or a meter or a test strip error has occurred.</li> <li>If your test result matches how you feel, contact your healthcare professional immediately.</li> <li>If your test result does not match how you feel, repeat the blood glucose test. See Chapter 2, Unusual Blood Glucose Results.</li> <li>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.</li> <li>If the second test result does not match how you feel, perform a control test with the control solution and a new test strip.</li> <li>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.</li> <li>If the control result is not within the acceptable range, see Chapter 4, Understanding Out-of-Range Control Results.</li> </ul>	

Display	Action
E-4	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.
8-5	Blood or control solution was applied to the test strip before the flashing drop symbol appeared on the display. Discard the test strip and repeat the blood glucose or control test.
E-7	An electronic error occurred, or in rare cases, a used test strip was removed and reinserted. Turn the meter off and on, or take the battery out for 20 seconds and reinsert it. Perform a blood glucose or control test.
8-8	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.
E-9	The battery is almost out of power. Change the battery now. If the message reappears after the battery has been replaced, remove the battery again, press any meter button, then reinsert the battery.
E - 10	The time and date settings may be incorrect. Make sure the time and date are correct and adjust, if necessary.

# 5 Maintenance and Troubleshooting

6

# **Product Limitations**

See the literature packaged with the test strips and control solution 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 Relative humidity operating range	Refer to the test strip package insert.	
Meter storage conditions	Temperature: -25–70 °C	
Memory capacity	500 blood glucose results and 20 control results with time and date	
Automatic power off	2 minutes	
Power supply	One 3-volt lithium battery (coin cell type CR2032)	
Display	LCD	
Dimensions	$94 \times 52 \times 21 \text{ mm}$ (LWH)	
Weight	Approx. 59 g (with battery)	
Construction	Hand-held	
Protection class	Ш	
Meter type	The Accu-Chek Aviva meter is suitable for continuous operation.	
Control solution storage conditions	Refer to the control solution package insert.	

# 6 Technical Information

**Electromagnetic Compatibility** – This meter meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. 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.

Performance Analysis - Refer to the test strip package insert.

Test Principle - Refer to the test strip package insert.

### Product Safety Information

### \land WARNING

- . Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the
  meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

### **Discarding the Meter**

### \land WARNING

- During blood glucose testing, the meter itself may come into contact with blood. Used meters
  therefore carry a risk of infection. Before discarding the meter, remove the battery or batteries.
  Discard used meters according to the regulations applicable in your country. Contact the local council
  and authority for information about correct disposal.
- The meter falls outside the scope of the European Directive 2002/96/EC Directive on waste electrical and electronic equipment (WEEE).
- Discard used batteries according to local environmental regulations.

# **Explanation of Symbols**

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

	Consult instructions for use
$\triangle$	Caution, refer to safety-related notes in the instructions for use accompanying this product.
X	Temperature limitation (store at)
	Manufacturer
REF	Catalogue number
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
<b>C €</b> 0123	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
(+ 1	3-volt coin cell type CR2032
X	Keep new and used batteries away from children.

6

# 6 Technical Information

On the finger pricker itself and on the packaging of the Accu-Chek FastClix finger pricker, you will encounter the following symbols, shown here with their meaning.

2	Use only once
$\Box$	Use by
LOT	Batch code
STERILE R	Sterilized using irradiation
CE	This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.

#### Guarantee

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

#### Warranty and Service Instructions

Roche warrants the meter against any material and manufacturing defects that may arise during proper use of the meter. For precise terms and conditions, please see the warranty card in the box. This warranty does not affect any statutory or other rights. The warranty ceases to apply if the meter has been misused or tampered with. Roche undertakes to repair faulty components free of charge or, at their discretion, to provide a fault-free replacement meter. Be sure to fill out the warranty form that came with your system and return it to Roche.

Statutory and other rights: This manufacturer's warranty is in addition to any statutory or other rights which may be acquired by the customer through his dealings with the meter supplier. The statutory provisions on rights in consumer goods sales in the country of purchase shall apply.

### **Additional Supplies**

#### Test Strips

Accu-Chek Aviva test strips

#### **Control Solutions**

Accu-Chek Aviva control solutions

#### Lancet Drums

Accu-Chek FastClix lancet drums

### Using the Accu-Chek FastClix Finger Pricker



- 1. Cap
- 2. Depth Indicator
- 3. Lever (for advancing to new lancet)
- 4. Lancet Counter
- 5. Release Button
- 6. Comfort Dial with Depth Selection



\*To obtain an AST converter cap, please contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

# 7 The Accu-Chek FastClix Finger Pricker

	<ul> <li>A used lancet drum has a visible red stripe on the white end.</li> <li>You cannot reuse a used lancet drum.</li> <li>Do not remove the lancet drum until you have used all 6 lancets.</li> </ul>
•2•1·	<ul> <li>The penetration depth indicator on the comfort dial shows the current depth setting. The higher the number, the deeper the penetration. The best depth setting is the lowest number that lets you get enough blood for a test. Try different depth settings to find the best one.</li> <li>For soft skin, we suggest a depth setting of 2. For thick skin, try a higher depth setting.</li> </ul>

#### **Inserting a Lancet Drum**

You must first load the lancet drum into the finger pricker to get it ready for use.



Remove the cap. Insert a new lancet drum, white end first, until it clicks firmly into place.



Slide the cap on until it stops by aligning the notch on the cap with the notch on the finger pricker.



You are now ready to use the first lancet. The lancet counter shows a number 6, meaning you have six new lancets remaining.

### NOTE

Once the lancet drum is inserted into the finger pricker, do not remove the lancet drum until completely used. The lancet drum cannot be reused once it has been removed from the finger pricker.

# \land WARNING

The Accu-Chek FastClix finger pricker is intended for patient self-monitoring by an individual person only. It must not be used to collect blood from more than one person as it does not incorporate any features to guard against cross-infection.

# \land WARNING

You must not insert the lancet drum into the finger pricker and simultaneously press the release button or hold the finger pricker with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

# \land 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).

# Taking a Fingertip Blood Sample



Wash and dry your hands.



Make sure you select the correct cap. Adjust the penetration depth by turning the comfort dial.



Press the finger pricker firmly against the side of your fingertip.

Press the release button on the end of the finger pricker all the way down to prime the lancet and prick the finger.



Load the next lancet by sliding the lever forward then slide it back all the way.

The lancet counter decreases one number.

# Taking an Alternative Site Blood Sample



Make sure you select the AST converter cap.

Dial the depth setting to 5½ for forearm or upper arm testing. Dial the depth setting to 3

2

for palm testing.



Press the finger pricker firmly against the selected puncture site and press the release button. Immediately lift the finger pricker off the site. Remove the AST converter cap by pulling it straight off.



Return the AST converter cap to the same position over the puncture site. Apply pressure to the site to help the blood drop form properly. Do not allow the cap to touch the blood drop.



Load the next lancet by sliding the lever (until it stops), then slide it back all the way.

The lancet counter decreases one number.

### NOTE

- Always use a new, sterile lancet each time you test to avoid infection.
- For safety reasons, once you advance to a new lancet, you cannot go back to a used lancet.
- NEVER reuse a lancet.
- NEVER share your finger pricker with anyone.
- If the blood drop is too small, release pressure for a few seconds, without removing the AST converter cap from the puncture site. Reapply pressure to the AST converter cap to get a sufficient blood drop.
- Once you perform a successful blood glucose test, you may want to find the lowest depth setting that
  provided enough blood with the least amount of pain.

### **Treatment of the Puncture Site**

Wipe the puncture site with a clean, dry tissue. If it continues to bleed, apply gentle pressure to the site with a plaster to protect it from dirt or infection.

## **Changing the Lancet Drum**

When you have used the sixth and last lancet, change the lancet drum.



Remove the cap.



Hold the lancet drum between your thumb and index finger and pull it straight out. A red stripe is visible on

the white part, indicating that the lancet drum has been used.



Throw the old lancet drum away. Always discard according to local regulations.



Insert a new lancet drum, white end first, until it clicks firmly into place. Slide the cap back on until it stops by aligning the notch on the cap with the notch on the finger pricker.

#### **Caring for the Finger Pricker**

Clean and disinfect the finger pricker regularly to prevent the transmission of infection. Follow these guidelines carefully to clean and disinfect without damaging the finger pricker.

#### When to clean and disinfect the Finger Pricker

- · At least once a week
- When there is blood on the finger pricker
- Before allowing anyone else to handle the finger pricker, for example, if someone is assisting you.

# \land WARNING

To avoid damaging the finger pricker:

- Do not dip the finger pricker and cap in any fluids.
- Use only water for cleaning and 70 % isopropanol for disinfecting.

#### NOTE

- · Clean the finger pricker and cap before they are disinfected to remove blood and dirt.
- To clean and disinfect the finger pricker and cap you need lint-free cloths, water, and 70 % isopropanol.

#### **Cleaning the Finger Pricker and Cap**

- 1. Remove the cap and lancet drum from the finger pricker.
- 2. Dampen a cloth with water.
- Thoroughly wipe the outside only of the finger pricker. Thoroughly wipe the inside and outside of the cap.
- 4. Dry the finger pricker and cap with a dry cloth.

#### **Disinfecting the Finger Pricker and Cap**

- 1. Remove the cap and lancet drum from the finger pricker.
- 2. Clean the finger pricker and cap.
- 3. Dampen a cloth with 70 % isopropanol.
- 4. Thoroughly wipe the outside only of the finger pricker for 2 minutes. Thoroughly wipe the inside and outside of the cap for 2 minutes.
- 5. Place the cap back on the finger pricker and wrap the finger pricker in the dampened cloth for 8 minutes.
- 6. Unwrap the finger pricker and let it air dry.

### Any Questions?

We want to give you the help you need for long and reliable service of your meter and finger pricker. Review your test procedure and make sure that you are performing the steps correctly. If you still have questions, please contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI). Please have your Accu-Chek Aviva meter, Accu-Chek Aviva test strips, and Accu-Chek Aviva control solutions available when you call.

### **IMPORTANT – READ CAREFULLY BEFORE USE**

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

# Index

# A

alternative site testing 10

# B

battery, changing 29 battery, installing 29 battery door 3 battery type 29, 35 beeper, setting 19 blood glucose results, unusual 13 blood glucose test 7 button, power/set 3, 6

### C

computer, transferring results to 24 control results, understanding out-of-range 28 control solution 25 control test, performing 26

#### D

display check 6 display messages 31

#### E

error messages 32

#### G

general marker 12 guarantee 39

### Н

high blood glucose 14 hyperglycaemia 14 hypoglycaemia 14 hypoglycaemic alert, setting 23

### L

low blood glucose 14

#### Μ

maintenance, meter 29 marking test results 12 memory, meter 15 meter, cleaning 30 meter, discarding 36

#### Ρ

post-meal marker 12 post-meal test reminder 12, 20 pre-meal marker 12 product limitations 35 product safety information 36 product specifications 35

#### S

settings, meter 17 supplies 39 symbols 37 symptoms, hypoglycaemia/hyperglycaemia 14

#### T

technical information 35 test reminders, setting 21 test strips 4, 5 time and date, setting 18 troubleshooting 31

#### U

use by date 5, 25

#### **United Kingdom**

Roche Diabetes Care Limited Charles Avenue, Burgess Hill West Sussex, RH15 9RY, United Kingdom

Accu-Chek Customer Careline <sup>1)</sup> UK Freephone number: 0800 701 000 ROI Freephone number: 1 800 709 600 <sup>1)</sup> calls may be recorded for training purposes

www.accu-chek.co.uk www.accu-chek.ie

LAST UPDATE: 2019-04



Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim, Germany www.accu-chek.com



ACCU-CHEK, ACCU-CHEK AVIVA, and FASTCLIX are trademarks of Roche.

© 2019 Roche Diabetes Care 07019505050(01)-0519