



Roche Diagnostics Limited
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

www.cobas.co.uk
www.accu-chek.co.uk

HOS 05166624001

Blood Glucose Management System

Accu-Chek® Performa

User manual for healthcare professionals



CONTENTS

3	Introduction
4	Staff Responsibilities
5	Protocol
6	About the Accu-Chek® Performa
7	Coding/Calibrating Your Meter
8	Performing an Internal Quality Control Test
	Performing a Blood Glucose Test
11	Dosing from a syringe
11	Capillary sampling using the Safe-T-Pro Plus
13	Capillary sampling using the Safe-T-Pro Uno
14	External Quality Assurance Scheme
15	Cleaning & Maintenance
16	Changing the Batteries
17	Contra-indications & Test Interference
18	Display Code Explanation

INTRODUCTION

Roche Diagnostics is part of an international health care organisation with an outstanding record in scientific achievement and innovative product development.

Dedicated to achieving the best possible standard of patient care, we are the largest provider of diabetes products and services in the world.

Designed to help you

This manual has been compiled by Roche Diagnostics to help you, the healthcare professional, achieve consistently reliable and accurate blood glucose results.

The different sections of the manual cover all aspects of working with Roche Diagnostics blood glucose monitoring systems, including comprehensive instructions on the use of meters, troubleshooting and maintenance, safety precautions and quality control procedures.

We have made this manual as comprehensive as possible, but if you have any queries please don't hesitate to contact your Biochemistry Dept, or Diabetes Specialist Nurse.

The purpose of this manual is to provide you with the information you need to achieve accurate results.

Together, we can work in partnership to ensure the best possible quality of care for patients.

STAFF RESPONSIBILITIES

It is essential that staff undergo formal training and understand the importance of a strict quality control programme. Use of meters by untrained staff can adversely affect the treatment of patients.

IMPORTANT: *A management or therapeutic decision based on an unreliable blood glucose result could be fatal.*

Recommendations¹:

- All staff who perform blood glucose measurements must be properly trained to use the equipment
- Untrained or insufficiently trained staff should not use a blood glucose meter
- Quality control (QC) checks should form part of the maintenance routine, with the biochemistry department directly involved
- Quality control procedures should aim particularly at maintaining the competence of all equipment users and ensuring the reliability of the results being obtained

In the event of an adverse incident

It is the responsibility of anyone operating a blood glucose meter to implement the following measures following an adverse incident:

- Report incident to Clinical Advisor, Manager, DNS or Biochemistry team
- Quarantine:
Meter, test strips, QC solution and log book
- Record details of:
Meter serial number, code number of strips and lot number of QC
- Inform the local Roche Diagnostics representative or Nurse Educator
- MHRA or IMB may need to be informed

1. Blood Glucose Measurements: Reliability of results produced in extra-laboratory areas. Department of Health (HN Hazard 87 13)

RECOMMENDED BLOOD GLUCOSE MONITORING PROTOCOL

1. Follow the manufacturer's guidelines and hospital policy (*standard operating procedure*) on testing at all times
2. Only a healthcare professional who has received appropriate training may carry out blood glucose monitoring at ward level^{1,2}
3. Each healthcare professional takes responsibility for ensuring the quality of all monitoring carried out by her/him, using the following procedures:
 - a) Quality control tests must be carried out:
 - according to manufacturer's instructions and hospital policy
 - when starting a new pack of Roche test strips
 - after changing the meter's batteries
 - after unexpected results, to check technique
 - each day the meter is used for patient tests
 - b) Only one pack of Roche test strips should be opened at any one time
 - c) The appropriate pack of Roche test strips must be stored with the meter for which it has been calibrated
 - d) The meter must be recalibrated each time a pack of test strips is renewed
 - e) All quality control tests must be recorded in the quality control log book³
4. A healthcare professional for each ward/department/site should be designated to ensure that the equipment is correctly maintained
5. Any sample reading below 2.8 mmol/L or above 20 mmol/L, or which is not in keeping with the clinical picture, should be verified by sending a venous specimen of blood to the laboratory for random blood glucose testing⁴. Please refer to your own Trust Blood Glucose Monitoring Policy for additional guidance.

This protocol should be followed in conjunction with the advice and guidance contained in NMC.

1. NMC (Code of Professional Conduct, 1992)

2. NMC (Scope for Professional Practice, 1992)

3. NMC (Standards for Records & Record Keeping, 1992)

4. NMC (Exercising Accountability, 1992)

ABOUT THE ACCU-CHEK® PERFORMA

Front view of meter



Back view of meter



Code Chip



On/Off/Set Button



**Top view
of meter**

**Golden End
(Electrodes)**



Test Strip



**Test Strip
Container**

CODING/CALIBRATING YOUR METER



When to code/calibrate

Before you use your meter for the first time and every time you open a new box of test strips, you need to code/calibrate the meter to match the strips.

Each code/calibration key provides your meter with the specific information it needs to accurately measure blood glucose.

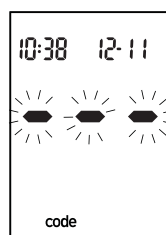
Do not use any other code/calibration key, except the one that arrives in the box with the pot of test strips.

Installation of Code/Calibration Key

A code key is properly installed when it snaps into place.

You will need to insert a new code key:

- Whenever one of these displays appear



See pages 17 and 18 for a full description of the error messages.

- Whenever you open a new box of strips:
1. Make sure meter is turned OFF
 2. Turn meter over so that you are looking at the back
 3. Remove old code key if one is installed and discard
 4. Insert new code key until it snaps into place
 5. Turn meter ON. A 3-digit code number appears. This number must match the code number on your vial of test strips. If it does not, repeat steps 1-5

NOTE : Always perform a QC test with each new pot of strips.

PERFORMING AN INTERNAL QUALITY CONTROL TEST



What are Internal Quality Control Tests?

They ensure that your system is working properly, that you are doing a test correctly, and the meter is providing accurate and reliable results.

When should I check my meter?

- Before using your meter for the first time
- When you open a new vial of test strips
- If you leave the cap off the vial of test strips
- If you drop the meter
- If the result does not agree with the clinical picture
- If you have repeated a test and the blood glucose result is still lower or higher than expected
- When you want to check the performance of the meter and test strip
- In line with the quality control policy in your organisation
- After changing the battery

What do I need?

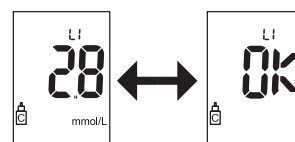
The Accu-Chek Performa automatically detects when you perform an internal quality control test. To perform a QC test, you need:

- Accu-Chek® Performa Meter
- Accu-Chek® Performa Test strips
- Accu-Chek® Performa Glucose Control Solutions
(Control 1 and Control 2)
- Log book

NOTE: When you open a new bottle of glucose control solution, write the expiry date on the label. Opened QC bottles are only good for three months.

PERFORMING A QUALITY CONTROL TEST

1. Insert a test strip into the meter.
The meter turns on.
2. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, take the test strip out and reinsert it into the meter.
3. Select the control solution you want to test. You will enter the level later in the test.
4. Put the meter on a flat surface, like a table.
5. Remove the control bottle cap. Wipe the tip of the bottle with a tissue.
6. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow end of the test strip. When you see ⌚ flash, you have enough control solution in the test strip. Wipe the tip of the bottle with a tissue then cap the bottle tightly.
7. A result appears on the display, along with a control bottle symbol and a flashing “L”. Do not remove the test strip yet. Press ► once to mark it as Level 1. If you tested the Level 2 control, press ► a second time.
8. Press ⏸ to set the level in the meter.
9. “OK” and the control result alternate on the display if the result is in range. The range is printed on the test strip container label. “ERR” and the control result alternate on the display if the result is not in range. Remove the test strip and discard it.
10. Record result in QC log book.



PERFORMING AN INTERNAL QUALITY CONTROL TEST

What if the result is not within the acceptable range?

If the result is not within the acceptable range.

Check the following:

- Did you use control solutions or test strips that were past their expiration date?
- Did you leave the cap off the vial of test strips or glucose control solutions?
- Did the code in the meter match the code on the test strip vial label?
- Did you follow the testing steps exactly?
- Did you use the correct QC solution (L1 with Control 1 or L2 with Control 2)?
- Did you select the appropriate control result level (L1 or L2)?
- Did you wipe the tip of the QC solution bottle before use?

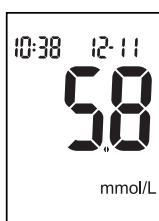
If your QC fails, first repeat the test. If the result is still not acceptable , do not use meter and contact your biochemist or DSN

PERFORMING A BLOOD GLUCOSE TEST



Capillary sampling using the Safe-T-Pro Plus/Uno

1. Wash hands thoroughly. Put gloves on
 2. Clean the side of the patients' finger using soap and water (*rinse well*) or gauze swabs. Ensure that the finger is thoroughly dry
 3. Promote blood flow to the site by allowing the arm to hang down by the side for a few seconds and then flex arm and fingers. If the hand is very cold, allow it to warm up before trying to obtain a blood sample
 4. Check expiry date of strips. Switch meter on
 5. Check that the code on the meter matches the code on the vial of test strips you are using
 6. Open test strip vial and remove the test strip. Replace vial cap
 7. Within 30 seconds, insert test strip (*yellow window facing up*) into test strip slot. The test strip symbol stops flashing and a blood drop will appear on the display
 8. Twist off protective cap until loose (*do not pull off until loose*)
 9. Firmly place lancet against side of finger and press firing button
 10. Once used, the lancet will permanently retract into its protective case. Safe-T-Pro Plus and Uno lancets are single use devices; dispose of whole device into a sharps bin
 11. Allow 5 seconds to elapse after pricking the finger and then rather than squeeze at the site of puncture, milk the blood down the hand towards the finger
 12. Touch the drop to the front edge of the yellow window of the test strip. Do not put blood on top of the test strip. When you see ⌚ flash, you have enough blood on the test strip.
- NOTE:** If you can still see yellow on the test strip after a second drop of blood is applied, remove the strip and repeat the test with a new strip. If the test pad is not completely covered with blood you may get an innacurate result.
13. Record result immediately using appropriate documentation
 14. Remove and dispose of test strip and any soiled materials in line with your policy on clinical waste
 15. Switch off meter



Dosing from a syringe

1. Transfer pipettes, small capillary tubes, adjustable volume pipettors (*i.e. Eppendorf pipettes*) and syringes may be used to apply venous, arterial and capillary blood to the test strip
2. Check expiry date of strips. Switch meter on
3. Check that the code on the meter matches the code on the vial of test strips you are using **See image A**
4. Open test strip vial and remove the test strip. Replace vial cap
5. Within 30 seconds, insert test strip (*yellow window facing up*) into test strip slot. **See image B**
The test strip symbol stops flashing and a blood drop will appear on the display
6. Touch the drop to the front edge of the yellow window of the test strip. Do not put blood on top of the test strip. When you see ⌚ flash, you have enough blood on the test strip.

NOTE: If you can still see yellow on the test strip after a second drop of blood is applied, remove the strip and repeat the test with a new strip

7. Record result immediately using appropriate documentation
8. Remove and dispose of test strip and any soiled materials in line with your policy on clinical waste
9. Switch off meter

EXTERNAL QUALITY ASSURANCE (EQA) SCHEME

Roche Diagnostics have the largest EQA scheme using the nationally accredited Quality Laboratory (QL) at the University Hospital of Wales.

The EQA scheme is available to any hospital using a Roche Blood Glucose monitoring system.

How does the scheme work?

Samples are sent from QL to a central administrative site on a regular basis. These should be tested exactly the same way as a sample from a patient. When the results are returned to the laboratory or logged on the website, the accuracy of your meter can be checked. This then forms part of the audit of the Blood Glucose testing procedure.

What to do when an EQA sample arrives

1. Complete and return the test on the same day
2. Use samples as if they were a normal blood sample
3. Carefully remove the lid
4. Gently squeeze bulb of pastette and draw sample into tube up to level shown
5. Gently squeeze bulb of pastette to form a large hanging drop
6. Apply drop to test strip as you would a patient sample
7. Ensure that entire test area is completely covered
8. Record result on Roche Diagnostics reporting labels supplied, and return to lab
9. Safely dispose of excess sample and pastette

IMPORTANT: *Use sample and return on the same day*

CLEANING & MAINTENANCE



Cleaning

- The meter should be cleaned regularly, in line with the policy in your organisation
- Always switch the meter off before cleaning
- Wipe with a slightly moist cloth and mild cleaning agent

Do not let liquid drip into the meter and take special care to keep moisture out of the code key slot and the test strip guide

Storage

- Keep your meter in the workstation to protect it from damage
- Keep the meter free from dust
- Protect the meter from extremes of temperature and humidity

Display Check

This verifies that all parts of the display are working

- Make sure that the meter is off
- Press and hold down the ON/OFF button
- The display should look exactly like the picture on the left
(if it does not, contact your biochemistry department or your DNS)



CHANGING THE BATTERIES



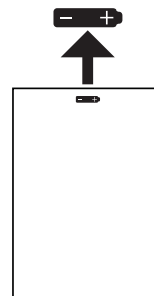
1.



2.

Warning Signs

When a battery symbol appears on the display, your battery is weak and has only enough power to run a few more tests.



Inserting a battery

1. Push the recessed plastic tab of the battery compartment forward (*toward the arrow*) to flip open the battery door
2. Insert the battery into the compartment with “+” side facing you
3. Snap battery cover back into place

Useful information: Your meter takes one 3-volt alkaline battery type 2032 (CR 2032, DL 2032)

ACCU-CHEK® Performa (TEST INTERFERENCES)

IMPORTANT. A minority of your patients may be affected by the following test interferences

Substance	Interference Limit	
Interference due to treatments		Therapeutic Range
Icodextrin / Maltose*	> 0.38 mmol/L	N/A
Treatments containing Icodextrin / Maltose	*EXTRANEAL™ (for patients on CAPD)	*OCTAGAM™, Gammagard (i.v. human immunoglobulin preparation)
Interference due to medical conditions		Physiologic Range
Galactose	> 0.44 mmol/L	< 0.28 mmol/L
Lipids	> 39.6 mmol/L	0.34 - 3.70 mmol/L (TRIG)
Haematocrit	No effect with Haematocrits between 10% & 70%	
Contra-indications		
Severe dehydration, Hypotension, Shock		} The recommendation from the MHRA is that a venous sample should be sent to the laboratory for verification
Peripheral circulatory failure		
Hyperosmolar non-ketotic coma (HONK)		
Diabetic ketoacidosis (DKA)		

IN THE EVENT OF AN ADVERSE INCIDENT:

1. Report incident to Clinical Advisor, Manager, DNS or Biochemistry team.
2. Quarantine meter, test strips, QC solution and log book. Also record details of the serial number of the meter, code number of the strips and lot number of QC.
3. Check and retain the log book (i.e. are the controls within range?).
4. Inform the local Roche Diagnostics representative or Nurse Educator.
5. MHRA or IMB may need to be informed.

- Patients receiving intravenous infusion treatments containing maltose (inc. EXTRANEAL™ or OCTAGAM™) should not be tested using Performa blood glucose monitoring system.
- The above-mentioned substances cause interference to glucose measurements obtained using the Performa blood glucose monitoring system.

DISPLAY CODE EXPLANATION



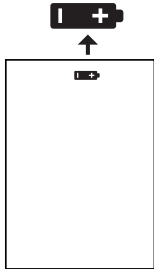
Never make treatment decisions based on an error message. If you have any concerns, call Roche Diagnostics.



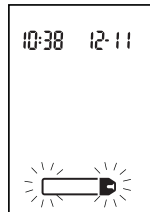
The meter will not turn on or the display is blank.

- Battery is dead – Insert new battery
- Display is damaged – Call Roche Diagnostics
- Meter is defective – Call Roche Diagnostics
- Extreme temperatures – move the meter to a more temperate area

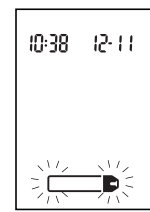
Screen messages



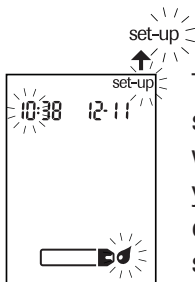
Battery power is low. Change the battery soon.



The meter is ready for you to insert a test strip.



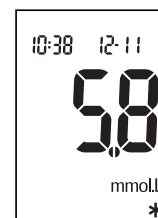
The meter is ready for a drop of blood or control solution.



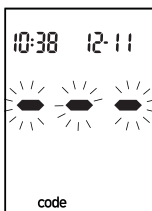
The meter is in set-up mode, waiting for you to change or confirm settings.



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



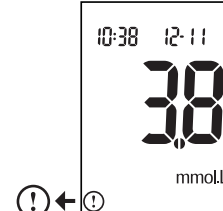
This test result was flagged.



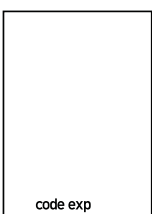
The meter is not coded or the code chip is not inserted. Turn off the meter and recode it.



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

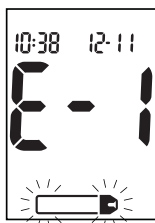


Blood glucose is below the defined hypo (low blood glucose) level.



The test strips will expire at the end of the month. Before the end of the month, insert a new code chip from a new box of test strips and ensure the code chip number matches the code number on the test strip container. Make sure the time and date in the meter are correct.

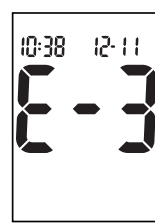
DISPLAY CODE EXPLANATION



The test strip is damaged. Remove the test strip and reinsert it, or replace it if damaged. If the message reappears, call Roche Diagnostics.



The code chip is incorrect. Turn off the meter and insert a new code strip. If this does not fix the problem, call Roche Diagnostics.



An error occurred during the test. Discard the test strip and repeat the test.



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.



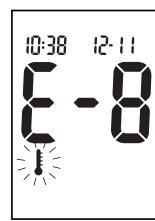
The code chip is from an expired lot of test strips. Ensure the code chip number matches the code number on the test container. Make sure the time and date in the meter are correct.



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



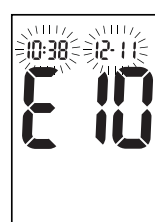
An electronic error occurred or, in rare cases, a used test strip was removed and reinserted. Turn the meter off and on, or take the battery out for a few seconds and reinsert it. Perform a blood glucose or control test. If the problem persists, call Roche Diagnostics.



The temperature is above or below the proper range for the meter (6 to 44°C). Move to an area between 6 and 44°C, wait five minutes and repeat the test. Do not artificially heat or cool the meter.



The battery is almost out of power. Change the battery now.



The time and date settings may be incorrect. Make sure the time and date are correct.

