Related Documents	
COSHH	Inform II Strips_16933 Performa IQC solutions_2824
Risk Assessments	Use of Performa blood glucose meter
Others	

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Significant changes from previous version:
Addition of result reporting responsibilities

Purpose
To describe the use of the Roche Accu-Chek® Performa blood glucose meter and Inform II strips for patient blood glucose testing by healthcare professionals.

Clinical indications
The Diabetes Control and Complications Trial (DCCT) confirmed the significant benefits of self-monitoring of blood glucose when practiced as part of a larger intensive strategy to tightly control glucose concentrations. The device used to monitor blood glucose must be reliable, accurate, fast, easy and convenient to use. The glucose meters used by patients and healthcare professionals are for monitoring, not diagnosis.
Staff that have been trained and are aware of the contra-indications to their use should only use these meters.

Principles of Measurement
The Roche Advantage method for measuring blood glucose is based on novel enzyme technology and microelectronics. When whole blood is applied to the strip, electrons are produced by the conversion of glucose to gluconolactone by the enzyme glucose dehydrogenase and the coenzyme PQQ. The electrons are transferred through a mediator, potassium ferricyanide. The resulting current of electrons is proportional to the glucose level in the blood. This dynamic process is monitored by the sensor and is translated into accurate glucose readings.

Instrumentation
Roche Accu-Chek® Performa blood glucose meter. Operating temperature 6°C to 44°C, 10 to 90% relative humidity.
Replacement meters are available from Clinical Biochemistry (see contact details).

Equipment

Roche Accu-Chek® Safe-T-Pro Plus lancing device
Disposable Gloves

Reagents

Roche Accu-Chek® Inform II Testing Strips. Product code 05942861. Store at 2°C to 30°C. Use at 8°C - 44°C. Use until the expiry date on the container, ensuring the lid is kept tightly closed.

The Test Strips contain no interference from maltose as indicated by the green  *symbol on the label.*

Roche Accu-Chek® Performa Control Solutions. Store at 2°C to 32°C.

Specimen requirements

Whole blood from capillary, venous or arterial samples may be used.
Blood collected in plain, heparin or EDTA containing tubes can be used. **DO NOT use blood taken into tubes containing fluoride**.

0.6 µL of sample is required.

Calibration

The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using the hexokinase method. This method is traceable to NIST standard.

A calibrator code chip is supplied with each box of Performa testing strips. The code chip is placed in the back of the blood glucose meter and correlates the results obtained by the meter to the reference values.

In order to obtain an accurate blood glucose reading the meter must be calibrated every time a new pack of testing strips is opened. Only one pack of testing strips should be open at any one time. **Always ensure that the number printed on the back of the code chip corresponds with the number printed on the pack of testing strips.**

To code the meter:

1. Discard any code chips from previously opened boxes of testing strips.
2. Open a new box of testing strips and locate the code chip.
3. Turn the meter off.
4. Holding the meter in your hand turn the meter over so that it is face down.
5. Remove the old code chip (if there is one in the meter) and discard it.
6. Take the new code chip and turn it over so that the code number is face down. Gently push the code chip into the slot until it stops. **Do not** force the code chip into the meter – it is designed to go into the meter only one way.
7. Leave the code chip in the meter until a new box of testing strips is opened.

Quality control

Internal Quality Control

The meter should be checked with both levels of quality control solutions, Level 1 and Level 2. Testing should be daily or, if the meter is used infrequently, prior to performing a patient blood glucose test. Additional checks should be carried out when a new box of testing strips is opened, if the test strips have been stored incorrectly, if the meter is dropped, if the battery is changed or if an unexpected patient result is obtained prior to repeating the test.

The control material is stored at room temperature and is stable for 3 months after opening. Write the date the bottle was opened on the bottle label. **Do not** use 3 months past this date or past the expiry date on the bottle label, whichever comes first.

Testing control solutions with known concentrations of glucose ensures that the meter and strips are performing acceptably. The label on the test strip container shows the acceptable ranges for the control solutions. The control results must be within the given acceptable ranges before patient testing.

Performing a quality control (QC) test on the Performa glucose meter:

Ensure all QC results are recorded in the QC Log Book.

1. Insert a test strip into the meter and ensure the calibrator code number on the meter display matches that on the strip container. Place the meter on a flat surface.
2. Gently mix the control solution. Remove the cap and gently squeeze the bottle to expel the solution. Discard the first couple of drops onto tissue paper and wipe the tip of the bottle with lint-free tissue.
3. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the front edge of the yellow window of the test strip. When the hourglass symbol flashes, sufficient solution has been applied. Re-cap the bottle tightly.
4. After a few seconds the quality control result will be shown on the display along with a control bottle symbol and a flashing 'L'.
5. Before removing the test strip, press ► once for Level 1 control solution and twice for Level 2. Press and hold the ⓘ button to set the control level.
6. Remove and discard the test strip.
7. If the control result is within range '**OK**' will be displayed. Continue with the second control solution or patient test.
8. If the result is out of range '**Err**' will be displayed. CHECK the following and then REPEAT the test:
   a) Meter — correctly calibrated for batch of strips in use; any error messages; was the correct control solution level selected (step 5 above)
   b) Test Strips — expiry date; strips are not bent or damaged; correct storage conditions
   c) QC solution — empty/nearly empty bottle; bottle has not been open more than 3 months; expiry date; correct storage conditions

If the result is now within range, continue with the second QC test or patient blood glucose as appropriate.

If result is still outside the range, do not use the meter and ensure no other operators can use it. Contact Clinical Biochemistry for further guidance (see contact details).

External Quality Control

To comply with the Trust POCT Policy, all healthcare professionals using a glucose meter MUST participate in the external quality assurance (EQA) scheme. It is the operators' responsibility to ensure they are enrolled on the scheme.

The EQA samples are supplied bi-monthly from WEQAS and distributed by Biochemistry. The sample should be treated as a patient sample and the result obtained returned to Biochemistry as soon as possible. The results are compiled by Biochemistry and report issued to each user. Performance is monitored by Biochemistry and users with poor performance and/or poor compliance will be contacted.

Method

1. Ensure internal quality control has been analysed on the meter within the last 24 hrs and the results were acceptable.
2. Wash and dry hands. Put gloves on.
3. Wash patient's hands and rinse and dry thoroughly. Do not use alcohol-based solutions or swabs or apply analgesic creams.
4. Remove one test strip from the container and immediately replace the lid.
5. Insert the test strip into the slot at the bottom of Performa meter in the direction of the arrows on the test strip (yellow window facing up). This turns the meter on.
6. Check that the calibration code displayed on the meter matches the code on the container of testing strips. A flashing blood drop will appear on the display.
7. Lance the side of the fingertip using the Roche Accu-Chek® Safe-T-Pro Plus lancing device, set at an appropriate penetration depth.
   - Twist off the protective cap
   - Place firmly against the finger and press the firing button
   - The lancet will automatically retract into its protective case.
   - Dispose into a sharps bin.
8. Use gentle pressure to massage blood to the fingertip from the palm of the hand and wait for a drop of blood to form.
9. Touch the drop to the front edge of the yellow window of the test strip. Do not put blood on the top of the test strip.
10. When the hourglass symbol flashes, sufficient blood has been applied. If no flashing hourglass symbol appears further blood can be added within 5 seconds. If some of the yellow target area remains exposed after a second drop of blood is applied, repeat the test with a new testing strip.
11. The glucose result appears on the display.
12. Remove and discard the test strip in clinical waste.
13. The meter turns itself off five seconds after the test strip is removed.

Reporting of Results

All results are displayed in mmol/L.

The test strips are plasma-referenced in line with the recommendations of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), i.e. although whole blood is applied to the test strip, the meter shows results that are equivalent to the glucose concentrations in plasma.

Responsibilities of personnel in authorising reporting and monitoring reports:

(i) Users are responsible for ensuring results outside the expected range are communicated immediately to the relevant member of staff, as highlighted in training and in accordance with the Trust POCT Policy.

(ii) Any therapeutic decision based on the POCT result is the responsibility of the person treating the patient.

(iii) Users are also responsible for ensuring results are recorded appropriately in the patient notes or log book, in accordance with the Trust POCT Policy.

Reference Range

These devices are intended for monitoring glucose concentration, not diagnosis and therefore a reference range is not applicable.
If 'LO' is displayed on the meter, blood glucose may be below 0.6 mmol/L.
If 'HI' is displayed on the meter, blood glucose may be over 33.3 mmol/L.
A high or low result should be confirmed on a venous sample analysed in the laboratory.

If the blood glucose result does not reflect the patient's clinical symptoms, or is unexpectedly high or low, a quality control test should be performed to check the performance of the meter. If this is satisfactory, the patient test should be repeated and if confirmed then medical staff informed.

Turnaround Time

All samples should be analyzed immediately

Assay characteristics

The Accu-chek Performa System complies with the requirements of EN ISO 15197 (In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).

Linearity:	0.6 to 33.3 mmol/L
Detection limit:	0.6 mmol/L
Test time:	5 seconds
Precision:	Within batch typically 3.3% CV Between batch typically 1.6% CV
Accuracy:	Glucose < 4.2 mmol/L – 34/36 results within ± 0.56 mmol/L Glucose > 4.2 mmol/L – 163/164 results within ± 20%

Interferences

Lipaemia:	Triglycerides > 20.3 mmol/L may produce elevated results
Galactose:	Blood concentrations of galactose > 0.83 mmol/L will cause over estimation of blood glucose.
Ascorbic acid:	IV administration of ascorbic acid which results in blood concentrations > 0.17 mmol/L will cause overestimation of blood glucose levels
Haemoglobin	No interference
Hypernatraemia:	No interference

The Test Strips contain no interference from maltose as indicated by the green symbol on the label.

Limitations

Haematocrit should be between 10 % and 65 %. Low haematocrit may cause higher results
High haematocrit may cause lower results

Blood glucose meters should not be used for patients who have peripheral circulatory failure. The results might not be a true reflection of the physiological blood glucose level. For example: in severe dehydration as a result of DKA or due to hyperglycaemia, hyperosmolar non-ketotic coma, hypotension, shock, peripheral vascular disease, severe vomiting and diarrhoea.
Glucose meters are also contra-indicated for patients who cannot recognize or respond to thirst sensations and in patients who have sustained uncontrolled diabetes.

Maintenance

1. **Changing battery**
   One round 3V alkaline battery is required to power the meter.
   - Open the battery door by pushing the tab in the direction of the arrow and pulling the door up. Remove the old battery.
   - Replace the battery - the positive (+) side should be uppermost.
   - Replace the battery door and wait 5 seconds before switching on the meter for use.

2. **Cleaning/Disinfecting the meter**
   The following parts of the meter may be disinfected: the area around the test strip slot, the display and the outer casing. The meter should be disinfected if there is any blood on the meter, carefully check all recesses, grooves and gaps and the test strip slot.
   - Turn the meter off.
   - Gently wipe the meter's surface with a soft cloth slightly dampened with any of the following cleaning solutions: Super Sani-Cloth
     70% isopropyl alcohol
     Mild dishwashing liquid diluted with water.
     10 % household bleach solution in water.
   - Allow the meter to dry before use.

MAKE SURE THAT NO LIQUID ENTERS THE METER. Do not spray anything onto the meter and do not immerse it in liquid.

3. To check the display

- Turn the meter off.
- Press and hold the ⏻ power button to see the complete display.
- Ensure that all the segments are working and clear.

The screen should look like this

Additional Information

Meter display warning / error messages

Meter won't turn on or display is blank

- Battery is dead.
- Display is damaged
- Meter is defective

Battery power is low

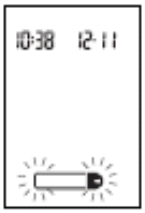
Meter is not coded

- Code chip not inserted.

Test strips will expire at end of current month

Blood glucose may be higher than measuring range of the system

Blood glucose may be lower than measuring range of the system

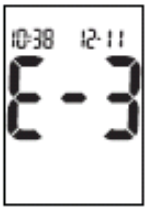


Meter is ready to use

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

Test strip is damaged
- Remove and reinsert
- Insert new

Code chip incorrect
- Insert new



Error during test
- Insert new test strip and repeat test.

Not enough sample drawn onto test strip.
- Insert new test strip and repeat test.

Code chip from expired test strips
- Ensure code chip matches test strips
- Check test strip expiry date
- Ensure time and date in meter correct

Sample applied to test strip before flashing drop symbol appeared.
- Insert new test strip and repeat test.

Electronic error, or used test strip inserted.
- Turn meter off and on again, or remove battery for 10 seconds.
- Repeat test

Temperature outside working range of meter (6-44°C).
- Move to correct temperature, wait 5 minutes and repeat test.
- DO NOT artificially heat / cool meter

Battery almost out of power
- Replace battery

Time and date settings may be incorrect
- Check and adjust if necessary

Contact Biochemistry if you cannot resolve an error message

Health and safety

All COSHH and risk assessment documents for the Roche blood glucose monitoring system are available from POCT if required (see contacts).

Contacts

Trust POCT Manager:	Kath Ashton	Tel: 0151 706 5587
Department of Biochemistry:	Office	Tel: 0151 706 4230

References

1. Guidelines for the Implementation of Near Patient Testing. *The Association of Clinical Biochemists.* September 1993 ACB Administrative Office, 2 Carlton House Terrace, London SW1Y 5AF.

2. Marks, V. Essential considerations in the provision of near-patient testing facilities. *Ann Clin Biochem,* 1988: 25, 220-25.

3. Extra-Laboratory Use Of Blood Glucose Meters and Test Strips: Contraindications, Training and Advice To The Users. *MDA Safety Notice 1996*

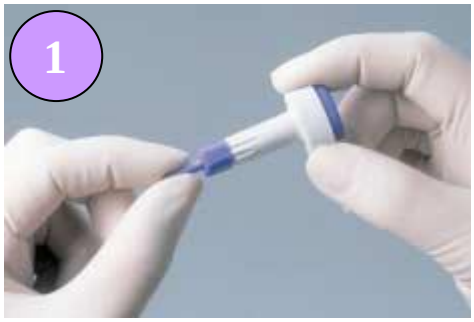
4. Blood Glucose Measurements: The Need for Reliability of Results Produced in Extra-Laboratory Areas. *NHS Hazard Notice 1989*

5. Near Patient Testing: Welsh Scientific Advisory Committee (Welsh Office) 1995.

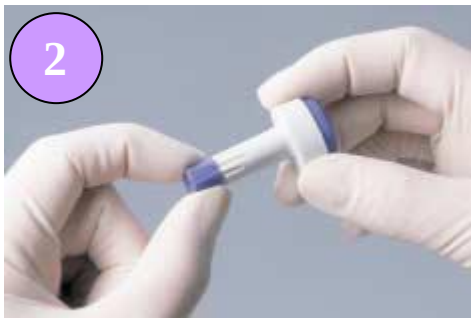
ACCU-CHEK® Safe-T-Pro Plus Lancets

Quick Reference Guide

Three simple steps:

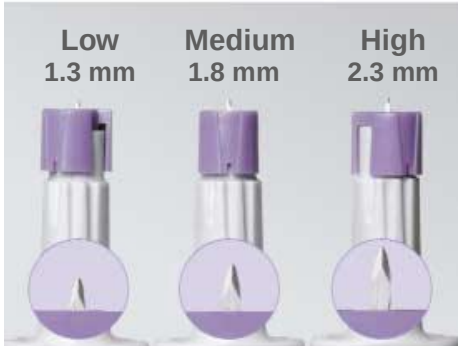


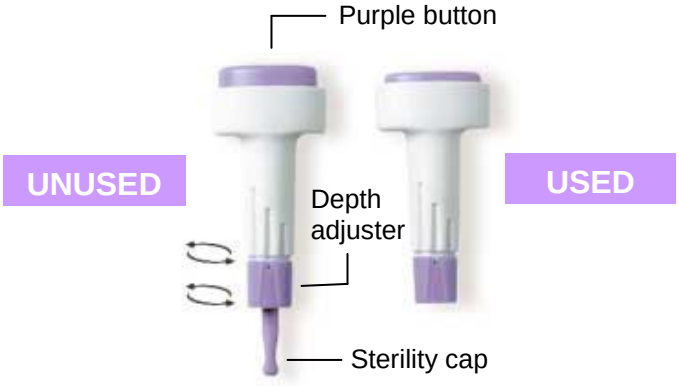
Hold the device and twist off the sterility cap by twisting it in either direction.
Throw the sterility cap away.



The depth adjuster is preset at medium depth: Select the depth you want by turning the depth adjuster.

Ensure the finger is clean and dry (soap and water).
Hold the Accu-Chek Safe-T-Pro Plus firmly against the side of the finger and press the purple button.





Dispose of used lancets into a sharps container

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