STANDARD OPERATING PROCEDURE FOR THE ROCHE ACCU-CHEK PERFORMA GLUCOSE METER

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The amendment must be authorised by the POCT Manager to ensure all copies including the electronic version are updated simultaneously				
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Ten or less minor amendments may be recorded before a new edition is issued.				
Major changes must result in the immediate review of the procedure.				
Document amendment does not replace the review process.				

HAZARDS AND PRECAUTIONS

For appropriate use of protective clothing, please refer to 'Use of Personal Protective Equipment (PPE) in Pathology and Phlebotomy

Substance	Hazards	Precaution	First aid Code*
Blood	Danger of infection	Follow standard precautions. See above. Dispose of in orange clinical waste bags.	A1, B, C, D
IQC	Danger of infection	Follow standard precautions. See above. Dispose of in orange clinical waste bags.	A1, B, C, D
EQA	Danger of infection	Follow standard precautions. See above. Dispose of in orange clinical waste bags.	A1, B, C, D
PDI Sanicloth 70 (cleaning wipe containing 70% isopropyl alcohol)	Irritating to eyes (R36) Highly flammable (R11)	Keep away from sources of ignition. No smoking	A, B, C

IF IN ANY DOUBT CONSULT A SENIOR MEMBER OF STAFF OR YOUR SAFETY REPRESENTATIVE

***Key:**

A1 **Ingestion: wash mouth thoroughly with water and give plenty to drink. In severe cases obtain medical attention.**
B **Eye contact: irrigate thoroughly with water. Seek medical help.**
C **Skin contact: wash off skin thoroughly with water.**
D **Inhalation: remove to fresh air. If severe call a physician.**

If First Aid treatment has to be given contact the nearest first aider but do not delay treatment to the casualty.

If necessary, call the crash team 2222.

Treat all body tissue and waste as potential infective.

In all cases, an Incident form must be filled in and report to Occupational Health or Accident Service if out of hours.

See Also Risk Assessments:
Blood or Body Fluid Analysis 47
Blood glucose, ketones and HbA1c measurement outside the laboratory 96

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0 INTRODUCTION

0.1 Purpose and Scope

The Roche Accu-chek Performa glucose meters are used for the determination of glucose concentration, mainly in capillary specimens, although arterial or venous specimens can also be used. This document describes the procedure to be followed to ensure the provision of accurate and reproducible patient results for the clinician to act upon.

It is essential that all staff using this equipment are properly trained and that quality assurance procedures are performed regularly. Consequences for patients can be very serious if an incorrect result is acted upon.

These meters are used mainly by GP surgeries, mental health trust units and outreach clinics of the hospital. As the GPs and Mental health units are outside our Trusts scope we have tried not to refer to Trust policies but to refer users to their own local policies. Those from inside the Trust should refer to Trust policies.

0.2 Clinical Indication

Glucose analysis plays an important role in the evaluation of patients with diabetes and in other circumstances such as patients on steroids or patients with signs and symptoms of diabetes.

Glucose meters can only be used as a monitoring or screening tool and should not be solely used in the following conditions:

- The acute management of unstable diabetic states e.g. DKA, HONK or Hypoglycaemia (venous or arterial specimens may be of benefit in these cases, see details in section 1.2 Patient Preparation);
- To make a diagnosis of diabetes mellitus;
- To confirm a diagnosis of hypoglycaemia;
- Where the observed result is not in keeping with the patient's clinical status;
- Where the patient has peripheral shutdown.

In these circumstances, diagnosis and treatment decisions should only be made after laboratory confirmation of screening results, except hypoglycaemia where treatment may be given on the basis of Performa blood glucose results of <4mmol/L. However laboratory testing is required to confirm hypoglycaemia or if a patient is hypoglycaemic repeatedly.

0.3 Responsibilities

POCT Management group ensure:

- The responsibilities, authority and interrelationships of all personnel involved in POCT are specified and communicated within the organisation;
- Staff performing POCT receive appropriate training, supervision and competence testing;
- All proposals to introduce any product, device or system for POCT are evaluated for their clinical effectiveness and cost efficiency;
- The selection of POCT devices and systems includes their practicability and the comparability of their results with those obtained in the laboratory;
- The reports of the POCT quality assurance programme(s) are reviewed by the group and advice on improvement is provided and implemented.

Senior Clinical Biochemistry Management Staff ensure:

- Departmental policies and procedures are in accord with the requirements of the MHRA bulletins, Trust Medical Device Management Policy and Pathology Accreditation [CPA(UK)Ltd] standards and any other quality standards to which the organisation subscribes;
- The needs and requirements of the users are reviewed regularly;
- Persistent problems are escalated to the relevant manufacturer and actioned;
- Determining and documenting back up plans if equipment is out of action;

Clinical Biochemistry Staff with POCT responsibilities ensure:

- Regular tasks in the management of the POCT service are carried out;
- Persistent problems are notified to senior departmental staff;

Users ensure:

- Their annual training is kept up to date and they are competent to practice;
- The correct specimen is obtained from the correct patient under the correct circumstances and the correct specimen is tested;
- The specimen is collected with minimal discomfort to the patient;
- The test is carried out according to the manufacturer's instructions;
- The test is correctly recorded in the device or record book and in the patient's notes;
- The specimen is disposed of according to local Policy;
- Clinical biochemistry POCT staff are informed in the event of problems with the device;
- The results are reported as appropriate.

Practice Managers ensure:

- Users of the equipment keep their training up to date and maintain their competency.
- Adequate supplies of consumables are maintained;
- Appropriate resources are available;
- Proper records of training and competency are maintained;
- Ensures that faulty equipment is taken out of use;
- Notifies the POCT team if equipment is obsolete or no longer required;

Infection Control Nurse / Safety representative ensures:

- Performs a risk assessment for handling biological material;
- Advises on precautions to be taken when handling biological material including spillages, and safe disposal.
- Advises on safety of products before purchase;
- Updates COSHH details and advises on precautions to be taken when handling all material including spillage, breakage and disposal.

Manufacturers ensure:

- The user is kept up to date with information regarding the device and the associated products that they provide;
- Provide training sessions for the user in order to provide competent use of the instrument;
- Fulfil the criteria agreed in the purchasing contract or tender.

0.4 References

- Management and Use of IVD Point of Care Devices, MDA Bulletin DB2010(02) **PD-GEN-MDAPOCTMg**
- LDH Point of Care Testing Policy **MP-GEN-LDHPOCTPo**

0.5 Definitions

The USER - any person who handles the device whether it is used directly to produce results or indirectly for maintenance and Quality Assurance Procedures. This includes Clinicians, Nursing Staff, Healthcare Scientists and Medical Equipment Technicians as necessary.
EQAS – External Quality Assessment Scheme
POCT – Point of Care Testing
SOP – Standard Operating Procedure
IQC – Internal Quality Control
MHRA – Medicines and Healthcare Products Regulatory Agency

0.6 Related Documents

- Accu-Chek Performa Blood Glucose Meter Owner's Booklet **LI-BIO-PerfOpMan**

- Accu-chek Performa Test Strip Insert **LI-BIO-InformStp**
- Accu-chek Performa Control Insert **LI-BIO-InformIQC**
- Glucose Meter Patient Results and Quality Control record book
- Performa Training Presentation **MI-BIO-POCGluCom**

1 PRE-EXAMINATION PROCESS

1.1 Training & Competency

Blood glucose testing may only be carried out by trained and competent users. If no trained users are available, a fluoride EDTA (yellow topped) specimen must be sent to the laboratory with an ICE request or manual request form.
Blood testing shall only be performed by authorised personnel who must use appropriate personal protective equipment.
Training is available from your local POCT team who can be contacted on 01582 497991.
For sites in our EQA scheme 1 hour of training is available a year.

1.2 Patient Preparation

When there is decreased peripheral blood flow (peripheral shutdown), capillary blood does not represent the whole body situation and therapeutic decisions must not be based on capillary specimens. Examples of such situations include, but are not limited to:

- Severe Dehydration
- Hypotension
- Shock
- Peripheral circulatory failure
- Hyperosmolar non-ketotic coma (HONK)
- Diabetic Ketoacidosis (DKA)
- Unconscious patients
- Peripheral vascular disease
- Decompensated heart failure (NYHA Class IV)

In the above situations, capillary blood may give much lower results than comparative venous or arterial specimens and a fluoride EDTA specimen (yellow top) should be sent to the laboratory for analysis (do not use this specimen on the Performa meter) or venous/arterial blood can be used on the test strip. If using arterial or venous blood on the glucose meter ensure there is minimal delay (less than 5 minutes) between the specimen being taken and it being applied to the strip. If sampling from a venous or arterial line the line must be flushed before drawing the specimen.

1.3 Primary Blood Specimens

Always remember to gain consent from the patient before taking a blood specimen.
To obtain a good capillary blood specimen the following steps should be followed:

1. Wear protective gloves
Reason – health and safety precautions for exposure to bodily fluids.

2. Prepare the patient's skin
If mobile the patient should be encouraged to wash their hands with soap and water and thoroughly dry them. If you can not wash the whole hand, ensure the site to be punctured is clean and dry; damp gauze followed by dry gauze is recommended.
Do not use alcohol gel or any other alcohol containing product to clean the lancing site as this will cause falsely low results by deactivating the enzyme used in the strip.
Reason – washing the site ensures that no contaminants (e.g. any food residues containing glucose) transfer to the test strip leading to a falsely high result. Drying the site ensures that a drop of blood forms and that the blood is not contaminated with any fluid on the skin causing a falsely low result.

3. Promote blood flow to the site

Try to ensure the patient's hands are warm and have good blood flow (washing the hands as above with soap and water can help with this). Allow the arm to hang down by the side for a few seconds and flex the elbow and fingers.

Reason – promotes good blood flow towards the fingertips to produce a good specimen for testing.

4. Prick the finger

When lancing the finger, use the side of the finger between the nail and the pad.
Avoid using the index finger and thumb or any finger with a ring on it. Prick the finger using your lancet.
In the hospital we use Unistik 3 Comfort (purple) or Unistik 3 Normal (yellow).
To use the Unistik lancet, hold the body and twist off the lancet cap until it separates from the device (do not pull) and dispose of it. Identify the lancing site and press the newly revealed end firmly against the finger and press the release button. The single use needle retracts immediately leaving the device safe for immediate disposal into a sharps bin.
It is important that you utilise a single use lancet to minimise the risk of infection.

Reason – the side of the finger is less painful as there are fewer nerve endings and it is also where capillaries flow up the side of the finger. It is easier to apply the drop of blood to the test strip from the side of the finger. The index finger and thumb are the most used digits and so it is less painful to the patient if they are not used.

5. Wait a few seconds before milking the finger

Allow a few seconds to elapse after lancing the finger and rather than squeeze the puncture site, milk the blood down from the hand through the finger by gentle massage. After sampling ensure the patient applies pressure and some gauze to the lanced area to staunch the blood flow.

Reason – Allow a few seconds after lancing the finger because the capillaries do not bleed immediately. The blood will flow more easily if the lanced area is not squeezed; if the finger is squeezed too hard, capillaries contract preventing blood flow and squeezing the puncture site will contaminate the specimen with tissue fluid causing falsely low results.

1.4 Spillage of Clinical and Non-Clinical Waste

Spillage of Clinical and Non-clinical waste must be dealt according to your local policy. The meter, workstation and any other consumables must be cleaned regularly and particularly if any spillages occur. Tissue and water should be used to remove blood spillages followed by a PDI Sanicloth 70 (or other cleaning cloth/material containing 70% isopropyl alcohol). The meter must be cleaned between every patient with a PDI Sanicloth 70 (or other cleaning cloth/material containing 70% isopropyl alcohol).

1.5 Retention of Clinical Material and Records

The patient's results should be immediately recorded in the Log Book and the patient's medical notes.

1.6 Disposal of Clinical and Non-Clinical Waste

Clinical and Non-clinical waste must be disposed of according to your local policy. Dispose of used test strips as clinical waste. Dispose of used lancets as sharps.

2 EXAMINATION PROCESS

2.1 Analytical Principle

Glucose is analysed by amperometry. The enzyme on the test strip, a mutant version of glucose dehydrogenase (Mut.Q-GDH), converts glucose in the blood specimen to

gluconolactone. This reaction creates a harmless electric current that the glucose meter interprets to give a blood glucose result. The specimen and environmental conditions are also evaluated using a small electrical signal.

2.2 Limitations of Analytical Procedure

2.2.1 The device

Test strips: There are no effects when the test strips are stored between 2°C and 30°C. Do not freeze. Test strips should only be used between 8°C and 44°C and between 10-90% humidity. Do not store test strips in high heat or humidity atmospheres.
Strips must always be stored in their original container with the cap closed. When removing a test strip from the container close the cap immediately and use the test strip straight away.
Performa glucose meter: There are no effects on results when the Performa meter is used at temperatures between 12°C and 47°C or at humidity levels <90% at 32°C.
For a complete list of interferences, limitations and cross reactivity refer to the test strip insert. The measuring range of the device is 0.6 to 33.3mmol/L. Results less than 0.6mmol/L will be recorded as 'LO', results greater than 33.3mmol/L will be recorded as 'HI'.

2.2.2 Cross-reactivity & interferences

The following substances when in excess of the interference limit may produce falsely elevated glucose results. For haematocrit; a low haematocrit can cause a falsely high glucose result and a high haematocrit can cause a falsely low glucose result.

Substance	Interference Limit	Example/Note
Galactose	>0.83 mmol/L	Galactosaemia
Triglycerides	>20.3 mmol/L	Extremely lipaemic blood (very high triglycerides)
Ascorbic acid	>0.17 mmol/L	Intravenous administration of ascorbic acid
Haematocrit	<10% or >65%	Severe anaemia or polycythaemia

2.2.3 Specimens unsuitable for analysis

Anticoagulants containing fluoride or iodoacetate may interfere with test results, so blood taken from a yellow topped specimen container cannot be used on the Performa II meter as false results will be produced. Alcohol from alcohol wipes or hand rub will also prevent the test from working properly. A list of common interferences is found in the pack insert.

2.2.4 Safety Notices

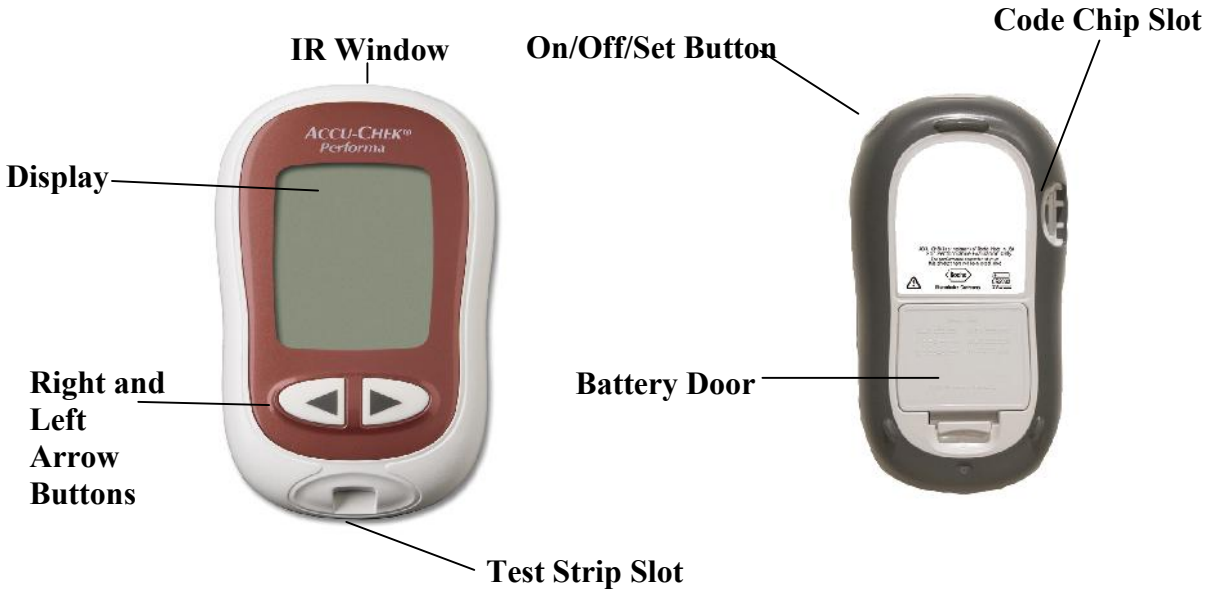
There are no current safety notices for this device.

2.3 Central Database and Connectivity

There is currently no connectivity or central database for the Performa meters

2.4 Equipment

The Performa meters are supplied by Roche diagnostics and will be kept in a workstation in your area of work. Replacement meters can be obtained via the POCT team on 01582 497991 if required.



2.5 Reagents/Consumables

Item	Source
Single use Lancets	Local Supplies
Gauze	Local Supplies
Cleaning materials	Local Supplies (cloth or similar must contain 70% isopropyl alcohol)
Internal Quality Control (IQC)	POCT team (supplied on an automatic rolling programme every 3 months)
External Quality Assurance (EQA)	POCT team (every 2 months)
Batteries	POCT team
Test strips	For GP surgeries a limited number of free of charge strips are available through the POCT team. For Mental Health Units/outreach clinics supplies are via L&D Pharmacy
Workstations	POCT team
Record books	POCT team

2.6 Calibration

Roche test strips may experience batch variations, so to ensure the accuracy of the system a code number which is printed on the test strip vial and a code key are supplied with each pack of strips.

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.

If you use the Accu-Chek® Performa while incorrectly calibrated, inaccurate blood glucose readings could result.

You will need to insert a new code key:

- Whenever you open a new box of strips
- Whenever one of these displays appear:

No code key

Incorrect code key

Expired lot

To calibrate the meter:

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 with a code key that matches your batch of strips.

2.7 Quality Assurance Programme

2.7.1 Internal Quality Control (IQC)

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

Quality control tests must be carried out:

- Before using your meter for the first time

- Each day before the meter is used for patient tests
- When starting a new pack of Roche test strips
- If you leave the cap off the vial of test strips
- After changing the meter's batteries
- If you drop the meter
- After unexpected results

We recommend that in low use areas IQC is carried out on a weekly basis regardless of whether patient testing is taking place. IQC material is stable 3 months from the date of opening. The POCT team therefore send out IQC on a 3 monthly basis to all the sites in our EQA scheme. The bottles are labelled with the date of their expiry. No area should therefore be without in date quality control material, however if these bottles are lost or damaged replacements can be obtained from the POCT team.

Performing IQC

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 vial of control solution you want to test. You will enter the level later in the test.

4. Put the meter on a flat surface.

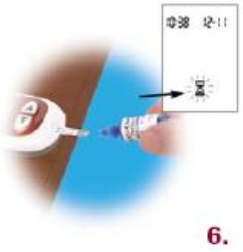
5. Gently mix the IQC samples

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 the hour glass flash, you have enough control solution in the test strip.

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 the left arrow button once to mark it as Level 1. If you tested the Level 2 control, press a second time.

8. Press the ON button 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 also 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 the record book.

11. If the result is within the expected range you can continue with patient testing.
    If the result is outside the expected range do not use the meter for patient testing. Check expiry dates, storage conditions and procedure, re-mix QC and re-test
    If results now in range – proceed with patient testing
    If results still out of range – Refer to the Troubleshooting guide (Section 2.10) for further information. Or contact the POCT team on 01582 497991 for further information/discussion.

2.7.2 External Quality Assessment (EQA)

EQA is a program that allows testing sites to assess the quality of their performance by comparing their results with those of other units.

Samples are sent from Welsh External Quality Assurance Scheme (WEQAS) to the POCT Team every two months. WEQAS provide aqueous solution that contains an unknown concentration of glucose. The sample will be forwarded to each registered participant by the POCT team. EQA should be tested on every meter in exactly the same way as a sample from a patient. Each meter receives its own letter and the serial number of the meter is noted and should be checked against the number on the reverse of the meter.

IMPORTANT: For best performance perform test and return results on the same day as receipt.

Apply the sample in a similar manner to the IQC solutions.

The return form should be completed and returned to the POCT Team (also record the results in your record book). When the results are returned to the POCT team they log the results on the WEQAS website, the accuracy of your meter/test strips/operator is then checked. A report of your performance is then returned to your area and should be kept with your records. Performance is highlighted as green (good), yellow (acceptable) or red (poor performance/unacceptable). It is important that the EQA results are returned as it is the only true way to check the meters, consumables and operators performance. Poor performance and non-returns will be followed up with each area individually. Poor performance is defined as a result >15% from the mean. For Trust sites poor performance or non-returns are recorded and managed as non-conformities.

Please note it is good practice to maximise the number of users involved in EQA sample analysis in order to monitor the overall performance.

Example of our EQA distribution letter:

2.8 The Test Procedure

Each user of the Performa meter must be trained and be assessed as competent (See Appendix 1 – Self assessment competency form).

If the meter is not working report the problem to the POCT team on 01582 497119 (Mon-Fri, 9am-5pm) and/or follow the Troubleshooting guide (Section 2.11). If you have more than one meter in your area please use an alternative, if this is not possible an ICE request form or manual request must be made and accompanied by venous blood taken into a yellow topped bottle and sent to the local laboratory.
Gloves must be worn when using the meter for patient testing.
Ensure the IQC has been performed prior to patient testing on this day.
Ensure the test strips are in date by checking the expiry date on the side of the pot.

Performing a patient test:

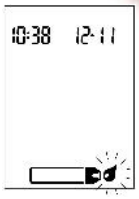
1. Open test strip pot and remove a test strip. Replace the cap on the pot of strips ensuring you hear a click to show the lid is on tightly. Insert the strip into the meter.


1.

2. Check that the code on the meter matches the code on the vial of test strips you are using.

2.

3. Ensure the test strip symbol stops flashing and a blood drop has appeared on the display.

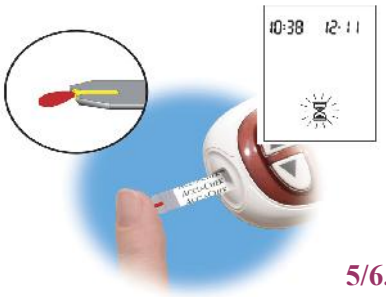


3.

4. Lance the finger according to the instructions in section 1.2

5. Touch the drop of blood to the front edge of the yellow window of the test strip (do not put blood on top of the test strip).

6. When you see the flashing hour glass you have enough blood on the test strip. If you applied blood, but do not see the flashing hour glass you may reapply more blood within five seconds.



5/6.

7. Your result appears on screen. Record result immediately in your record book and in the patient's notes.

8. Remove and dispose of test strip, lancet and any soiled materials in line with local policy on clinical waste.

9. Switch off the meter.

7.

2.9 Results

Record the results in the Patient Result and Quality Control Book and in the patient's notes.
The Patient Results and Quality control book must contain the following:

- Date
- Time
- Quality Control Results
- Patient's NHS number or DOB
- Patient's first and last names in full
- Patient's result
- Comments/Action taken
- User's signature
- Print name of user

The book should be kept with the meter and when full kept in a secure place for the lifetime of the meter (or if required by other guidelines for the longest time period necessary). Any problems, error codes or breakdowns should be recorded in the book.
Results should be recorded immediately, before the strip is removed from instrument. Once the strip is removed the result will only be displayed for 3 seconds. In the event that a result is not taken down before the screen clears the test should be repeated. Do not attempt to review the result in the meter memory; this is unsafe as they are not linked to patient demographics.

2.10 Maintenance

The user is responsible for the routine maintenance of the meter

2.10.1 As required

- **Cleaning**

The meter should be cleaned regularly, always clean the meter if there is visible soiling and preferably clean the meter additionally once a week.
Wear gloves to clean the meter and always switch the meter off before cleaning.
Wipe with a slightly moist cloth and mild cleaning agent. We recommend PDI Sanicloths or similar cleaning cloth containing 70% isopropyl alcohol. Do not use regular alcohol wipes. 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.

- **Battery replacement**

The meter uses one 3-volt lithium battery that lasts for approximately 2000 tests.
When a battery symbol appears on the display, your battery is weak and has only enough power to run a few more tests.
Push the recessed plastic tab of the battery compartment forward (in the direction of the arrow) to flip open the battery door, remove the battery.
Insert the new battery with the + side up i.e. visible to you.
Put the battery door back in place and snap it closed.

2.11 Troubleshooting

Should you have any queries or problems please feel free to contact the POCT team for advice on 01582 497991. Some additional useful information is detailed below.

Repeated IQC Failures:

In no circumstances should the Performa meter be used if the QC does not pass as incorrect patient results will be produced. If IQC fails, repeat the QC and check the following:

- Ensure you use the correct QC solution (L1 with Control 1 or L2 with Control 2)
- Ensure you select the appropriate control result level (L1 or L2)
- Ensure you gently mix the QC solution before processing the test
- Check expiry date of strips and Performa Glucose Control solution (NB. Once the solutions are opened they expire after three months but should be labelled with the date of expiry). If either or both of these are out of date, change them (you may need to call the POCT team to get replacements) and then repeat the test.

If the QC still fails:

- If you have more than one meter at your site try the QC solutions from the other meters box, if this passes, the QC solutions which have been failing are probably at fault. This can occur if the lids of the bottles are swapped over or if the lids are left off the solutions. Call the POCT team to get the solutions replaced.
- If you have a spare box of test strips open these, calibrate the meter using the code/calibration key and run QC. If the QC then passes it is likely the old test strips were at fault. This can happen if the lid is left open on the test strips as they absorb moisture from the atmosphere and deteriorate. Call the POCT team to get a new pot of strips.
- Very rarely there may be a problem with the meter and this may need to be replaced. Call the POCT team to arrange this.

Error codes:

A list of error codes and suggested actions is included in your user manual, but a summary is detailed below:

E1 – The test strip is damaged. Remove the test strip and reinsert it, or replace it if damaged.
E2 – The code chip is incorrect. Turn off the meter and insert a new code chip.
E3 – An error occurred during the test. Discard the test strip and repeat the test.
E4 – 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.
E5 – The code chip is from an expired lot of test strips. 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 (see user manual).
E6 – 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.
E7 – 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 control test.
E8 – The temperature is above or below the acceptable range for the meter (6-44^{o}C). Move to an area with a temperature within the range and wait five minutes before repeating the test. Do not artificially heat or cool the meter.
E9 – The battery is almost out of power. Change the battery now.
E10 – The time and date settings may be incorrect. Make sure the time and date are correct and adjust if necessary (see user manual).
In any case if you can not solve the problem contact the POCT team on 01582 497991.

3 POST-EXAMINATION PROCESS

3.1 Reference Values

There is no stated reference range for a random glucose result.
Blood glucose varies widely even within the individual patient depending on the time of their last meal, especially in known diabetics.

3.2 Reporting the Results

The person performing the test is responsible for the results.
If the result is unexpected or very abnormal please check all procedures and re-check IQC. Repeat patient test if IQC is within range. The requesting Doctor should be informed immediately of any unexpected or clinically significant results. If there is concern over the results contact senior staff in your area or the POCT team for further advice.

3.3 Interpretative Comments

Alert critical values - Results <2.5 mmol/L and >20 mmol/L should be confirmed by the Clinical Biochemistry Department. Please send a blood sample in a yellow topped tube for glucose confirmation. All tests not in keeping with the patient presentation should be confirmed by sending a venous specimen of blood to the laboratory.
Decisions on treatment should be made by appropriate staff in your area taking into account the limitations of the device and remembering factors such as:

- Failure to wash the hands can result in falsely high results if the hands are contaminated with glucose
- Washing the hands with alcohol can cause falsely low results
- When there is decreased peripheral blood flow (peripheral shutdown), capillary blood does not represent the whole body situation and therapeutic decisions must not be based on capillary specimens. Examples of such situations include, but are not limited to:
    - decompensated heart failure (NYHA Class IV).
    - diabetic ketoacidosis (DKA)
    - peripheral vascular disease
    - shock
    - severe dehydration
    - hypotension
    - peripheral circulatory failure
    - hyperosmolar non-ketotic coma (HONK)
    - unconscious patients

In the event of peripheral shutdown venous or arterial blood from a plain syringe can be used on the meter.
For patients with known diabetes and glucose results <4mmol/L consider treatment appropriate for hypoglycaemia.

3.4 Reviewing Previous Results

No attempt should be made to retrieve the result from the instrument memory.
Previous results can only be reviewed in the patient's notes or from the Patient Results and Quality Control Record Book.

3.5 Performance Criteria

The system is calibrated with reference to the glucose hexokinase method and is traceable to a NIST standard. The r^2 correlation value in comparison studies range between 0.94 and 1.06.
The system accuracy according to EN ISO 15197 showed that 199 out of 200 specimens (99.5%) are within the minimum acceptable performance criteria.
The mean within series imprecision is <3.5%, CV 3.3%.
The mean day-to-day imprecision is <1.7%, CV 1.6%.
The detection limit is 0.6mmol/L.

3.6 Documentation

Patient results are documented according to Section 2.7

3.7 Audit of Results and Indication

EQA results are used to audit this process. In addition all POCT is subject to periodic horizontal and vertical audits and spot checks.

3.8 Comparability

Comparability data between the Performa test strips and the laboratory method is available from the POCT team on request. It is logged on the QPulse document control system in the laboratory.

3.9 Uncertainty of Results

The degree of uncertainty for results is expected to be within acceptable limits provided all calibration and control procedures have been followed correctly and that the sample collection, identification and processing has been followed correctly.
See section 2.2 Limitations of Analytical Procedure and 3.5 Performance Criteria

4 SELF ASSESSMENT OF COMPETENCY FORM

POCT Annual Self-Assessment Competency Statement for Glucose testing using the Roche Performa Glucose Meter

Do not use this device unless you are competent to do so

Surname: …… Forename(s): ……

Location: ……..... Job Title: ……..

Self-verification of competence is undertaken by assessment against the statements below. These statements are designed to help you assess your competency to use this POCT (Point of Care testing) equipment. Responsibility for safe use remains with you, so if you are in any doubt regarding your competence to use the device, you should seek guidance.

You must be able to answer yes to all the questions before considering yourself competent and completing the competency statement in section B overleaf. If you are in any doubt or feel that you are not competent please complete section A over leaf and contact the POCT team (Ext 7991) or your manager to instigate further learning or training.

Ask yourself the following general questions:	**Response**
1. Have I attended a training session about the device in the last year?	Yes / No
2. Have I performed a patient test under supervision by a competent practitioner?	Yes / No
3. Have I read the Standard Operating Procedure (SOP) for the device? (These can be found on the Intranet under Point of Care Services)	Yes / No
4. Do I know what infection control precautions to take when using the device?	Yes / No
5. Do I know the circumstances when the device should not be used including test interferences and limitations?	Yes / No
6. Do I know what action to take based on the results, including if the result is unexpected or suspicious?	Yes / No
7. Do I know when and where to seek help, or how to report an error or incident?	Yes / No
Ask yourself the following device specific questions:	
8. Do I know how and why the finger must be cleaned before testing?	Yes / No
9. Do I understand that glucose testing should not be carried out on a finger prick sample in patients who are peripherally shutdown?	Yes / No
10. Do I know when and how to carry out a Quality Control (QC) test?	Yes / No
11. Do I know when and how to carry out Calibration on the meter?	Yes / No

POCT Annual Self-Assessment Competency Statement for Glucose testing using the Inform II Glucose Meter

Do not use this device unless you are competent to do so

Surname: ……. Forename(s): …….

Location: ……..... Job Title: ……..

Complete either Section A or B whichever is appropriate to you.

Section A

I require further training before I can use the Inform II glucose meter for testing in a competent manner.

Signed:……. Date:…….

Section B

I certify that I am aware of my responsibility for continuing professional development and I understand that I am accountable for my actions. With this in mind I make the following statement:

I am competent to use the Inform II glucose testing POCT device

Signed:……. Date:…….

Please return this form to the POCT team, Clinical Biochemistry, Luton & Dunstable Hospital. Telephone Ext 7991. We suggest you also keep a copy for your personal records.