

Use of the Inform II for Glucose Analysis

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1 Purpose and Principle

The Roche Accu-Chek Inform II system is intended for *in vitro* diagnostic use in the quantitative determination of blood glucose levels in venous, capillary, arterial and neonatal whole blood samples. The system may only be used to monitor effective glucose control and should not be used to diagnose diabetes. The Accu-Chek Inform II will automatically store a record of patient and quality control glucose results and will transfer data.

The test strip is impregnated with a modified glucose dehydrogenase enzyme which converts glucose into gluconolactone. This reaction creates an electrical current which the meter converts to a blood glucose result. The sample and environmental conditions are also evaluated using AC and DC signals.

2 Patient Preparation & Sample Requirements

- 0.6uL of fresh capillary, venous or arterial blood.
- Heparin (sodium/lithium) and EDTA anticoagulated venous samples can also be used.
- All human blood samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including lab coats, gloves and eye-protection must be worn when handling open blood samples or derivatives thereof.

3 Tasks, Responsibilities and Authorisations

These procedures must only be carried out by staff members who have received face-to-face glucose Accu-chek Inform II training with POCT or with a link trainer and completed competency paperwork.

Access is given in Cobas IT middleware and paperwork is stored in the X-drive>Biochemistry>POCT>Training Logs.

Competency is recertified every 2 years.

Tasks	Responsible	Authorised
Glucose analysis using Accu-chek Inform II meter	Trained personnel	SBMS

4 Equipment

Each Inform II meter has an associated docking station, enabling recharging of the battery and transfer of data to the laboratory IT system and CPD.

Any faults should be reported to the Point of Care Team using the extension numbers below (leave a message to be actioned if there is no answer):


York	772 5890
Scarborough	771 2659
Bridlington	771 3321

The equipment is supplied by Roche who have a technical service department.

Tel 08081001920

5 Chemicals and Reagents

- **Accu-Chek performa test strips (ref: 05225469) supplied by pharmacy**
 Store between 2-30C. Do not freeze.
 Use at temperatures between 14-40C and humidity 10-90%.
 Store all unused strips in their original container and close the lid immediately after use.

Name	Classification & Specific Instructions Summary
	<p>Description: Accu-Chek performa control solutions Preparation: N/A Storage: Store between 2-30C. <u>Do not freeze.</u> Supplier: Roche Diagnostics</p> <p><u>Risk Statement & Control Measures</u> This product is unlikely to cause harmful effects under normal conditions of use. Wear gloves and eye protection when handling stock solution.</p> <p><u>Action in the event of Spillage</u> Clean with absorbent material. Dispose of absorbed material in accordance with LM-SOP-WASTMAN</p> <p><u>Hazard Identification & First Aid Measures</u></p> <div style="text-align: center;">  <p>HAZARDOUS/ IRRITANT</p> </div> <p>Eye contact: Immediately flush eye with plenty of water. If irritation persists seek medical advice. Skin contact: Rinse well with water Inhalation: Move to fresh air. If symptoms persist seek medical advice. Ingestion: Rinse mouth with water. If symptoms persist seek medical advice</p>

All solutions are supplied ready to use. They are stored and distributed by Pharmacy.

Once the controls solutions have been opened, they last 90 days and must be dated for first use or expiry.

6 Risk Assessment (Environmental and Safety Controls)

For full risk assessment please see PC-HSR-ACCUCHEK

Risk	Control measures
Electricity – Potential Fire Hazard	Equipment PAT tested by estates
Infection – Danger of blood splash	Wear gloves – staff to undertake training
Sharps – Lancet use for capillary sampling	Use approved safety lancets – Dispose in sharps bins
Incorrect Result Reporting – Interpretation of chromatograms By non-laboratory staff	Staff to undertake training – Biochemistry to provide advice and interpretation for unusual patterns / error codes



Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure




7 Calibration

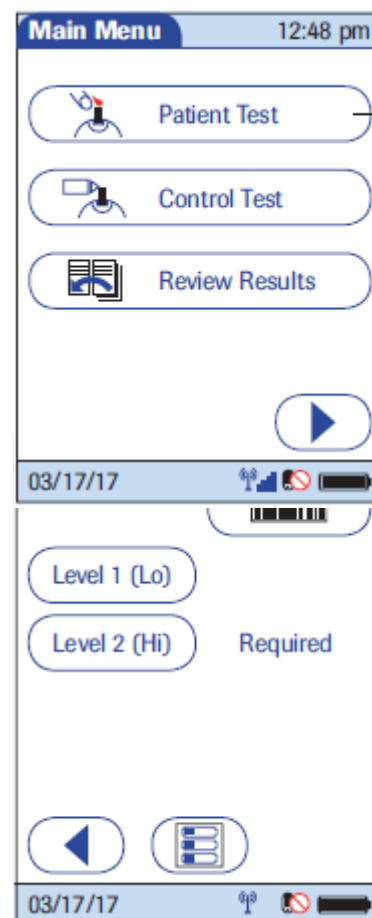
Calibration of the meter is not required by end users as the calibration is undertaken centrally by members of the point of care staff. The system is calibrated using reference values obtained with the hexokinase method. This method is traceable to an NIST standard.

8 Quality Control

- Two levels of Quality Control (QC) solution should be performed every 24 hours, the time remaining before the next control is indicated when the meter is powered up.

8.1 How to analyse Quality Control samples every 24 hours

1. Power up the meter using the on/off button 
2. Scan your operator ID barcode (or type in manually)
3. Enter your 6-digit password and press  to display Main Menu
4. Touch 'Control Test' to display the Control Test menu.
5. Select Level 1 or Level 2 (they can be analysed in any order).
6. Scan the barcode from the corresponding control solution bottle.
7. Scan the strip lot number.
8. At the prompt, insert the test strip as far as it will go with the lettering facing upwards. Please remember to close the test strip vial.
9. At the flashing drop prompt, apply the well mixed control sample to the tip of the strip. When sufficient sample has been detected the meter will beep and the analysis will begin.
10. The hourglass icon shows the test is running. The result is available after 5 seconds.
11. If the **QC passes** press the  and repeat using the other control solution from step 5.
12. If the **QC fails**, check:
 - The QC material is in date and well mixed.
 - Retry if with new QC material.
 - Retry using a new pot of strips.
 - Contact the point of care team as detailed in section 3 if it fails again and quarantine the meter.
13. The strip can be removed and disposed of in accordance with local guidelines.



9 External Quality Assurance (EQA)

All meters are enrolled in External Quality Assurance (EQA) scheme. Every 3 months a sample will be sent to each ward area, please follow the instructions set out in the accompanying letter and return results **promptly**.




EQA reports are monitored by the POCT coordinator and discussed at the POCT committee meetings.

10 Procedural Steps

10.1 Obtaining Patient Capillary Samples

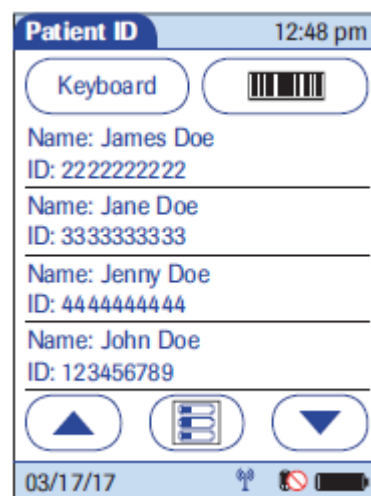
1. The test may be requested verbally by qualified members of staff, clinicians or via documented protocols. Please document the source.
2. Protective gloves must be always worn.
3. Take the workstation and glucose meter to the patients' bed side.
4. Positively identify your patient (name, DOB and NHS number)
5. Explain the procedure to gain verbal consent.
6. Ask patient which finger they would like the sample taken from. If they show no preference please use the middle, ring or small finger.
7. Clean the patients' hands or finger prior to testing. DO NOT USE ALCOHOL WIPES OR GEL.
8. With the single use lancet, puncture the chosen finger on the side of the pad no lower than the nail bed. Draw a small drop of blood for use on the test strip. If no blood is visible milk the finger from the heel on the hand downwards.
9. Give the patient a clean swab for the puncture site when test is complete.


10.2 Analysis of the patient sample

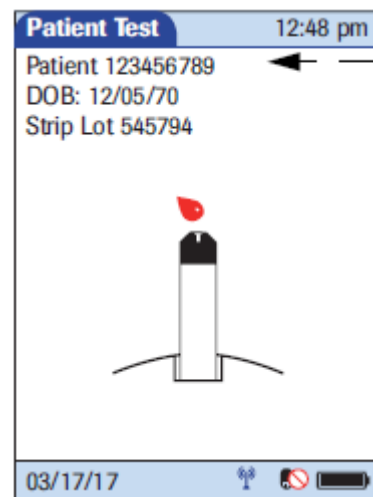
1. Power up the meter using the on/off button 
2. Scan your operator ID barcode (or enter manually)
3. Enter your 6-digit password then press  to display the Main Menu.
4. Press 'Patient Test' to display the patient test screen.
5. Pick your patient ID from the ward list OR scan patient's **NHS number** from their wristband OR enter the patient's **NHS number** using the keyboard then press 

(If no NHS number is available, please use the **full** case note number. The unknown barcode should only be used on visitors or staff).

6. At the 'Patient Confirmation' pop up, check patient details are correct and press the green tick. If the patient information is not correct press the X and check and re-enter the NHS number. If no patient details are available, please check the NHS number is correct.
7. At the 'Strip Lot' screen, scan the barcode from the pot of strips.



8. When prompted, insert the test strip as far as it will go, with the lettering facing upwards. Please remember to close the test strip vial.
9. When prompted with a flashing red drop, a blood sample to the tip of the strip. When sufficient sample has been detected the meter will beep and the analysis will begin.
10. The hourglass icon shows the test is running and the result is available after 5 seconds.
11. To add a comment, press the speech bubble and select a comment from the list or free text your own. Confirm the comment by pressing .
12. Please ensure the result is entered in the patients' notes/e-obs. Results must be documented and given to both the patient and the clinician.
13. The strip can then be removed and disposed of in accordance with local guidelines.



11 Reporting of Results

The result should be documented in either the patients' notes or observations and reported to both the patient (if appropriate) and the clinician. YOU MUST DOCUMENT THIS PROCEDURE.

All results are obtained in mmol/L. The meter can analyze glucose levels between 0.6mmol/L and 33.3mmol/L. Results less than 0.6mmol/L display **LO** at results screen. Results above 33.3mmol/L display **HI** at results screen. Results should be documented in the patients' notes. The results will also go directly into the patients' electronic notes.


If the blood glucose results obtained do not reflect the patient's clinical symptoms, please run the quality controls to confirm the meter is working:

- QC FAIL = follow QC failure instructions in section 10.1
- QC PASS = Repeat the patients test. If the result is still inconsistent, please send a sample to the biochemistry department for confirmation.

11.1 How to review last patient results on the meter

1. Press 'Review Results' from Main Menu.
2. Find and select the correct patient ID.
3. Last glucose result will be displayed with any comments added.

11.2 How to review all glucose results for a single patient

1. Press 'Review Results' from Main Menu.
2. Press patient.
3. Find patient ID on the list or type in patient NHS number and press  to confirm.

4. The results displayed are all the results for that patient on that day.
5. To look at the previous days results press the down arrow.

12 Reference Intervals

- Fasting glucose: 2.5- 6.0mmol/L (taken from the WHO guidelines).
- Critical Alert: < 4.0mmol/L, > 16.0mmol/L. Please escalate your patient immediately. (Limits set by diabetes specialist team).
- Hypoglycaemia: < 4.0 mmol/L. Patient should be treated as per the Hypoglycaemia protocol and retested following treatment (protocol written by diabetes specialist team and available on the Trust Intranet).

13 Maintenance and Troubleshooting

13.1 Cleaning the meter and workstation

- The meter and workstation can be cleaned with commercially pre-moistened cleaning cloths such as Clinell Wipes.
- Cloths dampened with mild soapy water, 70%isopropyl alcohol or 0.625% sodium hypochlorite are acceptable.
- Wipe away any excess cleaning solution before use.
- **DO NOT ALLOW LIQUID TO ENTER THE STRIP PORT**
- Do not spray the meter or base unit directly.
- Do not use solutions containing ether polyhexanide or mixtures of bleach and detergents.

13.2 Meter or Connectivity Problems

- Battery not charging or appears hot.
 - Dock the meter and ensure 'Docked' appears in the top left.
 - Reset meter by holding down the on/off button for around 10 seconds.
- Display/Screen freezes
 - Reset meter by holding down the on/off button for around 10 seconds.
- If WiFi system fails and the meter requests downloading
 - Dock the meter in a hard-wired network cable base station and ensure 'Docked' appears in the top left. After a few minutes the meter should have downloaded and be 'Idle, it can now be returned to its own base station.

For any other errors please report the fault to the POCT Team as detailed in section 3. If the meter fails out of hours, please use another meter, or request a training meter from the Biochemistry department.

14 Performance Characteristics

14.1 Precision and Detection Limits

- Inter batch precision.

	Low	Medium	High
Roche Mean	2.03	11.19	19.09
SD	0.14	0.36	0.49
CV	6.98	3.24	2.55

- Intra batch precision

Instrument	Low	High
Roche Mean	2.75	17.30
SD	0.07	0.14
CV	2.57	0.82

- Assay detection limit.

The lowest value displayed is 0.6mmol/L. The measurement range is 0.6-33.3 mmol/L

15 Known Limitations

Common interfering substances known to cause over estimation of POC blood glucose are:

- Intravenous administration of **N-acetylcysteine**. Do not use Accu-Chek meters during intravenous infusion of N-acetylcysteine.
- Blood Galactose > 0.83 mmol/L
- Triglycerides > 20.3 mmol/L
- Intravenous administration of ascorbic acid which results in blood concentrations in excess of 0.17 mmol/L

The meter should not be used with capillary samples on patients with compromised peripheral circulation as the results will not reflect the true physiological blood glucose level. This may apply in the following conditions:

- Severe dehydration
- Diabetic ketoacidosis

- Severe hypotension
- Severe shock

In these occasions you may use venous or arterial blood on the meter.

The meter should only be used on patients with a haematocrit between 10% and 65%.

The system is approved for use with neonatal blood, but caution is advised in the interpretation of glucose values below 2.8mmol/L.

16 Related Forms/Templates and Documents

PC-HSR-ACCUCHEK

PC-SOP-INFORMII

17 References

- Accu-Chek Inform II operators manual
- Accu-Chek Performa test strip insert
- Method evaluation stored in Q-Pulse under file name PC-EVA-ROC-GLU