

STANDARD OPERATING PROCEDURE SOP/POCT/45/10

Title: Abbott FreeStyle Precision Pro Glucose Meter Effective date: 15/03/2022

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Summary of Significant Changes at this Revision

- Include the E-learning module name and that this is how training is received and competency achieved.
- The meter will do a full upload (the equivalent to docking) if the meter is turned on and left for several minutes.
- The screen will show the parallel arrows moving at the bottom of the screen.

<p>Purpose and Scope</p> <p>The FreeStyle Precision Pro Blood Glucose monitoring system is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood samples. The system is for professional use and is not for use in diagnosing diabetes mellitus. The system is to be used as an aid in monitoring the effectiveness of diabetes control programmes e.g. How to approach writing a risk assessment and documentation required</p>	<p>Items Required</p> <p>Workstation FreeStyle Precision Pro glucose meter FreeStyle Precision Pro glucose test strips Medisense High and Low internal quality control solutions (IQC) Docking station Lancet</p>
<p>Definitions and Abbreviations</p> <p>FPP = FreeStyle Precision Pro POCT = Point of Care Testing NPT = Near Patient Testing IQC = Internal Quality Control QC = Quality Control EQA = External Quality Assurance</p>	<p>Grade / Qualifications</p> <p>Nursing Staff: All Trained operators Health Care Assistants: All trained operators Biomedical Scientists – all grades Supervised Trainee BMS Staff</p> <p>Competencies Required ESR training module: 427 RUH POCT Glucose Analysis (FPP meter) eLearning</p>
<p>Safety Precautions for This Procedure:</p> <ul style="list-style-type: none"> - Training for use of glucose meters - Needle stick injury policy - Immunizations - PPE - Sharps Disposal policy - Procedure for spillages of body fluids - Pathology Health and safety policy - Training for treatment of wounds. - EQA screened for HIV and Hepatitis - PPE. - < or > and ▲ or ▼ symbols are displayed to flag abnormal results. - Meters cannot be used without valid iQC 	<p>Risk Assessment: Current Version of: RA/CH/29 found on the POCT intranet page. Procedure Risk Assessment Score = 15 (Medium risk)</p>

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1. CLINICAL RELEVANCE/PURPOSE AND LIMITATIONS OF THE EXAMINATION

The FreeStyle Precision Pro Blood Glucose monitoring system is intended for *in vitro* diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood samples. The system is for professional use and is not for use in diagnosing diabetes mellitus. The system is to be used as an aid in monitoring the effectiveness of diabetes control programmes.

1.1. Limitations

- FreeStyle Precision Pro glucose test strips are designed for use with fresh whole blood.
- The minimum sample volume is 0.6 µl.
- **The system is not designed for use with serum or plasma samples.**
- **Do not use blood collected into fluoride or oxalate.**
- Venous and arterial whole blood samples collected into lithium heparin and EDTA may be used if analysed within 30 minutes.
- Care should be taken to clear arterial lines before blood is drawn and applied to the test strip.
- Blood glucose results are displayed as mmol/L.
- Use meter between 15^o and 40^oC.
- Store the test strips between 4^o and 30^oC.
- Haematocrit range is 15%-65%.
- Test results may be erroneously low if the patient is severely dehydrated, severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state (with or without ketosis).
- Do not use during intravenous infusion of high dose ascorbic acid or during xylose absorption testing.
- The following substances have no significant effect on blood glucose monitoring system above the normal concentration of substance or above the normal therapeutic levels:

Substance	Therapeutic Agents
Bilirubin (unconjugated)	Maltose
Cholesterol	Paracetamol
Triglycerides	Ascorbic Acid
Uric Acid	Dopamine
lactate	Ephedrine
Galactose	Ibuprofen
Pyruvate	L-Dopa
Beta-hydroxybutyrate	Methyldopa
	Salicylate
	Tetracycline
	Tolazamide
	Tolbutamide

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2. REFERENCES AND DEFINITIONS:

REFERENCES

- FreeStyle Precision Pro Blood Glucose Monitoring System – Operator’s Manual (PDF) EXT/POCT5
- Package insert for Abbott Freestyle Precision Pro Blood Glucose Testing Strips (EXT/POCT/3)
- Point of Care Testing Policy (772/2018)
- RUH Medical Equipment Policy (713/2011)
- Freestyle Precision Pro (FPP) Meter Glucose/Ketone Analysis Competency Sheet (FM/CH/TRG/76)

DEFINITIONS

FPP = FreeStyle Precision Pro

POCT = Point of Care Testing

NPT = Near Patient Testing

IQC = Internal Quality Control

QC = Quality Control

EQA = External Quality Assurance

3. ACTIONS AND METHODS:

3.1. Principle and Method of the Procedure Used for the Examination

Glucose measurement: Bioamperometry:

Glucose in the blood reacts with the enzyme NAD-glucose dehydrogenase on the test strip. The chemical reaction releases NADH, which then reduces Phenanthroline Quinone. A voltage is applied across the test strip. The current generated from the sample is proportional to the concentration of glucose in the sample and is expressed in mmol/L.

3.2. Specimen Requirements and Means of Identification

- The system is not designed for use with serum or plasma samples.
- Do not use blood collected into fluoride or oxalate.
- Venous and arterial whole blood samples collected into lithium heparin and EDTA may be used if analysed within 30 minutes.
- A unique patient identification number must be used for every patient sample analysed.

3.3. Patient Preparation

- Wash your own hands and put on gloves prior to patient testing
- The site of sampling should be chosen to cause minimum discomfort and skin damage.
- The site of the puncture must be cleaned before collecting the sample

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3.4. Environmental and Safety Controls

Refer to risk assessment (QMS/RA/CH/29)

- Precision Xceed Pro test strips: No Hazard
- Medisense Lo and Hi Control solutions: No Hazard
- External Quality Assurance (EQA) samples: Treat as Biohazard
- Gloves must be worn at all times when processing controls, EQA and patient samples.
- Dispose of all test strips, finger pricking device, port protectors, control solutions and EQA in a sharps bin or yellow bag for incineration as appropriate.

Any adverse incidents regarding the use of the FreeStyle Precision Pro blood glucose meter must be reported via the ward manager/practice manager to the Point-of-Care testing committee for evaluation and reporting on to the MHRA.

3.5. Required Reagents, Quality Controls, Calibrators and Equipment Preparation

- Workstation
- FreeStyle Precision Pro glucose meter
- FreeStyle Precision Pro glucose test strips
- Medisense High and Low internal quality control solutions (IQC)
- Docking station
- Lancet

3.6. Maintenance

- Store the meter in the workstation case (NOT the docking station).

Cleaning the exterior surface of the monitor:

- Clean surface of meter with damp cloth and mild soap.
- Turn off the meter prior to cleaning.
- It is acceptable to clean the surface with hospital detergent wipes,
- Do not clean the strip port.
- Do not pour liquid into the strip port or onto the buttons.
- Do not place the meter in water.

Replacing the Batteries:

- Batteries: The meter will display an empty battery icon and **Low Battery** when a battery change is required.
- Replacement batteries are available from POCT Ext. 6044, or email ruh-tr.biochempoc@nhs.net with your request.

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Replacing the Strip Port:

Should blood or control solution come into contact with the strip port module, the meter should be cleaned and dried, and the strip port replaced.

- Replacement port protectors are available from POCT Ext 6044 or email ruh-tr.biochempoc@nhs.net.
- Turn off the meter
- Place the meter screen down on a flat surface, with a Philips screw driver remove the single screw from the back of the strip port.
- Slide the strip port out and discard with the screw into a biohazard burn bin.
- Slide the replacement strip port firmly into place.
- Using the Philips screw driver insert a new screw to secure the new strip port.

3.7. Instructions for the Performance of the Examination**Patient testing**

- Press **On/Off** to turn on the meter – the Abbott logo and software version will be briefly displayed.
- Press **1. Patient Test.**
- Press **SCAN** to scan the Operator ID barcode.
- Manually enter the **Patient ID** via the keypad and press **Enter.**
- Press **SCAN** to scan the glucose test strip barcode.
- **1. Arterial/Capillary or 2. Venous** is displayed.
- Select sample type (1 or 2)
- **Insert Strip** is displayed.
- Open the foil test strip packet at the notch and tear down to remove the test strip.
- With the black contact bars facing up insert the strip into the test strip port until it stops and **Strip Inserted** is displayed.
- **Apply Sample** is then displayed.
- Apply a drop of blood from the patient's finger to the strip with the meter in a horizontal position to avoid it entering the strip port.
- When sufficient sample has been applied the meter beeps, displays **Sample Accepted** and automatically starts the test.
- The result, date and time are displayed after a 5 second countdown.
- **N.B. If insufficient sample has been obtained**, then no beep will be heard and **Sample Accepted** will not be displayed – in this case a repeat blood sample will have to be obtained from the patient in order to repeat the test – and this must be recorded in the patient's notes – and recorded as an incident in Datix if appropriate
- **If it is not possible to obtain an adequate blood sample** for testing by the finger prick method, then this must also be recorded in the patient's notes - and recorded as an incident in Datix if appropriate - and a venous sample should be collected and sent to the biochemistry laboratory for confirmation of the glucose.
- The **action range** is set at 4.0 – 15.0 mmol/l on all FPP meters - **except NICU**

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- **N.B. The action range for NICU FPP meters is 2.8 – 10.0 mmol/l** (at request of NICU consultant Bernie Marden)
- Results above the action range will be displayed with ▲ next to the result
- Results below the action range will be displayed with ▼ next to the result.
- If results are **above** or **below** the **action range** then a blood sample should be collected into a fluoride oxalate tube and sent to the biochemistry laboratory for confirmation of the glucose.
- The lower analytical range for the meter is 1.1mmol/l – results less than this will be displayed as <1.1 mmol/l
- The upper analytical range for the meter is 27.8 mmol/l – results greater than this will be displayed as >27.8 mmol/l.
- Remove the test strip from the test strip port and dispose of appropriately.
- The following options will then be displayed:
 - **1. Next Patient** – Select to run another patient sample.
 - **2. Patient History** – Select to display the last test result for this patient as well as allowing previous results to be viewed.
- If all tests are completed press **On/Off** to turn off the meter.

3.8. Procedure for Calculating and Recording of Results**Recording Results:**

Record the glucose result on the yellow blood glucose monitoring chart along with the date/time performed, the device (including location), the test strip number and the operator identity (of person performing the test and person transcribing the result - if different). If a patient is on a Variable Rate Intravenous Insulin Infusion then record the glucose result on the separate monitoring sheet.

Results are electronically stored in the meter and on the UniPoc website.

Recalling Patient Results

- Press **On/Off** to turn on the meter – the Abbott logo and software version will be briefly displayed.
- Press the **Menu** button.
- Press **1. Data review**.
- Press **SCAN** to scan the Operator ID barcode.
- The options in data review are:
 - **Patient by Operator ID**
 - **Patient by Patient ID**
 - **All Patient Data**
 - **Control Data**
 - **Proficiency Data**
 - **Linearity Data**
 -

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Operators:

- Only staff that are trained in accordance with the FreeStyle Precision Pro blood glucose meter Training Programme for the Trust, and are certificated, are authorised to use the FreeStyle Precision Pro glucose meter.
- Training is provided via an E-learning module on ESR, search for:
427 RUH POCT Glucose Analysis (FPP meter) eLearning
- There is a quiz at the end to assess competency
- This module must be completed every 2 years to maintain access to the meters.
- Refer to the NMC Professional Conduct Code 2008 and RUH Policies.

3.9. Potential Sources of Variation and Measurement Uncertainty of Measured Values

Potential sources of variation impact on uncertainty within a method. The variables that impact on the examination procedure have been considered in the document QSP/30 - Uncertainty of Measurement.

Refer to spreadsheet on Q-pulse ref: FM/POCT/54 - Measurement of uncertainty for FreeStyle Precision Pro Glucose meters.

3.10. Performance characteristics and interferences

- See VAL/POCT/11 (pathology quality management system) for final validation/verification signoff list.
- See manufacturer’s kit insert (EXT/POCT/3)
- See manufacturer’s operator’s manual (EXT/POCT5)

Validation and Verification Report

Please see the validation and verification report Q-pulse reference: QMS/VAL/POCT/11

3.11. Internal Quality Control and Calibration Procedures

Internal Quality Control (IQC)

Stability:

Unopened – up to expiry date stated on bottles/box.

Opened – 90 days from time of opening (expiry date must be noted on bottles).

Both Lo and Hi controls must be assayed.

IQC Testing:

IQC must be performed on each individual FreeStyle Precision Pro glucose meter daily.

The FreeStyle Precision Pro glucose meters are formatted to request QCs every 24 hours – the message ‘**Glucose QC Due Now**’ will be displayed, and the system will be locked out until

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acceptable results for both Lo and Hi QCs have been obtained:

- Press **On/Off** to turn on the meter – the Abbott logo and software version will be briefly displayed.
- Press **2. Control Test**.
- Press **SCAN** to scan the Operator ID barcode.
- Press **SCAN** to scan the low control solution lot no. barcode.
- Press **SCAN** to scan the glucose test strip barcode.
- Open the foil test strip packet at the notch and tear down to remove the test strip.
- With the black contact bars facing up, insert the strip into the test strip port until it stops and **Strip Inserted** is displayed.
- Gently invert the required control solution bottle 3-4 times.
- Remove the cap and wipe the nozzle with a clean gauze or tissue.
- Apply a small drop of solution to the test strip target area, allowing the target area to fill completely.
- Wipe the nozzle of the control solution bottle before replacing the cap.
- **N.B.** Apply the QC solution with the meter in a horizontal position to avoid it entering the strip port.
- When sufficient sample has been applied, the meter beeps, displays **Sample Accepted**, and automatically starts the test.
- Control results appear as **PASS** or **FAIL** after a 5 second countdown.
- If a **PASS** result is obtained for the Lo QC press **1. Next Level**, and repeat the procedure using the Hi QC.
- If a **FAIL** result is obtained for the Lo QC press **2. Repeat Test**, and repeat the procedure with the Lo QC.
- The system will be locked out until acceptable results have been obtained for both Lo and Hi QCs.
- After the Hi QC select **1. Exit**, then **1. Patient Test** – then follow the patient testing procedure.

Press **On/Off** to turn off the meter when all tests are completed.

Calibration

Scanning the barcode label on each glucose test strip foil packet prior to use automatically calibrates the meter and checks the expiry date.

Glucose test strips are stable up to the expiry date stated on the packaging - store between 4°C and 30°C.

Retain package insert until box of test strips has been used.

Traceability: See pack insert (EXT/POCT/3) under header 'Calibration Reference'.

3.12. External Quality Assessment Schemes

External Quality Assurance/Control differs from IQC in that the accuracy of the procedure is not known until after the results have been issued. The user does not know the glucose concentration at the time of analysis and the results are assessed independently.

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- A Welsh external quality assessment scheme (WEQAS) sample is distributed to all authorised FreeStyle Precision Pro meter users every three months by biochemistry with a result sheet.
- The sample must be analysed (as per Patient Testing 3.6) on every FreeStyle Precision Pro meter located on the ward/department.
- Record the serial number of each individual meter that is used and record the glucose result for the EQA sample.
- Return the result sheet to the biochemistry department.

3.13. Reference Limits, Reportable intervals, Reporting and Interpretation

Reference Limits

- Normal fasting blood glucose range for an adult without diabetes is less than 6.1 mmol/L.
- Two hours after meals, the blood glucose range for an adult without diabetes is less than 7.8 mmol/L.

Reportable Intervals

All point of care testing devices have limitations and these should be remembered at all times. Confirmation of grossly abnormal results by a laboratory sample is essential.

- The blood **glucose meter alone cannot make a diagnosis of diabetes** or hypoglycaemia and a confirmatory sample must be sent to the laboratory.
- All results must be interpreted with respect to the patient's condition.
- If an **unexpected high or low glucose result** is obtained, a repeat test must be performed and a venous sample sent to the biochemistry laboratory.
- If a **glucose result is <4.0 mmol/l or >15.0 mmol/l** a venous sample should be sent to the biochemistry laboratory for confirmation.
- **Blood Glucose Action Limits by Non - Qualified Staff:** Blood Glucose results <4 mmol/l or >15 mmol/l must be reported to a trained member of the nursing/medical staff.

The glucose test strip has been evaluated with neonatal blood. As a matter of good clinical practice, **caution is advised in the interpretation of neonate glucose values <2.8 mmol/l.**

Results outside Reportable Intervals

- The lower analytical range for the meter is 1.1mmol/l – results less than this will be displayed as <1.1 mmol/l.
- The upper analytical range for the meter is 27.8 mmol/l – results greater than this will be displayed as >27.8 mmol/l.

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Reporting and Interpretation

If results are above or below the reportable range then a blood sample should be collected into a fluoride oxalate tube and sent to the biochemistry laboratory for confirmation of the glucose. These results must be reported to a trained member of the nursing/medical staff.

Data upload

For wireless location:

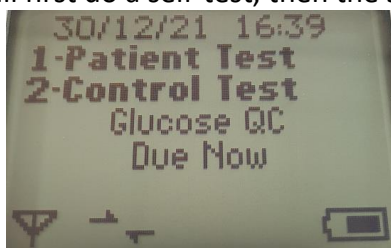
- Meters that are configured for wireless connection will upload a result automatically once the operator leaves the test results screen.



- If the meter is switched off (by pressing 1) the upload will pause and resume when switched back on.
- The meter will automatically switch off when the upload is complete.
- Meters should still be docked on regular intervals (preferably every 24hrs) to identify location of the meter.

Full data Upload for wireless meters

- Wireless configured meters will do a full exchange of data when the meter is first turned on.
- The screen when turned on will first do a self-test, then the screen will look like this:



- The parallel arrows at the bottom of the screen will move then disappear (this may take a few minutes).
- Data of new users will have uploaded to the meter and patient/QC results will have downloaded to the data manager system.

For non-wireless locations:

- Data uploading is required once every 24hrs.
- **Upload Due Now** message will be displayed when this is required and the meter cannot be used until this has been completed.
- To start the upload of data place the meter into the docking station.
- The monitor will first turn on, if it isn't already, and then automatically upload data to the

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management system.

- During communications, the **Data Uploading** screen appears, with rotating arrows to indicate that the system is working.



- The arrows may occasionally pause.
- Data transfer takes approximately 10 – 20 seconds.
- During data upload the meter cannot be used for testing.
- After upload is complete, the meter will display **Upload Successful, Turning Off** and then shut down.
- If an error occurs with the data upload – retry. If the problem persists contact Biochemistry Ext 4712.

3.14. Personnel Involved in Interpretation, Authorising, Reporting and Monitoring of Reports

- Only trained staff can operate the meter, results must be written into notes (see 3.8 above) by member of staff testing the patient.
- Clinical staff are responsible for the interpretation of the glucose result.

REFERENCES

- FreeStyle Precision Pro Blood Glucose Monitoring System – Operator’s Manual (PDF) EXT/POCT5
- Package insert for Abbott Freestyle Precision Pro Blood Glucose Testing Strips (EXT/POCT/3)
- Point of Care Testing Policy (772/2018)
- RUH Medical Equipment Policy (713/2011)
- Freestyle Precision Pro (FPP) Meter Glucose/Ketone Analysis Competency Sheet (FM/CH/TRG/76)

Copy number	Location held
1	Electronically through Q-Pulse.
2	Intra net POCT page.