STANDARD OPERATING PROCEDURE SOP/POCT/50/7

Title: Abbott FreeStyle Precision Pro Meter – Ketone Analysis

Effective date: 10/08/2021

Summary of Significant Changes at this Revision

- Edit the formatting and order of headings to match ISO: 15189 and the glucose SOP.
- Include wireless upload/download.
- Include POCT to definitions

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Purpose and Scope

The Abbott FreeStyle Precision Pro Blood Glucose/Ketone monitoring system is intended for in vitro diagnostic use for the quantitative measurement of β-ketone (beta-hydroxybutyrate) 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.
The meter uses single-use test strips to measure the concentration of β-ketones in fresh capillary and venous whole blood sample.

Items Required

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

Definitions and Abbreviations

FPP = FreeStyle Precision Pro
POCT = Point of Care Testing
NPT = Near Patient Testing
IQC = Internal Quality Control
QC = Quality Control
EQA = External Quality Assurance
β-OHB = β-hydroxybutyrate
MHRA = Medical and Healthcare products Regulatory Agency

Grade / Qualifications Required

Nursing Staff: All trained operators
Health Care Assistants: All trained operators
Biomedical Scientists – all grades
Supervised Trainee BMS Staff

Competencies Required:
Current Version of: QMS/FM/CH/TRG/76

Safety Precautions for This Procedure:

- 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.
- Meters cannot be used without valid iQC
- > Symbol is displayed to flag abnormal results.

Risk Assessment:
Current Version of: QMS/RA/CH/29
Procedure Risk Assessment Score = 15 (Medium risk)

TABLE OF CONTENTS:

1. CLINICAL RELEVANCE/PURPOSE AND LIMITATIONS OF THE EXAMINATION

This POCT device must be used in accordance with the Trust POCT Policy.

1.1. Limitations

All point of care testing devices have limitations and these should be remembered at all times:

- Freestyle Precision Pro β-ketone test strips are designed for use with fresh whole blood samples **(capillary and venous samples only)** – venous samples should be collected into lithium heparin or EDTA (whole blood) tubes, well mixed, and used within 30 mins
- The β-ketone test strip has not been evaluated for arterial and neonatal samples, or for alternative site testing
- The strip is not designed for use with serum or plasma samples
- Do not use tubes containing fluoride or oxalate
- The minimum sample volume is 1.5 µl.
- Blood β-ketone results are displayed as mmol/l.
- Use the meter between 18^0 and 30^0C.
- Store the test strips between 4^0 and 30^0C.
- Haematocrit range is 30%-60%.
- Test results may be erroneously low if the patient is severely dehydrated, severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state
- **Specificity** – The Freestyle Precision Pro system exhibits no interference from the following substances above therapeutic levels: Acetaminophen and ascorbic acid.
  The Freestyle Precision Pro system exhibits no interference from the following substances above normal concentrations: Acetoacetate, acetone, bilirubin, cholesterol, triglycerides and uric acid

2. References and Definitions

References

- Abbott FreeStyle Precision Pro Glucose and β-Ketone Monitoring System – Operator's Manual (PDF) EXT/POCT5
- Package insert for Abbott Freestyle Precision Pro blood β-ketone Testing Strips (EXT/POCT/9)
- NMC Professional Conduct Code 2008
- RUH Medical Equipment Policy
- POCT 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

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QC = Quality Control
EQA = External Quality Assurance

3. ACTIONS AND METHODS:

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

Ketones: The β-hydroxybutyrate (β-OHB) in the blood sample is catalysed to acetoacetate by β-hydroxybutyrate dehydrogenase. The co-enzyme (NAD) undergoes reduction in the process. When the reaction is complete, electrons generate a small current. The current is measured through built in electrodes. The size of the current is proportional to the amount of β-OHB in the blood sample.

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

3.4. Environmental and Safety Controls

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

- Freestyle Precision Pro Ketone 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 ketone 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/ketone meter
- FreeStyle Precision Pro ketone 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 biochemistry Ext. 4712, or email ruh-tr.biochempoc@nhs.net with your request.

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 07500050655 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

- All point of care testing devices have limitations – see **Section 1.1** for the limitations
- Only fresh capillary or whole blood venous samples should be used with the β-ketone test strips – venous (whole blood) samples should be collected into lithium heparin or EDTA tubes and used within 30 mins
- The minimum sample volume is 1.5 µl
- 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 β-ketone test strip barcode.
- **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 10 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 patient blood sample is needed and the test repeated with a fresh test strip – 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
- **It is possible to use venous samples for β-ketone analysis – N.B.** they must be collected into lithium heparin or EDTA tubes, well mixed, and used within 30 mins
- **If it is not possible to obtain an adequate venous blood sample** for testing, then this must also be recorded in the patient's notes - and recorded as an incident in Datix if appropriate
- See **Section 8** for **Clinical Interpretation of Ketone Results**
- The lower analytical range for the meter is 0.0mmol/l
- The upper analytical range for the meter is 8.0mmol/l – results greater than this will be displayed as > 8.0mmol/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.

Record the β-ketone result in the patient's case notes – **N.B.** also include the date/time performed, the device (including location), the test strip number and the operator identity (of person performing the test and the person transcribing the result).

3.8. Procedure for Calculating and Recording of Results

Recording Results:

Record the ketone result in the patient notes 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).

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**

Operators:

- Only staff that are trained in accordance with the FreeStyle Precision Pro glucose and ketone meter Training Programme for the Trust, and are certificated, are authorised to use the FreeStyle Precision Pro glucose/ketone meter.
- Training is provided by the following E-learning module found on ESR:
  - 427 RUH POCT Ketone Analysis (FPP meter) eLearning
- This consists of several training modules and an assessment that must be completed to be granted access.
- Refresher training is also provided via the E-learning module on ESR.
- It is still possible to have face to face training if required via your wards link nurse or diabetes specialist nursing team.
- 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 UoM summary tab.

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/9)
- 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 FPP meter daily.
The FPP meters are formatted to request QCs every 24 hours – the message **'Ketone QC Due Now'** will be displayed, and the system will be locked out until 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 β-ketone 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 – the display will alternate between **Insert Strip** and **Ketone**.
- 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 bleeps, displays **Sample Accepted,** and automatically starts the test.
- Control results appear as **PASS** or **FAIL** after a 10 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.

N.B. *When the FPP meter is enabled for both glucose and ketone testing, prompts will be given for both glucose and ketone QCs.*

To run glucose QC only (or ketone QC only)

- ***Select 2 – Control Test***
- ***Follow prompts for required test***
- ***Screen may display "Unexpected strip glucose expected Ketone entered"***
- ***Select 2 – Continue You can continue with glucose QC***
- ***When Lo and Hi QC levels have been analysed it will still show "Ketone QC due"***
- ***Select 1 – Patient Test to proceed with patient sample.***

NOTE: If there are no patient ketone samples to be run, then the ketone QCs do not need to be run.

Calibration

Scanning the barcode label on each β-ketone test strip foil packet prior to use automatically calibrates the meter and checks the expiry date.
β-ketone test strips are stable up to the expiry date stated on the packaging - stored between 4^0C and 30^0C.
Retain package insert until box of test strips has been used.

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 β-ketone concentration at the time of analysis and the results are assessed independently.

- An EQA sample is distributed to all authorised FPP meter users every three months by biochemistry with a result sheet.
- Children's Ward, A&E, MAU and Parry ward are the only RUH departments with FPP meters enabled for blood β-ketone analysis as well as glucose analysis
- The sample must be analysed (as per Patient Testing) on every FPP meter located on the ward/department enabled for β-ketone analysis
- Record the serial number of each individual meter that is used and record the β-ketone result for the EQA sample.
- Return the result sheet to the biochemistry department.

3.13. Reference Limits, Reportable intervals, Reporting and Interpretation

Reference Limits

Reportable Intervals

- The lower analytical range for the meter is 0.0mmol/l
- The upper analytical range for the meter is 8.0mmol/l – results greater than this will be displayed as > 8.0mmol/l.

Results outside Reportable Interval

Results must be urgently referred to a suitable clinician.

Reporting and Interpretation

Children's ward:
Management of a patient with DKA is outlined in the departmental protocol on Children's ward.

All other wards with a ketone activated meter and Diabetes Community nurses:
Please refer to the Diabetes nurse specialist for the management of a patient with DKA.

Data upload

For wireless location:

- Meters that are configured for wireless connection will upload 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.
- 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.
- Meters should still be docked on regular intervals (preferably every 24hrs) to identify location of the meter.

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 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 POCT 07500050655 or IT helpdesk on EXT 5444.

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.

Adverse Incidents

Any adverse incidents regarding the use of the FPP meter must be reported via the ward manager to the Point-of-Care testing committee for evaluation and reporting on to the MHRA.

References

- Abbott FreeStyle Precision Pro Glucose and β-Ketone Monitoring System – Operator's Manual (PDF) EXT/POCT5
- Package insert for Abbott Freestyle Precision Pro blood β-ketone Testing Strips (EXT/POCT/9)
- NMC Professional Conduct Code 2008
- RUH Medical Equipment Policy
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- Freestyle Precision Pro (FPP) Meter Glucose/Ketone Analysis Competency Sheet (FM/CH/TRG/76)

Copy number	Location held
1	Glucose Meters SOP File – Manual Lab
2	POCT section of intranet
3	Electronically through Q-Pulse.