Summary of Significant Changes at this Revision

CR 5279 Update section 10 as per re-wording by NP

Purpose and Scope

1. The Abbott Precision Xceed Pro/FreeStyle Precision Pro meter is a battery-powered device designed for the measurement of blood glucose in a Point of Care setting.
2. The meter uses single-use test strips to measure the concentration of glucose in fresh capillary, venous, arterial or neonatal whole blood samples.

Items Required

1. Abbott Precision Xceed Pro Meter
2. FreeStyle Precision Pro Meter
3. Abbott Precision Xceed Pro Blood Glucose Test Strips
4. MediSense Glucose & Ketone Control Solutions
5. WEQAS External glucose EQA sample
6. Lancing Devices

Definitions and Abbreviations

PXP = Precision Xceed Pro
FPP = FreeStyle Precision Pro
POCT = Point of Care Testing
NPT = Near Patient Testing
IQC = Internal Quality Control
QC = Quality Control
EQA = External Quality Assurance

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

Risk Assessment:
Current Version of: QMS/RA/CH/29
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1. Principle

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.

2. Precision Xceed Pro/FreeStyle Precision Pro System Components

- Workstation
- Precision Xceed Pro/FreeStyle Precision Pro glucose meter
- Precision Xceed Pro glucose test strips
- Medisense High and Low Control Solutions
- Docking station

When not in use, always store the meter in the workstation.

3. 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.

4. Internal Quality Control (IQC)

IQC solutions – Abbott Medisense Glucose & Ketone Control Solutions – Lo and Hi.

Stability: Unopened – up to expiry date stated on bottles/box.
        Opened – 90 days from time of opening – expiry date to be noted on bottles.

Both Lo and Hi controls must be assayed.

IQC must be performed on each individual Precision Xceed Pro/FreeStyle Precision Pro glucose meter daily.
The Precision Xceed Pro/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 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 bleeps, displays **Sample Accepted**, and automatically starts the test.
• Control results appear as **PASS** or **FAIL** after a 20 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.

6. **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

7. **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.
• **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 20 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 PXP/FPP meters - except NICU
• **N.B. The action range for NICU** PXP/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.
• Record the glucose result in the patient’s case notes.
• As well as recording the result in the patients notes also record 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).

**N.B. If any blood glucose result is <4mmol/l the patient must be treated as per the RUH hypoglycaemic protocol (except neonates on NICU – refer to departmental protocol)**
8. 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

9. External Quality Assurance (EQA)

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.

- An EQA sample is distributed to all authorised Precision Xceed Pro/FreeStyle Precision Pro meter users every three months by biochemistry with a result sheet.
- The sample must be analysed (as per Patient Testing) on every Precision Xceed Pro/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.

10. Limitations of the Precision Xceed Pro/FreeStyle Precision Pro Meter

**Laboratory Confirmation of Results** from the Precision Xceed Pro/FreeStyle Precision Pro Meter

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.

11. Limitations of Procedure

• Precision Xceed Pro 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° and 40°C.
• Store the test strips between 4° and 30°C.
• Haematocrit range is 20%-70%.
• 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 results:

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<thead>
<tr>
<th>Substance</th>
<th>Concentration Up To</th>
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<tbody>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>684 µmol/l</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>12.95 mmol/l</td>
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<tr>
<td>Triglycerides</td>
<td>16.95 mmol/l</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>1.39 mmol/l</td>
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<tr>
<td>Maltose</td>
<td>3.21 mmol/l</td>
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<tr>
<td>Galactose</td>
<td>2.50 mmol/l</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>1.3 mmol/l</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>284 µmol/l</td>
</tr>
</tbody>
</table>

12. Maintenance

• Store the meter in the workstation case.

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, 70% Alcohol or 10% Ammonia.
• Do not clean the strip port.
• Do not pour liquid into the strip port or 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.

Replacing the Port Protector:
Should blood or control solution come into contact with the port protector, the meter should be cleaned and dried, and the port protector replaced.
• Replacement port protectors are available from Biochemistry Ext 4712.
• Lift the port protector from its left or right edge – using a flat tool device e.g. small screw driver – N.B. Do not insert tool into strip port opening.
• Carefully pry the protector until it separates from the meter.
• Discard the port protector as a biohazard.
• Rest the flat bottom of the new port protector on the ledge of the test strip port.
• Push both sides of the port protector until the tabs snap into place.
• There should be no gap between the port protector and the meter around the edges.

13. Audit

It is the laboratory's responsibility to carry out regular audits of the Precision Web system and the various aspects of glucose meter usage within the RUH.

14. COSHH and Health and Safety

• 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.

15. Adverse Incidents

Any adverse incidents regarding the use of the Precision Xceed Pro/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.
16. Operators

• Only staff that are trained in accordance with the Precision Xceed Pro/FreeStyle Precision Pro blood glucose meter Training Programme for the Trust, and are certificated, are authorised to use the Precision Xceed Pro/FreeStyle Precision Pro glucose meter.
• Training is provided by an Abbott Nurse Educator, Diabetes Liaison Nurses or by the Link Nurse.
• Refresher training may be provided by a Link Nurse.
• Refer to the NMC Professional Conduct Code 2008 and RUH Policies.

17. Data Upload

• 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 Biochemistry Ext 4712.

18. Docking Station

The Abbott docking station provides a means for hands-free, automatic data transfer (upload/download) between the Precision Xceed Pro/FreeStyle Precision Pro meter and a PC running the data management application software.
There is a docking station attached to a PC in each department using a Precision Xceed Pro/FreeStyle Precision Pro glucose meter.

19. References

2. Package insert for Abbott Precision Xceed Pro Blood Glucose Testing Strips

3. NMC Professional Conduct Code 2008

4. RUH Medical Equipment Policy

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