STANDARD OPERATING PROCEDURE SOP/POCT/9/8

Title: Abbott Freestyle Optium H Glucose Meter for Community Hospital use

Effective date: 07/02/2017

Summary of Significant Changes at this Revision
Update approver/checker

Purpose and Scope

1. The Abbott FreeStyle Optium H 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.

Items Required

1. Abbott FreeStyle Optium H Meter(community)
2. Abbott FreeStyle Optium H Blood Glucose Test Strips (Community)
3. MediSense Glucose & Ketone Control Solutions
4. WEQAS External glucose EQA sample
5. Lancing Devices
6. Abbott Quality Control record book

Definitions and Abbreviations

POCT = Point of Care Testing
NPT = Near Patient Testing
IQC = Internal Quality Control
QC=Quality Control
EQA = External Quality Assurance
NMC = Nursing and Midwifery Council
MHRA = Medicines and Healthcare products Regulatory Agency.

Grade / Qualifications Required

Nursing Staff: All Trained operators
Health Care Assistants: All trained operators
Biomedical Scientists
Supervised Trainee BMS Staff

Competencies Required:
Current Version of: NA

Risk Assessment:
Current Version of: NA

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1. Abbott FreeStyle Optium H Glucose meter

FreeStyle Optium H meter

This meter is for use within the RUH Hospital and Community Hospitals, and should only be used with FreeStyle Optium H test strips (see pictures below). The FreeStyle Optium H meter requires calibration (see section 3 Calibration page 4).

FreeStyle Optium H meter

FreeStyle Optium H Glucose test strips

2. 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 quinine. 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. Calibration

The Freestyle Optium **H** meter **must** be used with FreeStyle Optium H strips only. The meter requires calibrating for every new box of test strips using the calibrator strip supplied in box. Failure to calibrate properly will cause incorrect results.

1) With the lot number facing upward, insert the contact bars of the calibrator into the monitor. The monitor will turn on automatically.
2) The lot number of the calibrator strip and test strip foil package will appear in the display window

3) Check that the lot number matches on all the items; Meter display window, test strip calibrator, test strip instructions for use, test strip foil packet. If the Lot # on all these items matches, calibration is complete
4) Use only the calibrator supplied with the test strips. Keep the calibrator until all the test strips in the box have been used then discard the calibration strip.

4. Internal Quality Control (IQC)

Lo and Hi controls must be assayed.
IQC ranges are located on the package insert of Test strips. Retain package insert until box of test strips has been used.

IQC must be performed on each individual Freestyle Optium H glucose meter daily, weekly or as required depending on usage. Quality control must be performed prior to testing a patient sample. Frequency will depend on protocol for ward/department.

1) Quality control solutions have a shelf life of 3 months once opened. Write date opened and expiry date on bottles.
2) Remove a test strip from its foil package
3) Insert the three black lines at the end of the test strip into the strip port.
4) Push the test strip in until it stops – the meter turns on automatically
5) Check date and time displayed are ok – change if required
6) Check lot number for box of test strips
7) To mark the test as a control test, Press and Release the middle button once. A QC bottle will be displayed.
8) Apply control solution to the test strip and the meter begins the test.
9) The display will show the countdown.
10) When the test is complete the control result will be displayed in the display window. Record the result in the QC record book.
11) Remove the test strip from the sample port and discard appropriately.
12) Repeat steps 2-12 for Hi control
13) If QC is acceptable proceed with patient testing.
14) If QC is outside manufacturers limits repeat. If the QC is still out contact the Abbott helpline on 08000321016.

5. Patient Preparation

The site of sampling should be chosen to cause minimum discomfort and skin damage. The site of the puncture must be cleaned with warm soapy water, rinsed and dried. Do not use alcohol wipes or hand wipes to cleanse the skin.

6. Patient Testing

All Point of Care Testing devices have limitations. Please be aware of the limitations prior to use.

1) Remove a test strip from its foil package
2) Insert the three black lines at the end of the test strip into the strip port.
3) Push the test strip in until it stops – the meter turns on automatically
4) Check date and time displayed are ok – change if required
5) Check lot number for box of test strips
6) When the words “apply blood” appear on the meter display obtain a drop of blood from the patient
7) Touch a drop of blood to the white area at the edge of the test strip. The blood will be drawn into the test strip.
8) Continue to touch the blood drop to the white area until the meter begins the test. It will beep.
9) At the end of the countdown the meter will beep again and the result will be displayed in the display screen.
10) Record the glucose result in the patients’ case notes. NB: Also include in the case notes the date/time test performed, the device used including location, the test strip number, and the identity of the person performing the test and the person transcribing the results if different.
11) Remove the test strip from the sample port and dispose of appropriately.
12) If the code LO or HI is displayed on the meter then medical attention must be sought. A blood sample must be collected into a fluoride oxalate tube and sent to the laboratory for glucose analysis. Refer to the User Guide for graphical instructions.
13) If unable to obtain an adequate blood sample repeat the test and record in the patient notes.

7. External Quality Control

External Quality 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 External Quality control sample is distributed to all authorised Freestyle Optium H meter users every three months by biochemistry with a result sheet.
The sample must be analysed (as per Patient Testing) on every Freestyle Optium H meter located on the ward or in the 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.

8. Limitations of the Freestyle Optium H Meter

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

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 less than 2.5 mmol/L or greater than 20.0 mmol/L a venous sample must be sent to the biochemistry laboratory for confirmation.

Blood Glucose Action Limits by non qualified staff

Blood Glucose results less than 4 mmol/L
Blood Glucose results greater than 10 mmol/L

Must be reported to a trained member of the nursing or 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 below 2.8 mmol/L.

Do not use the memory function on the Freestyle Optium H meter to retrieve patient results.

9. Limitations of Procedure

1) The system is not designed for use with serum or plasma sample.
2) FreeStyle Optium H test strips are designed for use with fresh whole blood
3) Venous and arterial whole blood samples collected into lithium heparin and EDTA may be used if analysed within 30 minutes.
4) Do not use blood collected into fluoride or oxalate
5) Blood glucose results are displayed as mmol/L. Do not use mg/dL.
6) Use meter between 15^{o}C and 40^{o}C
7) Store strips between 4 ^{o}C and 30 ^{o}C
8) Haematocrit range is 20%-70%

9) 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)
10) Do not use during intravenous infusion of high dose ascorbic acid or during xylose absorption testing.

10. Maintenance

Store the meter in the workstation provided.
Clean the surface of the meter with a damp cloth and mild soap
It is acceptable to clean surface with 10% bleach, 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

Batteries: The meter will display a small battery icon when it is necessary to change the battery. Replacement batteries are available from biochemistry Ext. 4712. Battery changes must be documented in the Quality Control Record book.

11. Supplies

Test Strips

- RUH and Community Hospitals order from RUH pharmacy (01225 82640)

Quality Control (QC)

- RUH and Community Hospitals should contact biochemistry Dept. at RUH (01225 824712).

Batteries and QC Log Books

- RUH, Community Hospitals order from Biochemistry Dept. at RUH (01225824712).

Faulty FreeStyle Optium H Glucose Meter

- Contact Abbott Diabetes Care HCP helpline 08000321016

Extra FreeStyle Optium H Glucose Meters

- RUH and Community Hospitals contact RUH Biochemistry (01225 824712)

External Quality Assurance Samples

- Biochemistry provides External Quality Assurance samples (EQA) and performance report feedback every three months to all FreeStyle Optium H meter users. For support when performance is poor, contact Abbott Diabetes Care HCP helpline 08000321016.

12. COSHH and Health and Safety

Freestyle Optium H Test Strips: No Hazard
Medisense Lo and Hi Control solution: No Hazard
External Quality Assurance (EQA) sample: Treat as Biohazard

Gloves must be worn at all times when processing controls, EQA and patient samples.
Dispose all test strips, finger pricking device, control solutions and EQA in a sharps bin or yellow bag for incineration as appropriately required.

13. Adverse Incidents

Any adverse incidents regarding the use of the Freestyle Optium H 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.

14. Operators

Only staff that are trained in accordance with the Freestyle Optium H blood glucose meter Training Programme provided by Abbott can use the meter.
Refer to the NMC Professional Conduct Code 2008.

15. References

1. Abbott Freestyle Optium H Blood Glucose Monitoring System – User's Guide

2. Abbott package insert for Freestyle Optium H Blood Glucose Testing Strips and Quality Control Solutions

3. NMC Professional Conduct Code 2008

4. RUH Medical Equipment Policy

Copy number	Location held
1	Manual Lab-Glucose Meters SOP Folder
2	Electronic Copy – POCT section of Intranet