Shropshire Community Health NHS
NHS Trust

Document Details	
Title	**Capillary Blood Glucose Monitoring and Continuous Glucose Monitoring Policy and Guideline for Adults with Diabetes**
Trust Ref No	1567-48978
Local Ref (optional)	
Main points the document covers	The purpose of this Policy and Guideline is to describe the framework which enables staff to perform capillary blood glucose and Continuous Glucose monitoring (CGM) accurately, safely, and appropriately with minimal discomfort to patients
Who is the document aimed at?	All Staff
Owner	Julia Morgan-Williams Adult Diabetes Service Lead
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Approved by (Committee/Director)	Clinical Policies Group Operational, Quality & Safety Group
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Required by NHLSA	No
Other	None

Amendments History		
No	Date	Amendment
1	Aug 2013	Review
2	November 2015	Review and amendments to incorporate IQC and EQA testing

3	February 2016	Amendments to incorporate IQC and EQA testing Guides
4	October 2016	Amendments made following changes to supply processes & updated Meter Model – Optium Neo H Meter
5	January 2019	General updates, referencing updates and introduction of new forms.
6	June 2022	Amendment to include Real-Time and Intermittently Scanned Continuous Glucose Monitoring
7	November 2024	Amendment to include Continuous Glucose Monitoring

Policies, Procedures, Guidelines and Protocols

Contents

1 Introduction

Capillary blood glucose monitoring, and Continuous Glucose Monitoring (CGM)should only be carried out as part of a patient's management plan. (NICE 2008, NICE NG17, NICE NG28) (Appendix 1)

Practitioners, patients, and carers should have a clear understanding of the purpose of self-monitoring and how to interpret and act on the results.

Incorrect technique, faulty or incorrect use of capillary blood glucose meters and CGM can lead to misleading results that may compromise the health and safety of the patient.

All those involved in all the above blood glucose monitoring systems should have a clear understanding of this clinical task in line with Medicines & Healthcare Products Regulatory Agency (2015, updated August 2023) and the Health & Social Care Act 2008 (Regulated Activities) Regulations 2014.

2 Purpose

The purpose of this guideline is to describe the framework which enables staff to perform all blood glucose monitoring accurately, safely, and appropriately with minimal discomfort to patients.

3 Definitions

Term / abbreviation	Explanation / Definition
COSHH	Control of Substances Hazardous to Health
DKA	Diabetic Ketoacidosis
EQA	External Quality Assurance
HHS	Hyperosmolar hyperglycaemic state

Registered Nurse	is professionally accountable for the delegation of the task
Non-Registered Practitioner	is defined as a health care assistant (HCA) or a health care support worker or carer
IQA	Internal Quality Assurance
MHRA	Medicines and health care Products Regulatory Authority
MIU	Minor Injuries Unit
NMC	Nursing and Midwifery Council
POCT	Point of Care Testing – Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care by specially trained healthcare professionals. These are tests which can be performed at the bedside and typically involve blood and urine testing
RCN	Royal College of Nursing
CGM	Continuous Glucose Monitoring

4 Duties

Staff who are employed by Shropshire's Community Health NHS Trust have a responsibility to ensure that they are trained and up to date in point of care testing procedure: blood glucose meters (MHRA 2013) and NMC (2023) and CGM training from Manufacturer of each individual device.

In most cases the relevant staff group are Registered Nurses in the community nursing team and Trust Hospitals, health care assistants (HCA) or support workers.

5 Assessment

Informed consent should be obtained following Shropshire Community Health NHS Trust Policy for consent and in accordance with the Mental Capacity Act (2005).

Exclusions

- Patient consent declined.
- Patient assessed as not suitable for capillary blood glucose monitoring or Continuous Glucose Monitoring by community nurse.
- Health care professionals (HCPs) who have not received training.

6 Quality Assurance

The need for quality assurance and training in the use of blood glucose meters and CGM was identified in the Medicines and Medical Devices ACT 2021 and MRHA 2024, Roadmap towards the future regulatory framework for medical devices.

MRHA (2013) state that training should be provided to all staff who use blood glucose testing and should be refreshed at appropriate intervals. Only staff whose training and competence has been established and recorded should be permitted to carry out blood glucose testing.

All users should perform an internal quality assurance (IQA) before using the capillary blood glucose meter for the first time under the following circumstances:

- Once every 24 hours in high use areas or when undertaking patient visits or clinics
- If the result does not agree with the clinical presentation/picture of the patient
- After the battery has been changed
- When a new packet of test strips is opened
- If the meter has been dropped or damaged

For CGM, as per manufacturer's instructions for an appropriate internal quality assurance (IQA) and in the following circumstances a blood capillary glucose test:

- If the result does not agree with the clinical presentation/picture of the patient
- If the patient is hypoglycaemic (blood glucose level below 4mmol/l)
- Any damage or suspected damage or failure of the equipment

6.1 Procedure for Quality Assurance

Staff undertaking capillary blood glucose monitoring will use the meters provided by Shropshire Community Health NHS Trust (SCHT) procurement service, following completion of training. Patient's own meters **should not** be used routinely if SCHT staff are performing the procedure for the patient and administering insulin or adjusting medication based on the results. CGM, where agreed for patient use, may be used by SCHT staff following individual staff training and in the presence of an Individualised Diabetes Care plan.

However, on occasions it may be appropriate to use the patient's own glucose meter/reader/mobile phone where the patient is involved in their own glucose testing including with CGM e.g., patients in care homes whereby insulin administration has been delegated and in these circumstances the patient's own meter must be used. In this situation internal quality assurance must be carried out as per manufacturer's instructions by the carer delegated to the task and a record kept in the care home with the patient's blood glucose meter. IQA solutions must be obtained from the patient's meter manufacturer on an individual patient basis only. SCHT IQA solutions **must not** be supplied.

Staff will also use a safe sharps device namely a single use disposable lancing device e.g., Unistik 3 Comfort.

It is the responsibility of the health care professional to ensure, the meter has been internally quality assured before patient use or as soon as possible after patient use, if an urgent situation has arisen. See Appendix 2 on how to undertake this procedure.

6.2 Glucose Monitoring

Results of all systems of glucose monitoring are used effectively to manage diabetes. Glucose monitoring can form a part of a patient's diabetes management plan and self-management education.

NICE (2015, updated 2022) states that capillary blood glucose monitoring, and CGM where eligible, should be available if:

- the person is on insulin or
- there is evidence of hypoglycaemic episodes.
- the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery.
- the person is pregnant or is planning to become pregnant.

NICE guideline [NG17] Type 1 diabetes in adults: diagnosis and management;

- Offer adults with type 1 diabetes a choice of CGM, based on their individual preferences, needs, characteristics, and the functionality of the devices available.
- If multiple devices meet their requirements and preferences, offer the device with the lowest cost.

NICE guideline [NG28] Type 2 Diabetes in Adults: management

Offer CGM to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:

- They have recurrent hypoglycaemia or severe hypoglycaemia.
- They have impaired hypoglycaemia awareness.
- They have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary glucose monitoring but could use a CGM device (or have it scanned for them).
- They would otherwise be advised to self-measure at least 8 times a day.

Advise adults with diabetes who are using CGM that they will still need to take capillary blood glucose measurements (although they can do this less often). Explain that this is because:

- they will need to use capillary blood glucose measurements to check the accuracy of their CGM device.
- they will need capillary blood glucose monitoring as a back-up for when their blood glucose levels are changing quickly and including if hypoglycaemic.
- they will need capillary blood glucose monitoring as a back-up for if the CGM device fails to work.

In addition, consider short-term blood glucose monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):

- when starting treatment with oral or intravenous corticosteroids or
- to confirm suspected hypoglycaemia

Staff performing glucose monitoring should have a clear understanding of how to interpret and act on the results of the diagnostic test as per Diagnostic test and screening procedure policy to ensure glucose monitoring remains necessary and effective part of the patient's diabetes management plan, continuous assessment of the following factors should be routinely considered:

- Self-monitoring skills.
- Quality assurance of the equipment used.
- The appropriate frequency of testing or monitoring.
- The impact on the quality of life.
- Continued therapeutic benefit from capillary blood glucose monitoring once patient stabilised if on oral diabetic agents.

6.3 Contra-indications to Point of Care Testing

All Point of Care testing devices have limitations, and this should be always remembered. The following conditions can affect the accuracy of blood glucose monitoring and it may be necessary to obtain a venous sample for more accurate results (MRHA 2013)

- Peripheral circulatory failure and severe dehydration e.g., diabetic ketoacidosis (DKA), hyperosmolar hyperglycaemic state (HHS), shock and hypotension. These conditions cause peripheral circulatory shutdown, which can cause artificially low capillary results.
- Some renal dialysis treatments (check solutions used).
- Hyperlipidaemia: a cholesterol level above 13mmols/L may lead to artificially raised capillary blood glucose levels.
- Haematocrit levels above 55% may lead to inaccurate levels if the blood glucose is more than 11mmols/L (Dougherty & Lister 2011)

6.4 Equipment for Capillary Blood Glucose Testing

- Alcohol hand rub
- Blood Glucose Meter- Optium Neo H Meter
- Optium Neo H Test Strips & Optium Neo H beta Ketone H Strips **(NB Do not use standard Freestyle Optium patient use only test strips).**
- Single use, 'safe sharp' lancet device
- Sharps Container - correctly labelled and within 3 months of assembly
- Medisense Quality Control Test Solution
- Cotton wool/gauze
- Disposable gloves
- Disposable apron - if required following a risk assessment
- Documentation/Diary
- Detergent wipes suitable for cleaning of equipment

For CGM

- CGM reader/patient mobile phone.
- Follow CGM manufacturer's guidance on assessing glucose level.

6.5 Calibration

Before a meter is used for the first time and with each new box of Optium Neo H or Optium Neo H Beta Ketone test strips the meter must be calibrated. This means the meter is set to 'match' the strips being used by coding it with the calibration strip supplied in the packet of test strips. The calibration strip programmes the meter with the lot number, expiry date and test strip technology.

Calibration Process

1. Ensure the meter is switched off.
2. Locate the Calibration strip from the packet of test strips and check expiry date of both the strips and the IQA solution to be used.
3. Insert the plastic calibration strip into the meter with the number facing upwards.
4. The meter will turn on and should display the number written on the test strip in the meter display screen. Check that the lot number on the meter display window matches with the number on the test strip calibrator and the last five digits on both the test strip foil packet and test strip insert.
5. This has now coded/calibrated the meter.
6. Check that the number in the display screen matches the number on the calibration strip.
7. If it doesn't repeat the process above and if the problem persists, do not use the meter, and report the fault.
8. Once calibrated accurately remove the test strip and keep it with the box of test strips in the IQA workstation until all the strips have been used.

9. Discard the calibration strip once all the strips have been used in the appropriate waste bin.
10. On opening a new packet repeat the above process

6.6 Procedure

Procedure	Rationale
Identify patient	To ensure correct patient identity
Obtain consent & cooperation	To gain informed consent & understanding
Approach patient confidently & explain procedure & encourage to ask questions	To relax patient & involve patient in treatment
Ensure meter is accurate by performing quality assurance test (see appendix 2) Guidelines for Internal Quality Assurance Check for Optium Neo H Meter	To ensure accuracy & functionality of meter
Decontaminate hands with soap and water or alcohol hand rub. Put on gloves and apron if required.	To reduce risk of infection
Wash patient's hands in warm water ensuring thoroughly dry before test. Do not use alcohol wipes or hand wipes to cleanse the skin	To prevent contamination & encourage blood flow to fingertips
Insert Optium Neo H test strip to switch meter on	To ensure reliable blood glucose ensure the correct date and time are presented on screen, and that there is adequate battery Check the unit of measure and ensure that it is reading in mmol/L prior to each use.

Procedure	Rationale
Select site for finger sample to be taken. Use side of fingers NOT TIPS, try to avoid index finger & thumb. Rotate sites	The side of the finger is a less painful area and less likely to cause neuropathy & callous formation
Prepare single use lancet device & apply to selected site. Puncture side of finger with device & obtain blood sample. Dispose of single use lancet device in sharps bin immediately	To prevent needle-stick injury & obtain sample of blood
Apply blood to test strip according to manufacturer's instructions when prompted by display screen	To obtain blood glucose reading
Provide client with cotton wool/gauze. Apply pressure to puncture and monitor for excess bleeding.	To stop bleeding & prevent cross infection
Remove gloves and apron if used and dispose of in appropriate waste to comply with SCHT waste management policy and perform hand hygiene again.	To prevent contamination and reduce risk of infection
Record blood glucose results on appropriate documentation	To provide a contemporaneous record
Inform client of result & act on /report unexpected results accordingly as laid out in individual care plan	To involve patient in care & ensure appropriate management of hyperglycaemia/hypoglycaemia
Clean device with detergent wipes after use	To prevent contamination and reduce risk of infection

Figure 1: Insertion of test strip

Figure 2: Sampling technique

6.7 Limitations

All Point of care testing (POCT) devices have limitations, and this should be always remembered.

All results taken using POCT must be interpreted considering the patient's condition. If an unexpected high or low blood glucose result is obtained, a repeat test must be performed and an IQA performed to confirm meter accuracy.

Measuring Range of Optium H Strips
1.1 - 27.8 mmols/L.
Results of less than 1.1mmols/L give a display as low.
Results greater than 27.8mmols/L give a display as HI or error code E4.

6.8 Health and Safety

Disposable gloves should be always worn when processing patient testing, IQA control testing or External Quality Assurance (EQA) procedures.

Care should be taken to ensure that the lancets are disposed of in a sharp's container and the used test strips are disposed of immediately into the normal waste stream.

Dispose IQA and EQA control solution in the normal waste streams a yellow sharps bin or yellow bag for incineration as appropriately required.

Product wrappers and cotton wool should be disposed of in the appropriate waste stream.

6.9 Cleaning

The Optium Neo H meters should not require much cleaning as with correct use blood and control solutions do not enter the meter. However, if the meter does get soiled it can be wiped with a damp cloth and mild soap/ detergent.

Do not immerse or place the meter in water.

Document any cleaning in the Quality Assurance Record Book /Log sheet and keep logbook with the IQA workstation.

6.10 Control of Substances Hazardous to Health (COSHH) Regulations and Health and Safety

Item	Risk
Freestyle Optium Tests Strips The reagent area of each test strips contains: Glucose Oxidase Non-Reactive Ingredients	No Risk
Abbott Lo and Hi Control Solutions Glucose Non-Reactive Ingredients Do not swallow or inject the solutions. PPE equipment: Gloves must be worn at all times when processing control solutions.	Low Risk Low Risk
EQA control solution	Treat as a Biohazard

7 Adverse Incidents

Any adverse incidents regarding the Optium Neo H meters must be reported via Datix and by the team leader /ward manager to the medical device lead/trust safety advisor for evaluation and reporting to the MHRA as appropriate.

8 Supplies

Freestyle Optium H Test Strips & Freestyle Optium H Beta Ketone H Strips should be ordered via the Oracle procurement system:

- Freestyle Optium Neo H Glucose Test Strips pack 100 7131375
- Freestyle Optium H Ketone Test Strips pack 10 7112575

Quality Control Solution (should be ordered via the Oracle Procurement System

- Quality Control Solution (1 high, 1 low solution) 8013920

Batteries: Order via Oracle Procurement System.

- The battery used is the flat CR2032 Lithium.

Additional Optium Neo H meters for new staff/replacement equipment can be requested from the remaining supply and the request emailed to shropcom.shropshiredsn@nhs.net with supplying the staff member's name, team, and base.
Single Use 'safe sharps' lancets: Order via Oracle Procurement system

9 Storage

- Store test strips between 4 and 30 degrees Celsius. Keep away from direct sunlight and heat.
- Store Optium Neo H meters between 10-50 degree Celsius.
- Store Quality Control solution between 3-30 degrees Celsius.
- Do not use test strips beyond their expiry date written on the foil packet and outer box.
- Use test strip immediately after opening foil packet.
- Do not use wet, bent, or damaged test strips.
- Do not use the strip if the foil packet has been punctured or torn.
- The Quality Control solution expires 90 days after opening and the bottle labelled with the date the solution was opened and due to expire.

10 Consultation

This Policy has been developed by the Diabetes Specialist Nursing Service in consultation with:

- Shropshire Community Health NHS Trust Infection Prevention and Control Team
- The following Guidelines was referred to: NICE (2015) Type 2 Diabetes in adults management: Available online at www.nice.org.uk/guidance/ng28. Last updated 31 March 2022 and NICE (2015) Type 1 Diabetes diagnosis and management Available online at www.nice.org.uk/guidance/ng17 Last Updated 31 March 2022

11 Dissemination

These guidelines will be disseminated by the following methods:

- Managers Informed via DATIX system who then confirm they have disseminated to staff as appropriate.
- Staff via Team Brief
- Published to the staff zone of the trust website,

12 Implementation

The registered nurse must complete the self-assessment competency tool for capillary blood glucose (appendix 3) and a copy kept in their NMC portfolio/training records.
A non-registered practitioner must have been assessed and signed as competent to carry out all aspects of the task using the summative assessment document (Appendix 4) (NMC) if undertaking this procedure.

The non-registered practitioner must be reassessed as competent for capillary blood glucose monitoring on an annual basis by a registered nurse using the summative assessment documentation (appendix 4) and a copy of this be kept by the non-registered practitioner and the registered nurse. A Certificate for POCT for Non-Registered Practitioners should be completed by the Trainer and trainee as per Appendix 7.

Managers are responsible for the competency assessment of staff once the initial training has been provided.

13 Monitoring Compliance

Compliance of this Guideline will be carried out by:

- Monitoring of related Datix incident reports carried out by service managers.
- Following incident reporting follow up actions will be coordinated by service managers and the community Trust Safety Manager.

14 References

- The Medical Devices Regulations 2002 (legislation.gov.uk)
- Dougherty and Lister (2011) **The Royal Marsden Manual of Clinical Nursing Procedures**, (8th Ed), Blackwell Publishing: Oxford
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- Medicines & Healthcare Products Regulatory Agency (2013) **Point of Care testing: Blood Glucose Meters, advice on using** PowerPoint Presentation (publishing.service.gov.uk)
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- NMC (2018) The Code: Professional standards of practice and behaviour for Nurses, Midwives and Nursing Associates. NMC: London NMC Accountability and Delegation: NMC London. Available online from:delegation-and-accountability-supplementary-information-to-the-nmc-code.pdf accessed 26 June 2023
- Skills for Health (2005) CHS131 Obtain and test capillary blood samples.
- Trend (2011 updated 2021) **An integrated career & competency Framework for Diabetes** Nursing. 6th Ed. SB Communications Group: London
- Trend UK (2017 https://mydiabetesmyway.scot.nhs.uk/media/1173/170131-trend_bg_online.pdf
- Shropshire Community Health NHS Trust (2015) Policy on Management of Diagnostic Testing and Screening Procedures

15 Associated Documents

This guideline may be used in conjunction with the following SCHT policies and guidelines:

- Management of Hypoglycaemia Guideline
- Prevention and Management of Needlestick Injuries: including Inoculation Incidents and Exposures to Blood Borne Viruses (BBV) Policy
- Hand Hygiene Policy
- Standard Precautions including Surgical Hand Scrub, Gowning and Gloving Policy

- Check to Protect – Safer Sharps
- Waste Management Policy
- Cleaning and Disinfection Policy
- Consent to Examination or Treatment Policy
- Incident Reporting Policy
- SCHT Policy for Management of Diagnostic and Screening Tests

16 Appendices

- Appendix 1: Patient Groups that require Capillary Blood Glucose Testing
- Appendix 2: Internal Quality Assurance (IQA)
- Appendix 3: Diabetes Management Self-Assessment Competency Framework
- Appendix 4: Summative Assessment for Non-Registered Practitioners and Registered Nurses/Practitioners
- Appendix 5: External Quality Assessment (EQA) for Community Hospitals only
- Appendix 6: Internal Quality Control (IQC) Record Sheet /logbook
- Appendix 7: Certificate of POCT Training

Appendix 1: Patient Groups that require Glucose Testing

In patients with type 2 Diabetes where blood glucose levels are regarded as stable there is normally no requirement for regular capillary blood glucose testing unless the patient is on insulin or oral medication that may increase the risk of hypoglycaemia. For patients with type 1 Diabetes glucose monitoring is always required. The table below provides some guidance on monitoring patients on specific treatment. (Exceptions noted below)

Type 1 Diabetes	Capillary blood glucose monitoring and Continuous Glucose Monitoring required as part of individuals management plan and prior to driving (NICE 2015 www.nice.org.uk/guidance/ng17 updated March 2022)

Type 2 Diabetes	
Insulin treated diabetes.	Capillary blood glucose monitoring and Continuous Glucose Monitoring, where appropriate and eligible with NICE guidance NG28(2015- updated March 2022) required as part of individuals management plan. Testing will be required to adjust insulin doses where appropriate and prior to driving
Diet only controlled diabetes	Capillary blood glucose monitoring unnecessary
Patients taking Metformin alone	Capillary blood glucose monitoring unnecessary
Patients taking Sulphonylurea alone or in combination with any other anti-diabetic agent.	Capillary blood glucose monitoring required to identify hypoglycaemia and before driving. To test up to twice a week as part of a self-management plan to understand how food and activity affect diabetes management to improve diabetes management
Patients taking Repaglinide or Nateglinide alone or in combination with any other anti-diabetic agent.	Capillary blood glucose monitoring required to identify hypoglycaemia and prior to driving. To test up to twice a week as part of a self-management plan to understand how food and activity affect diabetes management to improve diabetes management
Patients taking Glitazone alone or in combination with metformin	Capillary blood glucose monitoring unnecessary
Patients taking a Gliptin alone or in combination with metformin	Capillary blood glucose monitoring unnecessary
Patient using GLP-1 agents	Capillary blood glucose monitoring unnecessary (do not cause hypoglycaemia)
Patient using GLP-1 agents in combination with a Sulphonylureas	Capillary blood glucose monitoring required to identify hypoglycaemia and prior to driving. To test up to twice a week as part of a self-management plan to understand how food and

	activity affect diabetes management to improve diabetes management
Patient using SGLT-2 agents in combination with Insulin or Sulphonylureas.	Capillary blood glucose monitoring and Continuous Glucose Monitoring, where appropriate and eligible with NICE guidance NG28(2015- updated March 2022) required as part of individuals management plan. Testing will be required to adjust insulin doses where appropriate and prior to driving

Exceptions

Testing or more frequent testing may be necessary in patients where blood glucose levels are unstable. Specific guidance and counselling should be given in each individual case:

- Patients troubled by low blood glucose.
- Patients who have had their medication changed or have started medication for an alternative condition e.g., steroids.
- Patients who are unwell.

The individual needs of each patient must be considered according to treatment regimen and level of control.

Specific needs of patient groups should also be considered e.g., terminally ill, drivers, fasting patients.

Appendix 2: Internal Quality Assurance (IQA)

The need for quality assurance and training in the use of blood glucose meters has been identified in the document Management and use of IVD point of care test devices (Medicines & Healthcare Products Regulatory Agency (MHRA) 2013).

The guidance states “only staff who training and competence has been established and recorded should be permitted to carry out POCT”.

The meter must have an internal quality control check performed to establish if the meter if functioning correctly. This may be daily in high use areas such as community hospital wards.

In addition, an IQC should be undertaken after an unexpected patient result, if the meter is dropped, batteries are changed or is the strips have been stored incorrectly and on opening a new packet of test strips.

Quality Assurance is an essential component of POCT and includes measures taken to ensure that results are reliable. These include:

- Correct identification of the patient
- Appropriate test selection
- Obtaining a satisfactory specimen
- Analysing and recording the results promptly and correctly
- Taking appropriate action
- Documenting all procedures and maintaining accurate records

Abbott Diabetes Care Glucose Control Solution (Lo and Hi solutions)
Lo and Hi Solutions should be stored at room temperature. They are stable until the expiry date printed on the vials or for **90 days** from the vials being opened whichever comes first. The date the new control solutions are opened should be written on the vials along with the new expiry date.

Abbott Diabetes Care Quality Control supply record books or the trust A4 Quality Assurance Log Sheets may be used and kept in a designated folder. Each ward or community nursing base must have a central IQA station where logbooks for all meters are recorded.

Logbooks can be ordered via the Abbott Diabetes Representatives or staff can use the form; Appendix 6 can be used and kept in an A4 Folder clearly marked as an ‘Internal Quality Assurance Logbook’.

Procedure

Once opened the quality control solutions are stable for 90 days. On opening the vials expiry date should be written on the bottle.

For legal reasons the internal quality control logbook/sheets must be kept for 12 years from when they were completed. Completed logbooks/ folders should be returned to Records Manager for archiving.

Internal Quality Assurance: Step by Step Guide

- Remove paper insert from the Optium Neo H Strip packet and locate IQA reference range.
- Check the LOT number & expiry date of test strip match.
- Open the test strip by using the triangular notch in the foil.
- Open the test strip immediately prior to use.
- Insert the test strip into the meter.
- The meter will turn on.
- When the  blinks press the  button until this icon appears 
- The meter is now ready for you to apply the low-level control solution to the test strip.
- Invert the bottle to mix the solution.
- Wipe the QC solution nozzle with a clean gauze/tissue before and after each test.
- Replace the cap securely on the bottle immediately after use.
- Apply a drop of the 'Lo' control solution until 3 short lines appears on the screen with the meter in a horizontal (flat) position to avoid it entering the test strip port.
- The results will be displayed after a 5-second countdown.
- Compare the control solution results to the range printed on the blood glucose test strip insert; the results should fall within this range.
- The results will be stored in memory as a control solution result.
- Record the result in the IQA log/record book.
- If results are out-of-range repeat the QA test again.
- If the repeated result is out-of-range, follow organisational policy for out-of-range results.
- Remove the test strip and repeat the above process & steps again using the 'Hi' control solution.
- Record HI and LO QA test result in the QA logbook.

Failure to adhere to the most current instructions could result in you as an individual being liable for any error in testing.

Appendix 3: Diabetes Self-Assessment Competency Framework for Capillary Blood Glucose Monitoring

Name:	Signature:
Designation:	Date:

The following document is designed to:

- Allow you to assess your competence in managing your patients in line with the KSF and Skills for Health Competency Frameworks CHS131
- To identify your own educational needs
- To ensure your own competency before using a blood glucose meter and Continuous Glucose Monitoring system

Verification of competence is undertaken by assessment against the following statements:

These statements are designed to indicate competence to use a blood glucose meter device and Continuous Glucose Monitoring system.

Responsibility for use remains with the user, so if you are in any doubt regarding your competence to use the device, you should seek education to bring about improvement.

You must be able to answer “yes” to all the questions before considering yourself to be competent. If you are not competent, instigate learning & then repeat self-verification.

A competency defines the knowledge understanding and skill required to perform a specific task (Skills for Health 2005).

Self-Assessment Competency Framework for Capillary Blood Glucose Monitoring

Please tick the boxes that best describes your current practice in each competency assessment statement:

Self-Assessment Date:			
Can you answer the following questions?	**Yes**	**No**	**More Support Required**
Why it is essential to ensure that the patients and operators' hands are clean prior to testing?			
How to conduct quality control testing			
How to identify the expiry date of the quality control test solution and its life once opened?			
How often the QC test should be performed and where the results are recorded?			
How to correctly insert a blood testing strip?			
The correct way to obtain a blood drop sample and where it should be applied on the test strip			
How to set the time and date on the meter?			
How to identify that the batteries require changing and how to change them if required?			
How to identify what action to take if the meter displays an error message			
Do you know the limitations for using capillary blood glucose testing?			
Note: *Keep this form in your personal portfolio or training record*			

Appendix 4: Summative Assessment for Non-Registered Practitioners for Capillary Glucose Monitoring Competencies

Name of Non-Registered Practitioner	
Name of Assessor	
Date Assessed	
Annual Reassessment Date	

Demonstrates knowledge of Capillary Blood Glucose Monitoring				
Performance Criteria	**Assessment Method**	**Achieved Y for Yes or R for reassessment required**	**Date**	**Assessor signature**
Why it is essential to ensure that the patient/client and operator's hands are clean prior to testing?	Questioning			
How to conduct quality control testing	Questioning			
How to identify the expiry date of the quality control test solution and its life once opened?	Questioning			
How often the QC test should be performed and where the results are recorded?	Questioning			
How to correctly insert a blood testing strip?	Questioning			
The correct way to obtain a blood drop sample and where it should be applied on the test strip	Questioning			
How to set the time and date on the meter?	Questioning			
How to identify that the batteries require changing and how to change them if required?	Questioning			

How to identify what action to take if the meter displays an error message	Questioning			
Describe what diabetes is, and the action insulin has on blood glucose levels. State normal blood glucose levels.	Questioning			
State how to maintain and store the blood glucose meter and test strips, and to perform quality assurance test according to manufacturer's guidelines	Questioning			
Identify 3 factors that may give rise to inaccurate blood glucose readings.	Questioning			
Identify 4 factors that could result in low blood glucose readings	Questioning			
Identify correct action to take in the event of 3 successive high blood glucose readings	Questioning			
Identify 4 factors that could result in high readings	Questioning			
Identify where to record blood glucose results & explain action in event of readings outside the client's individual targets	Questioning			
Describe the procedure for obtaining supplies	Questioning			

Non-Registered Practitioner demonstrates practical skills regarding Capillary blood glucose monitoring				
Performance Criteria	**Assessment Method**	**Achieved Y for Yes or R for reassessment required**	**Date**	**Assessor**
Inform the patient/client of need for blood glucose test	Observation	1. 2. 3.	1. 2. 3.	
Verifies patient/client ID and appropriately gains patient consent	Observation	1. 2.	1. 2.	

		3.	3.	
Check expiry date on test strips	Observation	1. 2. 3.	1. 2. 3.	
Follow manufacturer's procedure for use of meter.	Observation	1. 2. 3.	1. 2. 3.	
Prepare area for blood glucose test	Observation	1. 2. 3.	1. 2. 3.	
Prepare safe sharps device- single lancet for test.	Observation	1. 2. 3.	1. 2. 3.	
Performs correct hand hygiene technique before and after the application of Personal Protective Equipment	Observation	1. 2. 3.	1. 2. 3.	
Accurately perform blood test	Observation	1. 2. 3.	1. 2. 3.	
Demonstrate safe disposal of sharps and blood-stained equipment	Observation	1. 2. 3.	1. 2. 3.	
Accurately record blood glucose result in Community nurse documentation and Rio if SCHT staff or Client care records & cleaning of meter	Observation	1. 2. 3.	1. 2. 3.	

Non-Registered Practitioner Name:		**Signature:**	
Status:		**Date:**	

I confirm that I have assessed the above-named individual and can verify that he/she demonstrates competency in capillary blood glucose monitoring.

Mentor Name:		**Signature:**	
Status:		**Date:**	

Appendix 5: External Quality Assurance (EQA) for Community Hospitals only

External Quality Assurance (EQA)

External Quality Assurance differs from internal in that the accuracy 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.

EQA is coordinated by the Biochemistry department at Princess Royal Hospital. An external Quality Control sample is distributed to all authorised Optium neo-H users in the community hospitals on a Bi-monthly basis.

The EQA sample must be analysed (as per patient testing) on every Optium Neo H meter located on the ward or departments at the community hospitals as soon as possible on receipt of the solution.

Record the serial number of each individual meter that is used and record the blood glucose results for the EQA sample and document on the form supplied by Biochemistry.

Return the result sheet to Biochemistry at the address found at the bottom of the form.

Dispose of the solution bottle in a yellow infected waste bag.

The results will be returned to the ward/team and must be reviewed by the Ward Manager/Team Leader and the results filed. Poor performance of the EQA may necessitate some staff training.

Appendix 6: Internal Quality Control Record Sheet /logbook

Date	Time	Test Strip Batch Number	Expected Quality Control solution range		Quality Control Results		Operator
			Lo Solution	HI Solution	HI Results	Lo Results	
Example 7.7.2015	1400	43190	1.6-3.3mmols/l	16.7-23.2mmols/l	22.8mmol/ls	2.5 mmols/l	SN Mary Webb

Appendix 7: Certificate of Training for all Non-Registered Practitioners undertaking POCT

Staff Name: _____

Your trainer has explained and demonstrated the following regarding:

- Blood glucose testing equipment:
- Basic Principles of testing
- The correct use of the system (Meter, strips, control solutions, recording result)
- Described the consequences of improper use.
- Provided instructions for sample collection.
- Provided instructions on the documentation of results.
- Described how to complete an internal control test.

Please tick the boxes if you agree with the above

Your trainer has demonstrated and watched you perform and has assessed you as competent at this training session:

A test using:

- Optium Neo H meter

Please tick the boxes if you agree with the above

Name of Trainee _____

Signature _____

Name of Trainer _____

Signature _____

Date _____

This is to certify that the above trainee has been assessed as competent at the time of training. It is the trainee's responsibility to ensure that he/she adheres to the instruction and training received, at all times.