Mid Essex Hospital Services NHS
NHS Trust

Point of Care Capillary blood glucose/ketone monitoring with the NOVA meter	Clinical Guideline Register No: 08027 Status: Public

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Consulted With	**Post/Committee/Group**	**Date**
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1.1	Bev Farley	30/12/2007
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1. Purpose

1.1 This procedure covers the point of care monitoring of capillary blood glucose/ketones in clinical situations, with the NOVA meter. It may be helpful in the following situations (providing contra-indications are not present):

- Monitoring of glycaemic control in patients who are known to have diabetes mellitus (Type 1 or Type 2)
- Assessing blood glucose levels in patients with signs and symptoms of hypoglycaemia or hyperglycaemia

NB: Capillary blood glucose measurement must not be used as a diagnostic tool

1.2 This guidance document is written to support all Trust staff, which use NOVA Glucose/Ketone meters and provide information on how best to use them.

2. Background

2.1 Point of Care Testing (POCT), or near patient testing (NPT), is a term used to describe laboratory testing performed usually by non-laboratory staff, mainly medical and nursing staff outside the main laboratory.

2.2 POCT is widely used in the Trust and is likely to increase because of advancing technology and changing clinical practice.

2.3 A formal Policy specifying the leading role of Pathology, and where appropriate, representation from clinical and service departments (Accident and Emergency, ITU, Burns Unit, Nursing-diabetic nurse, Pharmacy) is essential. This will ensure that the whole process is conducted in accordance with the principles of Clinical Governance and national accreditation standards.

2.4 Professional partnership between Pathology and clinicians ensures that POCT equipment is suitable for its intended use, that it can be supported adequately, that safety and quality standards are met, that the results of investigations performed are recorded and that it is operated only by trained staff.

2.5 The established POCT group, with overarching responsibilities for all these areas, will achieve this for the trust.

2.6 Poor performance in blood glucose/ketones monitoring, outside the laboratory has been highlighted in National Patient Safety Agency, 2008. New guidance issued following problems with infusions and sampling from arterial lines and in The Pharmaceutical Journal (2014); all has been summarised in the Guidelines of the Joint Working Group for Quality Assurance and Guidelines from the Medical Devices Agency (MHRA).

3 Aims

3.1 To ensure that there is a complete audit trail from authorship to Trust ratification via appropriate consultation to satisfy the requirements of internal and external auditors.

4. Scope

4.1 The NOVA meter is used for monitoring blood glucose/ketone levels in hospital. It is used in both adult and paediatric patient populations including neonates.

4.2 This procedure applies to all staff working on sites where the Trust provides services

4.3 Testing is performed when ordered by the patient's health care provider. Only staff, that have completed training and the competency statement may use the meter to test blood glucose/ketones.

4.4 Members of staff must not use meters belonging to patients

4.5 It is acceptable for patients to use their own meters whilst in hospital, but the result obtained must not be used by staff to make alterations to treatment

4.6 Patient meter results must not be recorded in patient notes

4.7 Staff must not QC patient meters

5. Staffing and Training

5.1 Each "operator" using the NOVA Glucose/Ketone meter becomes competent through training provided by the Trust (in association with NOVA) or Superuser. Any question regarding training can be forward to POCT team via e-mail POCT-TEAM@meht.nhs.uk or extension number x 4152.

5.2 Monthly training sessions are set a year in advance and all dates are available on the intranet. There is no need to book the places as training is set up as drop in sessions, training to be reviewed annually. Existing users can also use e-learning to refresh on an annual basis available through the intranet.

5.3 The nurse in charge of the department /ward is responsible for informing the POCT team of any changes or problems with the meters (e.g. broken meter or meter that does not pass the quality assurance test)

5.4 Only individuals who have fulfilled the following criteria will be allowed to undertake capillary blood testing:

- Those who have undertaken the appropriate training
- Those who have been assessed as competent, utilising the equipment competency statement as a framework and have been issued the barcode.

5.5 All personnel who have successfully completed the Nova training and are registered on the Nova database have access to the Nova StatStrip Glucose Hospital Meter System.

5.6 Role and Responsibility of SUPERUSER - it is the SUPERUSER responsibility to ensure that new staff or those that have missed the training watch the presentation and follow the steps below

- Go on to the INTRANET
- New employee to watch the training power point presentation (PPT)
- New employee to do the meter quiz
- SUPERUSER marks the QUIZ and if satisfied, completes the competency document with the member of staff.
- If unsuccessful watch the PPT again and continue until quiz score is 100%
- Barcode request completed and signed off by the SUPERUSER
- Take the Bar code request form to Blood Science reception D228

5.7 Once trained all staff will be required to update their training every year by classroom based training, superusers or using the e-learning package.

- Go to the INTRANET – our services – new blood glucose information
- Take E-LEARNING testing (pass mark 75%)
- When successful perform Quality Control test 1 & 3 on Glucose meter within 7 days
- You will be recertified automatically
- Your barcode will be updated within next 3 working days

6. Reagents, equipment and material

6.1 NOVA workstations, which are located on ward, include:

- NOVA connected Glucose/Ketone Meter
- Docking station/s
- NOVA test strips
- Stat Strip Glucose or/and Ketone Test Strips, 50 glucose and 25 Ketone strips per vial
- Stat Strip Glucose Control Solution, Level 1(low)
- Stat Strip Glucose Control Solution, Level 3(high)
- UNISTIK 3 single use lancets

7. Storage and maintenance

7.1 Meter

- The workstation and contents should be stored between 15^{o}C and 40^{o}C and kept away from moisture (<85% humidity).

- The NOVA Stat Strip meter should be placed in docking station when not in use

- The NOVA Stat Strip meter contains a replaceable battery, which is located at the back of the docking station

7.2 Test Strips

- Quality Control must be performed on all new containers of test strips when first opened.

- Keep the test strips in the original container, replacing the vial cap after removing a test strip. Exposure to moisture may cause the meter to give an error message or give incorrect results

- The test strips are stable for 6 months for glucose and 3 months for ketones after opening

- Do not use test strips beyond the expiration date on the container

- It is essential to record the opened and discard date on the vial

7.3 Control Solutions

- Controls must be dated when first opened and are stable for 3 months.
- Unopened control solutions remain stable up to their expiration date when stored at room temperature.

7.4 Cleaning

- Clean and disinfect the meter after each use using a sani-cloth disinfectant wipe, blot with a dry paper towel and then follow with a water dampened cloth to remove any residue of cleaning solution

- Please take care to keep moisture out of the test strip area.

8. Internal Quality Control Testing

8.1 Quality Control Testing must be carried out in the following circumstances:

8.1.1 For Glucose

- Must be performed daily on wards or on the day a clinic runs
- When a new container of test strips is opened
- If the meter has been dropped and damage is suspected
- If the QC results fall outside the acceptable range
- If the patient results are unexpected or do not correlate to the patients clinical condition

8.1.2 For Ketone

- Must be performed weekly on wards
- When a new container of test strips is opened
- If the meter has been dropped and damage is suspected
- If the QC results fall outside the acceptable range

- If the patient results are unexpected or do not correlate to the patients clinical condition

8.2 Internal Quality Control Procedure

- Remove meter from docking station.
- Press “Login”, then press “Scan” whilst pointing bar code reader at your password barcode.
- From Patient Test Screen press “QC” key.
- From the “Enter Strip Lot” screen, scan the strip lot number from the side of the strip container then press “Accept”.
- From Patient Test Screen press “QC” key.
- From Patient Test Screen press “QC” key.
- Insert test strip
- Gently mix the QC bottle before sampling and discard the first drop from the bottle. The meter must remain on a flat surface during the whole QC process. Apply a small amount of control to the end of the test strip. The meter will beep when it has drawn up the correct amount of solution.
- The result will be displayed in 6 seconds for glucose or in 10 seconds for ketones, if test has “Passed”, press “Accept”.
- If both or either QC result is outside the expected range: Repeat
- If both or either QC result is still outside of the expected range: Check the expiry date control solution. If found to be out of date then replace with ‘in-date’ supplies and repeat the QC testing procedure
- If both or either result is **still** outside of the expected range: Contact POCT team for advice or a replacement meter.

9. External Quality Assurance (EQA)

9.1 External quality assurance is an essential part of any analytical procedure, allowing independent assessment of meter/user performance. It also ensures that results from different meters are comparable, both within the Trust and across the country.

9.2 Samples for assessment are sent out from the Biochemistry department at monthly intervals. The samples have unknown values and are to be tested as soon as possible and then discarded. Results will be submitted to WEQAS, either directly through Nova net or via the laboratory.

9.3 The sample should be tested on the day it is received if possible

9.4 The results of the Assessment will be sent to each ward link nurse

9.5 All trained staff should participate in the Assessment over a period of time i.e. the same person(s) should not perform the test on each occasion

9.6 Failure to comply with external QA testing could result in the removal of the meter from the clinical area as it is clinically unsafe to use a meter that is not fully validated

9.7 Routine EQA participation is necessary for compliance with MHRA and UK Accreditation Service (UKAS), and is good practise to ensure an accurate and precise patient result

10. Specimen Requirements

10.1 Use only whole blood samples – fresh capillary, venous or arterial

10.2 Capillary samples are obtained from finger stick and on children under 12 months of age, from heel prick. Samples must be tested immediately.

10.3 Alternate site capillary testing is unacceptable in a hospital setting.

11. Procedure for performing a test

11.1 Comply with each element of the following procedure:

- **Use of the meter is only possible by scanning YOUR UNIQUE BARCODE (which should be located somewhere where it is easily accessed e.g. on the back of your ID badge holder.) All data is logged so please do not allow any other member of staff to log on using your personal barcode. Contact Clinical Chemistry if you require a replacement barcode.**
- Remove meter from docking station.
- Press “Login”, then press “Scan” whilst pointing bar code reader at your unique barcode.
- From the Patient Test screen press “Accept”
- From the “Enter Strip Lot” screen, scan the strip lot number from the side of the strip container. Press “Accept”
- Enter the patient’s hospital number using the keypad or scan. Press “Accept”.
- Wash patient’s hand or heel with water and dry thoroughly
- Use a safety lancet to puncture the finger. Remember not to use the thumb or index finger.
- When the ‘Apply Sample’ screen appears touch the end of the test strip to the blood

drop until the well of the test strip is full and the meter beeps. If the test strip does not fill completely do not try to add a second drop of blood. A repeat test will be required.

- The test result will appear in 6 seconds. Do not remove the test strip while the countdown is in process.

- To add a comment before accepting or rejecting the result, press the “Comment” key. Accept your comment and then accept or reject the result. A comment must always be added if rejecting a result.

- The result must be entered in the patient’s notes, along with any appropriate action taken

- Return meter to the Docking Station – Meter must be docked after each use (yellow light indicates battery is charging / green light indicates fully charged). There is an extra slot at the back of the docking station for the spare battery to be stored and kept on charge.

12. Interpretation of results

12.1 Laboratory Testing

Notify Doctor / Registered Nurse for blood glucose results less than or greater than ordered parameters

12.2 Checking of results

A venous sample must be sent to the laboratory in the following situations:

- Where the user suspects a problem may exist with the meter or the result.
- When the meter shows an error message that cannot be resolved
- When the result does not fit with the patient’s clinical condition
- Any situation where capillary glucose testing is contra-indicated (see below)
- When making the diagnosis of diabetes mellitus.
- When the meter result is un-recordable i.e. HI/LO

12.3 MDA Safety Notice Contra-indications

- Training and advice to the users 19965 indicated that capillary testing should NOT be performed in certain situations (venous or arterial samples may be used)

12.4 Examples of contra-indications include

- Peripheral circulatory failure due to severe dehydration, hyperglycaemic-hyperosmolar state with or without ketosis, shock, hypotension, peripheral vascular disease or cardiac arrest
- Severe dehydration due to severe diarrhoea and vomiting, inability to recognise and respond to thirst sensations or sustained uncontrolled diabetes
- High concentrations of reducing substances such as increased uric acid in pre-eclampsia, intravenous infusion of ascorbic acid and Paracetamol Overdose

- Refer to the NOVA Support Manual for more information

13. Limitations

13.1 Please see Appendix 1 and 2 for the limiting concentrations.

13.2 At normal blood glucose levels the test strip results are not significantly affected by haematocrit levels in the range of 0% to 70%.

13.3 In situations of decreased blood flow, finger prick blood testing may not be appropriate, since it may not reflect the true physiological state (See contra-indications above).

13.4 Only one pack of test strips must be opened and in use at any time.

13.5 Manufacturer's guidelines and Trust Point of Care Working Group policy must be followed at all times. The Trust's POCT team can withdraw a meter from any site:

- If the device is not being maintained or used in accordance with these guidelines.
- If three consecutive external quality assurance results are not performed.
- If three consecutive external quality assurance results show poor performance.
- If any external quality assurance result returned as unacceptable performance

14. Low Glucose /Ketones Results

14.1 The manufacturer advises caution when using the NOVA blood glucose monitoring system, with respect to the interpretation of blood glucose results less than 2.5 mmol/L. This caution applies to all types of patient samples (including neonate samples).

14.2 For paediatric/adult blood glucose results reported as less than 2.5 mmol/L an appropriate (i.e. laboratory) reference method should be used to measure blood glucose levels in affected patients. Initiation (or adjustment) of treatment should be based upon the laboratory test result

14.3 For neonatal blood glucose results reported as less than 1.9 mmol/L an appropriate (i.e. laboratory) reference method should be used to measure blood glucose levels in affected adult patients. Initiation (or adjustment) of treatment should be based upon the laboratory test result

14.4 A **LO** error code will be displayed if the result is below 0.6 mmol/L for glucose or 0.1 mmol/L for ketones and if a repeat test result is still **LO**, a venous specimen must be sent immediately to the laboratory for glucose.

15. High Glucose/Ketones Results

15.1 Glucose levels above 13.9 mmol/L may indicate a potentially serious medical condition.

15.2 If a test result is above 33.3 mmol/L for glucose or 7 mmol/L for ketones, a **HI** error code will be displayed and if a repeat test result is still **HI**; specimen should be taken immediately to the laboratory for glucose analysis.

16. Equipment/Consumables

16.1 Broken / inactive meters

- Meters that fail to perform properly or have failed QC cannot be used for patient testing
- Meters removed from service must be returned to the POCT team for evaluation and replacement

16.2 Obtaining equipment/consumables

POCT team will supply:

- NOVA Stat Strip controls 1 and 3 (low, high)
- Work stations
- Replacement meters
- Docking stations

Pharmacy will supply:

- NOVA Stat Strip test strips Glucose and Ketone
- UNILET 3 comfort lancets (lilac or blue)

17. Incident Reporting

- An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users including patients or other persons.
- Whenever the policy is not complied with, Datix web incident form must be completed.

18. Audit

The evidence that this Policy has been followed will be:

- Assessed through two main audits performed twice a year by the company (NOVA) and POCT coordinator (Biochemistry)
- Audits will also include review of any risk events that had occurred internally during audited period (i.e. DATIX /complains)
- Audit Findings will be fed back to POCT coordinator, diabetic nurse, lead nurse via e-mail
- Reports are also issued to Clinical Areas to provide positive and negative feedback

19. Communication & Implementation

- Corporate services will ensure that the document is uploaded to the intranet and website and notified in Focus
- POCT coordinator will ensure that all key staff are notified via e-mail about new version of this document

20. References

Blood Glucose Measurements: Reliability of results produced in extra- laboratory areas. HN (Hazard) (89) 31. DHSS

Blood glucose monitoring guidelines. Consensus document. TREND 2017.

Guidelines on the use of Blood Glucose Monitoring Equipment by nurses in clinical areas. RCN Diabetes Nursing Forum. RCN, Nov 1991

Blood Glucose Monitoring Guidelines Consensus [Version 1.0] 11/07/2014

ISO 15197:2013(en): In vivo diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. International Organization for Standardization, Geneva

ISO 22870: 2016 (en): Point-of-care testing (POCT) Requirements for quality and competence

NICE (2016) Type 1 diabetes in adults. National clinical guidelines for diagnosis and management. NICE guideline [NG17] Available at https://www.nice.org.uk/guidance/ng17

NICE (2015) Type 2 diabetes in adults: National clinical guideline for diagnosis and management. Nice guideline [CG87] Available at https://www.nice.org.uk/guidance/CG87

NICE (2008) Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the post-natal period CG63. Available at https://www.nice.org.uk/guidance/cg63

In Vitro Diagnostic (IVD) Devices. Use, safety, management. Medical Devices Agency Device (MHRA) (2005)

MHRA Management and Use of IVD Point of Care Test Devices. Medicines and Healthcare Products Regulatory Agency, UK, 2013

Extra-laboratory use of blood glucose meters and test strips: Contraindications, training and advice to the users. Medical Devices Agency Adverse Incident Centre. Safety Notice MDA SN 9616 June 1996

Nova Operator's Guide – StatStrip CD and package inserts (test strips and quality control material)
Nova Safety Data sheets

Point of care Testing Committee guidelines

Trusts Sharps Disposal Policy.

Trusts Control of Infection Policy.

Trusts Standards for Documentation.

MDA/2011/044 May 2011: Risk of consecutive error codes.

Appendix1

Glucose Interferences:

The StatStrip Glucose and ß-Ketone Hospital Meter exhibits **no** interference for Glucose from the following substances up to the following concentration levels:

Tested Substances Concentration Level

Acetaminophen	10.0 mg/dL	0.66 mmol/L
Ascorbic Acid	10.0 mg/dL	0.57 mmol/L
Bilirubin	15.0 mg/dL	0.26 mmol/L
Cholesterol	500.0 mg/dL	12.9 mmol/L
Creatinine	6.0 mg/dL	0.53 mmol/L
Dopamine	10.0 mg/dL	0.53 mmol/L
Ephedrine	0.9 mg/dL	0.055 mmol/L
D(+) Galactose	350.0 mg/dL	19.4 mmol/L
Hematocrit (RBC)	20% - 65%	20% - 65%
Ibuprofen	48 mg/dL	2.33 mmol/L
L-Dopa	100.0 mg/dL	5. 07 mmol/L
D(+) Maltose Monohydrate	240.0 mg/dL	6.66 mmol/L
D(+) Maltotetraose	240.0 mg/dL	3.6 mmol/L
D(+) Maltotetriose	240.0 mg/dL	4.76 mmol/L
Methyl-Dopa	1.0 mg/dL	0.042 mmol/L
Oxygen	All concentrations	
Salicylate	30.0 mg/dL	1.87 mmol/L
Tetracycline	30.0 mg/dL	0.62 mmol/L
Tolazamide	15.0 mg/dL	0.48 mmol/L
Tolbutamide	45.0 mg/dL	1.67 mmol/L
Triglycerides	750.0 mg/dL	8.78 mmol/L
Uric Acid	20.0 mg/dL	1.05 mmol/L

Appendix 2

Ketone Interferences:
The StatStrip Glucose and ß-Ketone Hospital Meter exhibits no interference for ß-Ketone from the following substances up to the following concentration levels:

Acetaminophen	20.0 mg/dL	1.32 mmol/L
Aceton	10 mg/dL	1.72 mmol/L
Acetoacetate	10 mg/dL	0.93 mmol/L
Ascorbic Acid	20.0 mg/dL	1.14 mmol/L
Bilirubin	10.0 mg/dL	0.18 mmol/L
Captopril	10 mg/dL	0.46 mmol/L
Cholesterol	500.0 mg/dL	12.9 mmol/L
Creatinine	6.0 mg/dL	0.53 mmol/L
Dopamine	2.0 mg/dL	0.53 mmol/L
Ephedrine	0.9 mg/dL	0.035 mmol/L
Glucose	900 mg/dL	50.0 mmol/L
Ibuprofen	48 mg/dL	2.33 mmol/L
L-Dopa	100.0 mg/dL	0.51 mmol/L
Methyl-Dopa	1 mg/dL	0.42 mmol/L
N-Acetyl-L-Cysteine	10 mg/dL	0.61 mmol/L
Salicylate	30.0 mg/dL	1.87 mmol/L
Tetracycline	30.0 mg/dL	0.62 mmol/L
Tolazamide	15.0 mg/dL	0.48 mmol/L
Tolbutamide	45.0 mg/dL	1.67 mmol/L
Triglycerides	750.0 mg/dL	8.47 mmol/L
Uric Acid	20.0 mg/dL	1.05 mmol/L