Use of the Nova Statstrip Blood Glucose Meter Clinical Guideline

V3.1

July 2020
1. **Aim/Purpose of this Guideline**

1.1. To ensure that blood glucose and ketone results produced by the Nova Statstrip system are safe and reliable.

1.2. This version supersedes any previous versions of this document.

**Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We cannot rely on opt out, it must be opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the [Information Use Framework Policy](mailto:rch-tr.infogov@nhs.net) or contact the Information Governance Team rch-tr.infogov@nhs.net

2. **The Guidance**

2.1. **Intended Use**

2.1.1. The Nova StatStrip System is intended for *in vitro* diagnostic use by health care professionals for the quantitative measurement of glucose and ketone in fresh capillary, venous, arterial, whole blood samples.

2.1.2. Nova StatStrip system is specifically indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control. It is not for diagnosis of or screening for diabetes.

2.1.3. The Meter is calibrated to provide plasma equivalent results to laboratory methods.

2.1.4. Re: Patient own home blood glucose and ketone monitors - only results obtained from the Nova Stat Strip meter system are validated to modify treatment in any way.

2.2. **Personnel and Training Requirements**

In accordance with the RCN nursing Forum Guideline (1993) and the Trust’s Point of Care Testing Committee’s guidelines, no member of staff should use the blood glucose monitoring system without complete training and certification, which needs updating on a regular basis.
2.2.1. **Training Option 1: Nova 1 Hour Induction Classroom Session**

2.2.1.1. These sessions are primarily aimed at new users, but you can attend for an update if required.

2.2.1.2. Staff are welcome to drop-in - however spaces are limited to 20 per session so to guarantee a place, please book via the ESR or via Learning and Development.

2.2.2. **Training Option 2: Online Training**

2.2.2.1. This training is aimed at both new users and update training. The link is available via the Intranet - Resources A-Z - 'D' - 'Diabetes blood glucose meter e-learning'
http://www.brainshark.com/novabio/royalcornwallnew

2.2.2.2. If you are new to the system then you will need to have the barcode on the front of your ID badge activated. Please email h.hobba@nhs.net if there are any problems.

2.2.2.3. New users trained via e-learning are required to run both levels of quality control material as a test of practical competency, before their barcode is activated for 2 years.

2.2.3 Please be aware that staff require update training every 2 years for this medical device.

2.2.4 If your barcode is not working, it is likely you are due a training update. Please complete the online update, details above, or contact Clinical Chemistry on ext 2556 or 2837 for advice.

2.2.5 Agency Staff are permitted to use this system once online training and the practical competency has been successfully completed. Clinical Chemistry will issue each operator with a unique barcode in order to log onto the meters.

2.3 **Equipment**

2.3.1 Nova Statstrip glucose or glucose and ketone meter

2.3.2 Nova Statstrip docking station

2.3.3 Nova workstation containing Owen Mumford Unistix lancets, gauze, Statstrip glucose test strips, Statstrip ketone test strips (if applicable), glucose control solution level 1 (low) and glucose control solution level 3 (high)

2.4 **Storage and Stability**

2.4.1 The workstation and contents should be stored between 15°C and 40°C and away from moisture.
2.4.2 The glucose test strips are stable for 6 months after opening. Please date new test strip pots with the date of opening and date of expiry.

2.4.3 The ketone test strips are stable for 3 months after opening. Please date new test strip pots with the date of opening and date of expiry.

2.4.4 The quality control solutions are stable for 3 months after opening. Clinical Chemistry will distribute new bottles every three months. Please date new QC bottles with the date of opening and the date of expiry. The same QC is used for glucose and ketone.

2.5 Cleaning

2.5.1 After each use clean and disinfect the meter using a sani-cloth disinfectant wipe (yellow top), blot with a dry paper towel and then follow with a water dampened cloth to remove any residue of cleaning solution.

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

2.6 Running a Patient Sample

2.6.1 Remove meter from docking station.

2.6.2 Press “Login”. Press “Scan” whilst pointing bar code reader at your barcode password.

2.6.3 From the Patient Test screen press “Accept”.

2.6.4 From the “Enter Strip Lot” screen, scan the strip lot number from the side of the strip container. Press “Accept”.

2.6.5 Scan the barcode on the patient’s wristband.

- If the patient does not have a wristband or a barcoded sticker in their notes, then please manually enter the Hospital (CR) Number.

- If the patient is ‘unknown’ and does not have a valid hospital identifier - scan the barcode in the emergency generic ID barcode located on the inside of the workstation lid. Please note that this is only for use in NNU, Wheal Fortune, Delivery Suite, Emergency Department (Treliske) and Urgent Care Clinical (WCH).

- **For all other areas, in the event of needing an urgent glucose in the absence of a valid hospital number** patients can either be conveyed to Emergency Department where the emergency generic ID code is operational, or/and an urgent venous blood glucose sample will need to be obtained via the laboratory.
2.6.6 Collecting the Sample

For Children younger than one year
Please refer to the Trust’s Clinical Guidelines for heel prick sampling in neonates and children

For Children >1yr and Adults:
Please note that this is NOT an alternative site testing meter.

2.6.6.1 Collect capillary blood from the side of the fingertips. Avoid using the pad and fingertip as there is a higher concentration of nerve endings in these areas. Thumb and index finger should be avoided for the puncture.

2.6.6.2 The patient’s hands should be washed with warm soapy water or water and a damp gauze. Alcohol wipes / gel should not be used.

- Twist the sterility cap from the single-use disposable lancet, remove and dispose.
- Hold the device between index finger, middle finger and thumb.
- Press device firmly against chosen puncture site
- Using your thumb, press down trigger completely
- Remove device from puncture site and dispose in sharps bin as per Trust sharps policy
- Wipe the first drop of blood with a tissue as this sample contains a higher proportion of tissue fluid that could give a false reading.

2.6.7 Insert test strip – please ensure you are using the correct strips before proceeding. Strips are colour-coded – Blue = Glucose / Green = Ketone. The meter will automatically know which test is running, there is no possibility of getting a glucose result from a ketone strip and vice versa.

2.6.8 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.

2.6.9 Wipe puncture site with a dry clean material such as gauze. If it continues bleeding, gently press the gauze onto puncture site.

2.6.10 Test result will appear in 6 seconds. Do not remove the test strip while the countdown is in process. To accept the result press ‘accept’. To reject the result press ‘reject’.

2.6.11 For results outside of certain limits, the meter will prompt you to add a comment. Press the “Comment” key, then add your comment before accepting or rejecting the result.
2.6.12 Screen Alerts:


2.6.13 The result must be entered in the patient’s notes, and the appropriate action taken, if any.

2.6.14 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.

**All data is recorded and regularly audited so please do not allow any other member of staff to log on using your personal barcode.**

**2.7. Internal Quality Control (Qc) Testing**

2.7.1. QC needs to be daily for areas that are not using every day it would be daily (within 24 hours) prior to use.

2.7.2. The Department of Health issued a Hazard Notice in 1987 (repeated in 1996) that highlighted the need for formal staff training and a strict quality control programme.

2.7.3. As with all systems it is important to check the quality of your results, ensuring that errors are detected and rectified at the time of testing. Therefore quality control testing must be performed daily, to assess user technique and accuracy of the strips and the meter.

2.7.4. Quality Control Procedure: Always keep the meter flat whilst applying samples and during testing

- 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.
- Scan the QC lot no. Press “Accept”
- Insert glucose or ketone test strip
- Gently mix the QC bottle before sampling and discard the first drop from the bottle. 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.

2.7.4.1. Result will be displayed in 6 seconds, 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 of strips and control solution. If either or both are 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 Clinical Chemistry for advice or a replacement meter.

2.8. **External Quality Assurance (Eqa) Testing**

2.8.1. 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.

2.8.2. These samples are distributed quarterly by Clinical Chemistry. The samples have unknown values and are to be tested as soon as possible and then discarded.

2.9. **Limitations and Important Information**

2.9.1. Results obtained using the meter should not be used for diagnosis of diabetes.

2.9.2. Any sample giving a meter glucose result below 2.8 mmol / L or above 25 mmol / L and any unexpected result not in keeping with the clinical picture or a sample which gives more than one error message MUST be confirmed by sending an urgent venous blood sample to Clinical Chemistry.

2.9.3. It is an essential requirement that all users are properly trained to use the blood glucose monitoring equipment.

2.9.4. **Blood glucose action limits for non-qualified staff**: Any result less than 4 mmol / L or greater than 15 mmol / L at any one time should be reported to a trained member of the nursing or medical staff.

2.9.5. Only one pot of test strips must be opened and in use at any time.

2.9.6. If blood is drawn from a venous or arterial line ensure that the line is flushed before drawing off the sample.

2.9.7. Do not use alcohol swabs to clean the patient’s skin before testing as alcohol can affect the test result.

2.9.8. Avoid using the thumb or index finger as the site of testing because these are the most frequently used digits.

2.9.9. Prick the side of the finger rather than the pad, as it contains fewer nerve endings so it is less painful for the patient.

2.9.10. Avoid squeezing the finger when trying to obtain a drop of blood for testing, if squeezed too hard the capillaries contract preventing
blood flow and tissue fluid will affect the glucose result obtained.

2.9.11. Do not use objects with sharp or abrasive ends when using the meter touch screen as this may cause damage.

2.9.12. Don’t hold the meter upside down when in as blood will track down the strip and contaminate the inside of the meter.

2.9.13. Manufacturer’s guidelines and Trust Point of Care Working Group policy must be followed at all times. The Trust’s point-of-care testing committee can withdraw a meter from any site if:

2.9.13.1. The device is not being maintained or used in accordance with these guidelines.

2.9.13.2. If three consecutive external quality assurance results show poor performance.

2.9.13.3. If any external quality assurance result returned as unacceptable performance

2.9.13.4. If three consecutive external quality assurance results are not performed.

2.10. Self-Monitoring By In-Patients

2.10.1. Patients with diabetes admitted to hospital may be accustomed to monitoring their own blood glucose levels using one of a number of different systems. The reliability of patient’s own Glucose meters cannot be guaranteed whilst in hospital. Therefore, as an in- patient, only results obtained from the Nova Stat Strip meter system must be used to form the patient’s blood glucose ward records and modify treatment in any way.

2.10.2. Patients may wish to continue to use their own meters to keep their own record of their blood glucose whilst in hospital, but this must not replace ward based monitoring using the stat strip meter system.

2.11. Contra-Indications and Interfering Substances

Very Important to note: Where peripheral blood flow is decreased, in cases of severe dehydration, hypotension, shock, peripheral vascular disease and hyperglycaemic-hyperosmolar state (DKA and HONK) with or without ketoacidosis, capillary samples (finger prick samples) and glucose meters are not to be used. Venous samples must be sent to the laboratory for glucose analysis in these circumstances. Please see hospital guideline for treatment and management of DKA

2.12. Health And Safety: Coshh

2.12.1. Biological Hazard: This method involves the handling of biological fluids, which must always be treated as potentially
hazardous, and handled in accordance with the Trust’s Personal Protective Equipment Policy, i.e. wear gloves and eye protection.

2.12.2. Test Strip:
- Glucose/Ketone Enzyme - No Risk
- Non-reactive ingredients - No Risk

2.12.3. Glucose/Ketone Control Solutions
- Glucose / Ketone - Low Risk
- Non-reactive ingredients - Low Risk

2.12.4. Mechanical Hazard: Handle blood-sampling sharps in accordance with Trust policy.

2.12.5. Electrical Hazard: The battery used in this meter may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate

2.13. Supplies And Contact Information

Clinical Chemistry:

Helen Hobba 01872 25 2556 / H.hobba@nhs.net
Kate Tregunna 01872 25 2837 / Katharine.tregunna@nhs.net
- Batteries
- QC material
- Meter Exchange
- Troubleshooting
- Feedback on Meter performance
- Advice on training
- Password Issues

Pharmacy: 01872 25 2588
- Test Strips
- Lancets

Diabetes Specialist Nurses
RCH Truro Site: Amanda Veall & Amanda Davis
01872 253104 WCH / SMH – DSN contact #4151

Point of Care Testing (POCT) Committee Chair
Dr Anthea Patterson 01872 25 2546
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Analytical performance and user competency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Analytical aspects led by the Chair of the Point of Care Testing Committee. Learning and Development lead on the training needs. The Medical Director provides the lead for clinical aspects of glucose monitoring.</td>
</tr>
<tr>
<td>Tool</td>
<td>All meters have 2 levels of quality control analysed every 24 hours which checks the test strip, meter and user competence. Quarterly quality assurance samples allow us to compare individual meters nationwide</td>
</tr>
<tr>
<td>Frequency</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Blood glucose and ketone issues are reported to the Point of Care Testing committee and actions are recorded in the minutes.</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Any necessary remedial action will be taken in conjunction with the key stakeholders, diabetes nurse specialists, the medical director and ward managers</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Some immediate remedial action can be undertaken by Clinical Chemistry via Bioconnect and Novanet. Changes can be disseminated to staff working in clinical areas directly via Lab staff and DSNs. Training updates can be used to deliver less urgent changes in practice.</td>
</tr>
</tbody>
</table>

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment
The Initial Equality Impact Assessment Screening Form is at Appendix 2.
### Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Use of the Nova Statstrip Blood Glucose Meter Clinical Guideline V3.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Clinical Guideline for the use of the Nova Statstrip glucose/ketone meter V2.0</td>
</tr>
<tr>
<td>Date Issued/Approved:</td>
<td>17th June 2020</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>July 2020</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>2nd May 2022</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Helen Hobba, Senior Biomedical Scientist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 25 2556 <a href="mailto:h.hobba@nhs.net">h.hobba@nhs.net</a></td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Detailed instructions on the use of the Nova Stat strip glucose meter</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>POCT, glucose meter, ketone meter, Nova, statstrip, point of care testing</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Approval route for consultation and ratification:</td>
<td>Pathology point of care testing (POCT) group</td>
</tr>
<tr>
<td>General Manager confirming approval processes</td>
<td>Richard Andrzejuk</td>
</tr>
<tr>
<td>Name of Governance Lead confirming approval by specialty and care group management meetings</td>
<td>Kevin Wright</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td>CoSHH 2002</td>
</tr>
</tbody>
</table>

**Related Documents:**

2. Nova package inserts (test strips and quality control material)
3. Nova Safety Data sheets
4. Point of Care Testing Policy
5. CoSHH 2002
6. Standard Infection Prevention And Control Precautions Policy
7. Sharps Safety Policy
8. Infection Prevention and Control Roles and Responsibilities Policy
9. Trusts Standards for Documentation
<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2013</td>
<td>V1</td>
<td>Initial Issue</td>
<td>Helen Hobba, Senior Biomedical Scientist</td>
</tr>
<tr>
<td>Nov 2016</td>
<td>V2</td>
<td>Update contact information</td>
<td>Helen Hobba, Senior Biomedical Scientist</td>
</tr>
<tr>
<td>Feb 2019</td>
<td>V3</td>
<td>Additional ketone information</td>
<td>Helen Hobba, Senior Biomedical Scientist</td>
</tr>
<tr>
<td>June 2020</td>
<td>V3.1</td>
<td>Additional information in section 2.11, alignment of paragraph at section 2.12 and transposed to latest Trust template</td>
<td>Helen Hobba, Senior Biomedical Scientist</td>
</tr>
</tbody>
</table>

**Version Control Table**

**All or part of this document can be released under the Freedom of Information Act 2000**

This document is to be retained for 10 years from the date of expiry. This document is only valid on the day of printing

**Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
## Appendix 2. Equality Impact Assessment

### Section 1: Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Use of the Nova Statstrip Blood Glucose Meter Clinical Guideline V3.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area:</td>
<td></td>
</tr>
<tr>
<td>Pathology</td>
<td>Is this a new or existing Policy?</td>
</tr>
<tr>
<td></td>
<td>Existing</td>
</tr>
<tr>
<td>Name of individual/group completing EIA</td>
<td>Contact details: Helen Hobba, Senior Biomedical Scientist</td>
</tr>
<tr>
<td></td>
<td>01872 25 2556</td>
</tr>
</tbody>
</table>

1. **Policy Aim**
   - Who is the strategy / policy / proposal / service function aimed at?
   - Safe use of the Nova Stat Strip Blood Glucose and Ketone Meter

2. **Policy Objectives**
   - Provide detailed instruction on the use of the Nova Stat strip glucose and ketone meter

3. **Policy Intended Outcomes**
   - Safe use of the Nova Stat Strip Blood Glucose and Ketone Meter

4. **How will you measure the outcome?**
   - Company Audits
   - Feedback from training sessions
   - Diabetic Nurse Specialist feedback

5. **Who is intended to benefit from the policy?**
   - Patients having Blood Glucose and Ketone monitoring in RCHT

6a). **Who did you consult with?**

b). Please list any groups who have been consulted about this procedure.
   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other
   - X

Please record specific names of groups:
   - Anthea Patterson, Chair Trust POCT Committee

c). **What was the outcome of the consultation?**
   - Agreed
7. The Impact
Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy could have a positive/negative impact on:

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female non-binary, asexual etc.)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender reassignment</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/ethnic communities /groups</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Religion/other beliefs</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marriage and civil partnership</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual orientation (bisexual, gay, heterosexual, lesbian)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If all characteristics are ticked ‘no’, and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

| Name of person confirming result of initial impact assessment: | Helen Hobba, Senior Biomedical Scientist |

If you have ticked ‘yes’ to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here: Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net