# POCT – Nova StatStrip® Meter (Glucose & Ketone)

**Contents** **Page No**

# 1 INTRODUCTION

## 1.1 PURPOSE

The Nova StatStrip® Glucose and ß-Ketone Hospital Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose or ß-ketone electrochemical test strips to measure glucose or ß-ketone. Samples include whole blood patient samples, Quality Control (QC) solutions or proficiency (EQA) solutions.

In addition to measuring glucose and ketone, the meter stores information on:

- Patient hospital number
- Test date & time
- Test result
- QC test data
- Operator (user)
- Reagent (strip) lot number

A user interface provides for a self-prompting environment via a colour LCD. The Docking Station recharges the batteries of the meter and connects to the Trust network.

The Nova StatStrip® Glucose and ß-Ketone Hospital Meter System is intended for use by **health care professionals** for Point-Of-Care usage for the quantitative measurement of glucose in fresh capillary, venous, arterial, and neonate whole blood and ß-Ketone in fresh capillary and venous whole blood samples.

The Nova StatStrip® Glucose and ß-Ketone Meter 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 used for diagnosis of or screening for diabetes.**

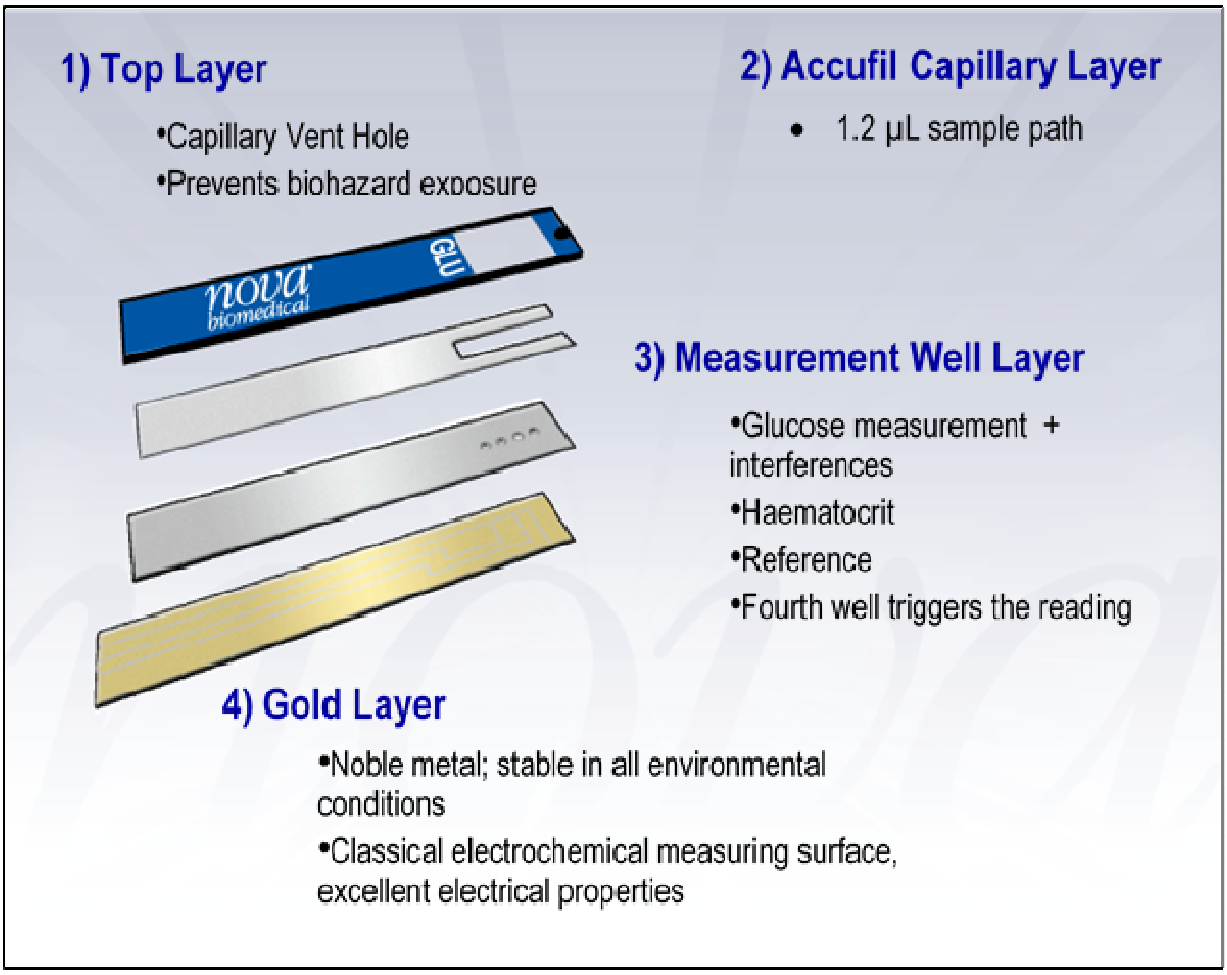
This Standard Operating Procedure (SOP) provides guidance on the operation of the Nova Biomedical StatStrip® blood glucose/ketone meter and is relevant to all locations throughout Salisbury NHS Foundation Trust.
The meter offers advanced security and connectivity features to improve patient safety, user interaction and to permit transfer of results to the electronic patient record (EPR) within the Trust IT system.

## 1.2 PRINCIPLE

The SOP provides instructions for the routine operation and maintenance of the StatStrip® glucose and ß-ketone hospital meter to permit the measurement of blood glucose and ketone at the point of care. Due to its unique test strip technology the meter is not affected by substances such as haematocrit, bilirubin, paracetamol and lactate, which are known to interfere with other commercially available meters. The strip has four layers that have been designed to generate a result that is equivalent of a laboratory measurement (Figure 1).

The four wells within the third layer of the test strip accurately measure glucose/ketone (depending on the test strip) within the sample and correct the measurement in the presence of interfering substances and haematocrit.

*Figure 1: The StatStrip® composition*




## Glucose

The StatStrip® blood glucose test is based on the measurement of electrical current caused by a reaction of glucose with the reagents at the electrodes contained within the strip. The technology employed is a modified glucose oxidase method and is based on the following:

| |
|---|
| **Equation 1**<br>Glucose + Enzymes (oxidised form) → Gluconic Acid + Enzymes (reduced form) |
| **Equation 2**<br>Enzymes (reduced form) + Ferricyanide → Enzyme (oxidised form) + Ferrocyanide |
| **Equation 3**<br>Ferrocyanide $\xrightarrow[\text{Electrode}]{-e^-}$ Ferricyanide |

The current generated at the electrode is proportional to the glucose concentration of the sample.

### ß-Ketone

The ß-ketone measurement is based on the following methodology:

| |
|---|
| **Equation 4**<br>ß-3-hydroxybutyrate + NAD $\xrightarrow{\text{Enzyme}}$ Acetoacetate + NADH + H+ |
| **Equation 5**<br>Mediator***** (ox) + NADH ⟶ Mediator (red) + NAD |
| **Equation 6**<br>Mediator (red) $\xrightarrow[\text{Electrode}]{\text{-e-}}$ Mediator (ox) |

***Mediator = Meldola's Blue > 0.42mg***

The current generated at the electrode is proportional to the ß-ketone concentration of the sample.

## 1.3 RESPONSIBILITY

Only staff that have received formal training are authorised to use the Nova Biomedical StatStrip® glucose/ketone meters. Training is delivered by a Nova Biomedical clinical trainer, a member of the POCT team or by a diabetes link nurse trainer.
A record of authorised users will be held in an appropriate data management system and maintained by the POCT team. Scanned copies of training competency forms are also held by the POCT team.

Operator barcodes for meter use are issued by the POCT team on receipt of a signed competency form. The barcodes are individual to each user and **must not be shared** - it is against Trust policy. **Staff are responsible for all actions completed using their barcode.**
All staff using the device are responsible for ensuring the meter is ready for use and appropriate quality checks are performed prior to testing patient samples.

## 1.4 REQUESTING INFORMATION

POCT blood glucose and ketone testing is performed on in-patients and those attending as out-patients at Salisbury Foundation Trust. On occasions it may be necessary to perform urgent glucose and ketone testing on others who do not fall into these two categories, such as unwell or collapsed visitor/member of staff. Blood glucose and ketone testing is available on demand.

# 2 SAFETY CONSIDERATIONS

## 2.1 RISK ASSESSMENT

Overall risk level has been assessed as: Low

## 2.2 COSHH ASSESSMENT

Bodily fluid is defined as a medium hazard. Gloves to be worn.



## 2.3 DISPOSAL AND ENVIRONMENTAL ASSESSMENT

Quality Control solutions are assessed as clinical waste and both glucose and ketone test strips are deemed as sharps – dispose of test strips immediately after use in an appropriate sharps container.

# 3 SPECIMEN REQUIREMENTS

**Specimens recommended**
Whole blood from a peripheral puncture without anticoagulant or fresh arterial, venous or capillary whole blood drawn into heparinised syringes or capillaries can be used.

Anticoagulants: sodium, lithium, and ammonium heparin.

Glucose testing: Capillary, venous, arterial and neonate whole blood.
Ketone testing: Capillary, venous and neonate whole blood.

**Specimens not recommended**
Arterial blood should **NOT** be used for ketone testing
Samples containing EDTA or Fluoride as preservatives must not be used.

**Storage and stability**
Capillary or syringe specimens are not stored as the analysis is immediate.

**Sample volume**
Glucose testing requires 1.2µL
Ketone testing requires 0.8µL

Additional information
Syringe samples must be applied to the end of the test strip, do not push the plunger as this can dispel a large volume of blood which will damage the meter.

# 4 EQUIPMENT

## 4.1 NOVA GLU/KET METER

Contact the POCT team if a new or replacement meter is required.


### 4.1.1 Cleaning and Disinfecting the Device

The StatStrip® meter should be cleaned after each patient test, using a Clinell™ wipe. The meters should never be immersed in any cleaning agent. If using a cleaning solution always apply the solution to a soft cloth to wipe the meter surface. Once complete, immediately dry thoroughly.

When cleaning the meter, ensure to follow the guidelines listed below:

- Clinell™ wipes are approved by the Trust for device surface cleaning.
- Dilute Bleach. A 10% solution of household bleach (Sodium Hypochlorite) may be used, if Clinell™ wipes are not available.
- 70% Isopropyl (rubbing) Alcohol may be used, if Clinell™ wipes are not available.
- Avoid harsh solvents such as benzene and strong acids.

***CAUTION:***

- ***DO NOT*** *immerse the meter or hold the meter under running water.*
- ***DO NOT*** *spray the meter with a disinfectant solution.*

## 4.2 NOVA DOCKING STATION

Contact the POCT team if a new or replacement docking station is required.

The meter should be docked when not in use to enable the in-use battery to remain fully charged and to update patient and operator details.

The meter is powered by a rechargeable 3.7v Lithium (Li) Polymer battery which should be sufficient for up to 8 hours use. The docking station has space to charge a spare battery.

The lights on the front of the docking station indicate the charge and connectivity status of the meter.


- The left light is green if the meter is connected to the network
- The middle light flashes green if the data is transferring
- The right light is green if the battery is fully charged or amber when re-charging

The spare battery slot at the back of the docking station also has a light to indicate the status of the spare battery. The light is green when fully charged and amber when charging.

## 4.3 BATTERY REPLACEMENT

Replacement batteries are available from the POCT team.

When the in-use battery of the meter is low on charge a message is displayed on the screen (see below). The battery can be replaced with the charged spare battery or the meter can be docked to recharge if not in use.

If a spare fully charged battery is available, it can be changed to allow for continuous operation…

1. Pull back on the cover latch to release the cover. Take the battery back off the meter

2. Remove the drained battery

3. Replace with a fully charged battery

4. Replace the battery cover.
5. Dock the meter.
6. Place the drained battery in the docking station to charge

# 5 REAGENTS

## 5.1 REAGENTS

### 5.1.1 Nova StatStrip® GLU Test strips

Test strips are available from Pharmacy.

**Storage and handling**

- Store at temperatures between 15 and 30 ºC (i.e. room temperature)
- Store away from direct sunlight
- Keep the vial tightly closed when not in use
- Test strips should only be stored in original vial
- Test strips are viable for **6 months** from date of opening.
- Vials must be labelled with the date of opening
- Do **NOT** use tests strips after the 6-month expiry date or after the manufacturer expiry date
- Do **NOT** refrigerate or freeze the test strips
- Do **NOT** use test strips manufactured by companies other than Nova Biomedical

### 5.1.2 Nova StatStrip® KET Test strips


Test strips are available from Pharmacy.

**Storage and handling**

- Store at temperatures between 15 and 30ºC (i.e. room temperature)
- Store away from direct sunlight
- Keep the vial tightly closed when not in use
- Test strips should only be stored in original vial
- Test strips are viable for **3 months** from date of opening. Vials must be labelled with the date of opening and the date of disposal
- Do **NOT** use tests strips after the 3-month expiry date or after the manufacturer expiry date
- Do **NOT** refrigerate or freeze the test strips
- Do **NOT** use test strips manufactured by companies other than Nova Biomedical

## 5.2 REAGENT PREPARATION

All reagents require no preparation. Test strips, QC solutions and External Quality Assurance (EQA) samples are supplied ready for use.

# 6 PROCEDURE

## 6.1 CALIBRATION INCLUDING TRACEABILITY

Calibration is not required. The meter is calibrated to provide plasma equivalent results to laboratory methods.

## 6.2 PROCEDURE

All POCT devices have limitations. Prior to patient testing, both levels of internal QC must have been processed and results within the acceptable ranges before proceeding with the patient test. If this is not the case, the device will 'lock out' and you will be prompted to run QC before proceeding with any patient testing.

### 6.2.1 Patient Testing

a) Remove the meter from the docking station
b) Follow the appropriate steps for sample collection
c) **Welcome:** Touch 'Login' soft key at the bottom middle of the screen
d) **Enter Operator ID:** Touch 'Scan' soft key and swipe the barcode reader at the top of the meter, over your operator barcode.
e) If the meter is locked perform QC levels 1 and 3 before proceeding with patient test.
f) **Patient Test:** Touch the green 'Accept' soft key. Or insert a glucose or ß-ketone test strip: the meter will adjust to the appropriate test.
g) NOTE: The header will turn from Grey to **Blue** for **Glucose** or **Green** for **ß-Ketone** after you insert the Test Strip.
h) **Enter Strip Lot:** Touch 'Scan' soft key and scan barcode on the side of the test strip container.
i) **Enter Patient ID:** Touch 'Scan' soft key and scan barcode on the patient wrist band. Then touch 'Accept'. Alternatively, type the correct patient hospital number (seven digits) using the on-screen keys, then touch 'Accept'.
j) **Confirm Patient ID:** If the patient ID is matched with the patient details on the meter a name and DOB are displayed. Press 'Accept' soft key to confirm that you have positively identified the patient.
k) If the details displayed do not match the patient you are testing, touch the 'Back' soft key to enter the correct patient ID using the keyboard feature.
l) If the correct patient details are not stored in the meter the Invalid Patient ID screen is displayed. Touch the grey 'New Patient Override' button on screen.
m) If a strip has not been inserted, the Insert Test Strip screen is displayed. Insert a test strip into the strip port at the bottom left of the meter.
n) **Apply Sample:** With the meter above the puncture site bring the tip of the test strip down vertically. Touch the end of the test strip to the blood drop until the

well of the test strip is full and the meter beeps.

o) **Testing Sample:** Countdown starts automatically until a result is displayed. **Six seconds for glucose** and **ten seconds for ketone**.

p) Remove the test strip manually or use the ejector button on the back of the meter to eject the strip directly into a sharps bin.

q) Appropriate comments can be added by pressing the 'Comment' soft key, bottom right of the screen. Comments MUST be added for all rejected patient results as indicated in red on the screen.

r) **Add Comment:** Touch the screen to select one of the comments displayed e.g. 'Repeat Test Required'. Or touch Free Text to enter a new comment. Touch 'Accept' soft key to confirm comment selected. All comments are transferred to the data manager.

s) **Patient Result:** 'Accept' or 'Reject' the result with or without a comment touch 'Accept' soft key. The meter will log you out and return to the **Welcome:** screen.

t) Return the meter to the docking station for result transmission and battery charging.

u) Record the result on the relevant documentation. Dispose of the test strip and lancet into a sharps container.

### 6.2.2 Recalling Test Results

The StatStrip® meter can store up to 1000 patient results, when connecting to the network this is limited to results from the last five days.

a) Remove the StatStrip® meter from the docking station.

b) **Welcome:** Touch 'Login' soft key at the bottom middle of the screen

c) **Enter Operator ID:** Touch 'Scan' soft key and swipe the barcode reader at the top of the meter, over your operator barcode.

d) **Patient Test:** Touch 'Review' soft key in bottom left of the screen.

e) All results are listed. The information can be sorted by touching the Patient ID, Date and Time or Type soft keys. Use the next page or previous page options at the bottom of the screen to move up and down the list

f) Touch the screen to highlight record you wish to view.

g) Touch 'Accept' soft key to display full details including patient ID, strip lot, date and time of test as well as the result.

h) **IMPORTANT**: Remember to log out by touching the blue bar at the top of the screen, then touching the grey 'Logout' soft key.

### 6.2.3 Obtaining a Test Sample

a) Explain the procedure to the patient and gain verbal consent for testing.

b) Wash your hands and wear gloves when taking and handling patient samples.

c) Prepare the site. Wash the patient's hand/finger with soap and warm water and dry thoroughly. Alcohol wipes can be used but the site must be dried well after use.

d) Holding the hand downward, massage finger with thumb towards tip to stimulate blood flow. If the fingers are unsuitable, an ear lobe may be used. The feet should never be used as a site for obtaining a capillary test for non-neonate patients.

Always check the skin integrity before performing a test and rotate sites as repeated lancing of the same area of skin can cause ulceration.

*For neonates and infants – Only use the heel. Puncture on the lateral aspects of the heel and never the sole. Consult the diabetes link nurse and/or a qualified health care professional for advice, regarding appropriate sites and techniques for performing heel punctures.*

e) Use a Trust approved disposable lancet to puncture the outer edge of clean dry finger, either side of the nail not the pad, and avoiding the thumb and forefinger. These areas contain more nerve endings and are therefore more uncomfortable for the patient.

*For neonates and infants – refer to departmental guidelines for lancet selection and its correct use.*

f) Gently milk the finger until a drop of blood is formed, take care not to squeeze the finger. Wipe away the first drop of blood to eliminate any contamination with extracellular fluid.
g) Gently massage to gain a second drop to be tested. Do not squeeze the end of the finger as this can introduce extracellular fluid into the sample and may produce erroneous results.

## 6.3 CALCULATION OF RESULTS

The meter delivers plasma equivalent results to laboratory methods. Therefore, the meter displays concentrations that refer to plasma although whole blood is always applied to the test strip.

## 6.4 LIMITATIONS OF PROCEDURE

All POCT devices have limitations. Never use a StatStrip® glucose/ketone meter for patient testing when there are interferences, or its use is contraindicated. When contraindications and/or interferences exist, blood glucose must be measured by an alternative method e.g. a venous sample sent to the laboratory or an arterial blood gas analysis.

The POCT meter alone cannot make a diagnosis of diabetes, hypoglycaemia or diabetic ketoacidosis – a confirmatory specimen must be sent to the laboratory. All results need to be interpreted considering the patient's condition.

If peripheral circulation is impaired, collection of capillary blood is not advised as the results may not be a true reflection of the physiological blood glucose/ketone level. Examples of this include shock, severe hypotension, hyperosmolar hyperglycaemia and severe dehydration.

*Increased* glucose results may be due to (e.g.):

- Analytical: Not cleaning test site properly
- Physiological/Pathological: Diabetes, medications (e.g. steroids), infection, eating immediately prior to testing (i.e. non-fasting)

*Decreased* glucose results may be due to (e.g.):

- Analytical: Introduction of extracellular fluid e.g. squeezing the test site to obtain sample
- Physiological/Pathological: Prolonged fasting, medications (e.g. insulin, oral hypoglycaemic agents), illness, prematurity in neonates

## Limitations - Nova StatStrip® GLU Test strips

The StatStrip® Meter should have results that agree with a laboratory result to within 20%. However, there are factors that may cause results to differ by more than 20% in some situations. These factors are:

- Blood source - only use whole blood. Do not use plasma or serum.
- Venous and capillary blood may differ in concentration by as much as 70 mg/dL (3.9 mmol/L), depending on the time of blood collection after food intake.
- Temperature and humidity extremes – strips must be used within an operating relative humidity of 10-90%. Testing outside these ranges may cause inaccurate results.
- Altitude – there is no effect of altitudes up to 15,000 feet above sea level.
- Venous specimens – Fluoride or EDTA should not be used as preservatives for venous specimens.

## Limitations - Nova StatStrip® KET Test strips

The ketone test strips give accurate results if the following limitations are observed:

- Blood source – use fresh capillary or venous whole blood. Do not use serum or plasma.
- The strips should not be used to diagnose Diabetic KetoAcidosis.
- Each test strip is single use.
  Altitude – there is no effect of altitudes up to 15,000 feet above sea level.
- Temperature and humidity extremes – strips must be used within an operating relative humidity of 10-90%. Testing outside these ranges may cause inaccurate results.
- The acceptable Hematocrit range for testing is 20-65%.

### 6.4.1 Analytical (dynamic) Range and Dilution

The measuring range on the StatStrip® device:

| | |
|---|---|
| Glucose | 0.6 mmol/L to 33.3 mmol/L |
| Ketone | 0.1 mmol/L to 7.0 mmol/L |

Results that are lower than the measuring range will be displayed as **LO**
Results that are higher than the measuring range will be displayed as **HI**

### 6.4.2 Performance Characteristics

N/A

### 6.4.3 Measurement Uncertainty

N/A

### 6.4.4 Interferences

#### 6.4.4.1Glucose Testing Interferences

The StatStrip® Glucose and β-Ketone Meter exhibits NO interference for glucose from the following substances up to the following concentrations:

| Tested Substances | Concentration |
|---|---|
| Acetaminophen (Paracetamol) | 0.66 mmol/L |
| Bilirubin | 0.26 mmol/L |
| Cholesterol | 12.9 mmol/L |
| Creatinine | 0.53 mmol/L |
| Dopamine | 0.53 mmol/L |
| Ephedrine | 0.055 mmol/L |
| D(+) Galactose | 19.4 mmol/L |
| Haematocrit (RBC) | 20% - 65% |
| Ibuprofen | 2.33 mmol/L |
| L-Dopa | 5.07 mmol/L |
| D(+) Maltose Monohydrate | 6.66 mmol/L |
| D(+) Maltotetraose | 3.6 mmol/L |
| D(+) Maltotetriose | 4.76 mmol/L |
| Methyl-Dopa | 0.042 mmol/L |
| Oxygen | All Concentrations |
| Salicylate | 1.87 mmol/L |
| Tetracycline | 0.62 mmol/L |
| Tolazamide | 0.48 mmol/L |
| Tolbutamide | 1.67 mmol/L |
| Triglycerides | 8.78 mmol/L |
| Uric Acid | 1.05 mmol/L |

### 6.4.4.2 Ketone Testing Interferences

The StatStrip® Glucose and β-Ketone Meter exhibits NO interference for β-Ketone from the following substances up to the following concentrations:

| Tested Substances | Concentration |
|---|---|
| Acetaminophen (Paracetamol) | 1.32 mmol/L |
| Acetone | 1.72 mmol/L |
| Acetoacetate | 0.93 mmol/L |
| Ascorbic Acid | 1.14 mmol/L |
| Bilirubin | 0.18 mmol/L |
| Captopril | 0.46 mmol/L |
| Creatinine | 0.53 mmol/L |
| Dopamine | 0.53 mmol/L |
| Ephedrine | 0.035 mmol/L |
| Glucose | 50.0 mmol/L |
| Ibuprofen | 2.33 mmol/L |
| L-Dopa | 0.51 mmol/L |
| Methyl-Dopa | 0.042 mmol/L |
| N-Acetyl-L-Cysteine | 0.61 mmol/L |
| Tetracycline | 0.62 mmol/L |
| Tolazamide | 0.48 mmol/L |
| Tolbutamide | 1.67 mmol/L |
| Triglycerides | 0.88 mmol/L |
| Salicylate | 1.87 mmol/L |
| Uric Acid | 1.05 mmol/L |

## 6.5 INSTRUCTIONS FOR DILUTION

N/A

# 7 QUALITY CONTROL

## 7.1 INTERNAL QUALITY CONTROL MATERIAL

### 7.1.1 Material

Nova StatStrip® Glucose and ß-Ketone Control Level 1 and Level 3



- The control solutions act as a quality control check to verify the accuracy of blood glucose and β-Ketone test results.
- Quality control solutions are available from the POCT team.
- Each level MUST be analysed once within a 24 hour period.
- The meter will not permit patient analysis without completion of successful QC analysis of both levels.
- Meters will display a warning message 2 hours before QC Expiry.
- If QC analysis fails or is not completed, the meter will lock.

Note: **Glucose** QC testing must be performed every day that the meter is in use. **Ketone** QC testing should be performed on the day that a patient or EQA ketone test is required.

QC analysis should also be performed under the following circumstances:

- If a patient test has been repeated and the blood results are still lower or higher than expected
- If there are other indications that the system is not working properly
- Whenever problems (storage, operator and instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

### 7.1.2 Storage and Handling

- Store at temperatures between 15 and 30$^{o}$C (i.e. room temperature)
- Store away from direct sunlight
- Keep the vial tightly closed when not in use
- Control solutions are viable for **3 months** from date of opening.
- Do **NOT** use control solutions after the 3-month expiry date or after the manufacturer expiry date
- Do **NOT** refrigerate or freeze the control solutions
- Do **Not** use control solutions manufactured by companies other than Nova Biomedical

### 7.1.3 QC Testing Procedure

a) Remove the meter from the docking station
b) **Welcome:** Touch 'Login' soft key at the bottom middle of the screen
c) **Enter Operator ID:** Touch 'Scan' soft key and swipe the barcode reader at the top of the meter over your operator barcode.
d) **Patient Test:** Touch 'QC' soft key
e) **Enter Strip Lot:** Touch 'Scan' soft key and scan barcode on the side of the test strip container.
f) **Enter QC Lot:** Touch 'Scan' soft key and scan barcode on the side of the QC solution container
g) **Insert Strip:** Place a test strip into the strip port at the bottom left of the meter.
h) Place the meter onto a flat surface.
i) Gently invert the QC solution to mix. Remove the lid and discard the first drop of solution to avoid contamination.
j) **Apply Sample:** Keep the meter on a flat surface. Gently squeeze the QC bottle to induce a hanging drop. Touch the drop of solution to the end on the test strip. The correct volume of solution will flow into the strip by capillary action.
k) **Testing sample:** The meter will beep to indicate successful aspiration and countdown automatically. A **glucose result is displayed after 6 seconds**. A **ketone result is displayed after 10 seconds**.
l) **QC Result:** If the result is within the acceptable range (printed on the QC bottle) 'PASS' will be displayed, touch 'Accept' soft key.
m) Remove the test strip manually or use the ejector button on the back of the meter to eject the strip directly into a sharps bin. The meter will log you out and return to the Welcome screen.
n) **QC Result:** If the result is not within the acceptable range (printed on the QC bottle) 'FAIL' will be displayed, touch 'Accept' soft key. Remove the test strip and discard into a sharps bin. The meter will log you out and return to the Welcome screen.
o) Check the tests strips and QC solution used are in date and analyse again. Ensure the QC solutions are well mixed, and the correct solution has been applied to the test strip.
p) If the QC test fails after completing checks, contact the POCT team and use an alternative meter
q) Repeat from step (b) for level 3 QC solution.

## 7.2 QC LIMITS AND ACTIONS

Control results must 'pass' before being considered acceptable. Patient testing can only proceed after both control levels have been performed correctly and at the proper testing interval i.e. within the last 24 hours.

If the QC results show as a 'fail' i.e. outside the acceptable range, the procedure below must be followed:

- Repeat with the QC again, ensuring that the handwritten expiry date on the solution bottle has not passed
- Repeat with fresh bottles of QC
- Repeat with a fresh pot of glucose or ketone test strips

## 7.3 EXTERNAL QUALITY ASSURANCE

External Quality Assurance (EQA) samples are distributed monthly by the point of care testing (POCT) team. EQA testing gives independent, objective assurance that the meter is giving accurate results for testing on patient samples and is necessary for continuing quality assurance.

The StatStrip® devices participate in the WEQAS (Welsh External Quality Assurance Scheme) Glucose and Ketone Scheme.

EQA samples assess the continued performance of the meter, test strips and user technique. Any member of staff trained to use the meter can analyse the EQA samples.

It is important that every meter is tested with each sample. **Both glucose and ß-Ketone EQA tests must be performed in locations where both tests are performed on patients**.

**Failure to complete 4 monthly consecutive EQA samples, will be reported to the Laboratory Medicine Management Team, via the POCT Section Report, to recommend removal of the meter.**

### 7.3.1 EQA Testing Procedure

a) Remove the meter from the docking station.
b) **Welcome:** Touch 'Login' soft key at the bottom middle of the screen
c) **Enter Operator ID:** Touch 'Scan' soft key and swipe the barcode reader at the top of the meter, over your operator barcode.
d) If the meter is locked perform QC levels 1 and 3 testing before proceeding with EQA test.
e) **Patient Test:** Touch 'Menu' soft key.
f) **Menu:** Touch 'Proficiency' on screen.
g) **Enter Strip lot:** Touch 'Scan' soft key and scan barcode on the side of the test strip container.
h) **Enter Proficiency Lot:** Touch 'Scan' soft key on screen and scan the barcode displayed on the accompanying distribution slip.
i) **Insert Strip:** Place a test strip into the strip port at the bottom left of the meter.
j) Place the meter on a flat surface. Gently invert the EQA sample to mix.
k) **Apply Sample:** Keep the meter on a flat surface. Gently squeeze the EQA bottle to induce a hanging drop. Touch the drop of solution to the end on the test strip. The correct volume of solution will flow into the strip by capillary action.
l) **Testing sample:** The meter will beep to indicate successful aspiration and countdown automatically. A **glucose result is displayed after 6 seconds**. **A ketone result is displayed after 10 seconds**.
m) **Proficiency Result:** Touch the 'Accept' soft key. The meter will log you out and return to the **Welcome** screen.

n) Remove the test strip manually or use the ejector button on the back of the meter to eject the strip directly into a sharps bin.

**If patient ketone tests are performed on the meter repeat from step (c) using ketone tests strips.**

# 8 REPORTING RESULTS

## 8.1 ENTERING RESULTS ON COMPUTER

Results should be directly written into patients notes/diabetic chart. Results are not directly entered into a computer system.

Results are automatically stored in the Nova Biomedical middleware (NovaNet).

## 8.2 VALIDATION AND AUTHORISATION

N/A

## 8.3 REFERENCE RANGES

The StatStrip® meters are configured to reflect ranges, action limits and treatment cut offs as described in the diabetic chart used in in the clinical areas. This applies to all patients with the exception of infants and neonates.

Adult ranges are configured on the StatStrip® devices as shown below:

| | |
|---|---|
| **Normal Glucose** | **4.0 – 12.0 mmol/L** |
| **Normal Ketone** | **<0.6 mmol/L** |

**TAKE ACTION IF:**
**Glucose < 4.0 mmol/L** (follow protocol on Diabetes monitoring chart)
**Glucose 12–16 mmol/L** (monitor patient – if still unwell consider possible DKA)
**Glucose >17.0 mmol/L** (seek advice immediately from appropriate medical staff)

**Ketones 0.6-1.5 mmol/L** (seek advice from **Diabetes Nurse Team-bleep 1223**)
**Ketones > 3.0 mmol/L** (**DKA**-take appropriate action-follow Trust protocols-contact **Diabetes Nurse Team on bleep 1223**)

*Reference ranges sourced from Trust Microguide: Adult Medicine/Diabetes/Blood Glucose Monitoring In Patients With Diabetes*

For neonatal and paediatric reference ranges, refer to local guidelines on Trust Microguide and in the clinical area.

## 8.4 ACTION LIMITS

As an aid to the operator, the StatStrip® meters are configured to prompt the individual when results exceed predefined limits.


Indicates result is lower than the meter measuring range


Indicates result is more than the meter measuring range

For neonatal and paediatric action limits, refer to local guidelines on Trust Microguide and in the clinical area.

See Section 8.3 Reference ranges

## 8.5 INTERPRETATION OF RESULTS

All results need to be interpreted considering the patient's condition. If unexpected results occur, or which do not agree with the clinical picture, quality control solutions should be performed immediately and the patient test repeated. Laboratory confirmation of patient result is advised.

# 9 REFERENCES

## 9.1 STANDARDS

N/A

## 9.2 RELATED DOCUMENTS

- Nova Biomedical (2020). Instructions for Use Manual –StatStrip® Glucose and β-Ketone hospital meter (ref 53736)
- Microguide: Adult Medicine/Diabetes/Blood Glucose Monitoring In Patients With Diabetes
- Nova package insert for Glucose Test Strip (42214
- Nova package inset for Ketone Test Strip (46951)
- Nova package insert for Glu/Ket QC Level 1 (46947)
- Nova package insert for Glu/Ket QC level 3 (46949)
- http://www.weqas.com/POCT