Scarborough, Hull and York Pathology Service

Ketone Analysis by Nova StatStrip

Document Author/Reviewer	Jane Mason
Document Owner	Rachel Lampard
Approved By	Rachel Lampard
Review Interval	2 Years

Changes from last version of this document

Change to new SHYPS template.

General update

Table of Contents

1 Purpose and Principle

Ketone measurement is important in diagnosing ketosis which is a state of elevated levels of ketone bodies in the body. It is almost always generalized throughout the body, with hyperketonemia, that is, an elevated level of ketone bodies in the blood. Ketone bodies are formed by ketogenesis when liver glycogen stores are depleted. The ketone bodies acetoacetate and β-hydroxybutyrate are used for energy. ß-hydroxybutyrate measured in whole blood represents 80% of the ketone bodies in ketosis. Ketone bodies are acidic, but acid-base homeostasis in the blood is normally maintained through bicarbonate buffering, respiratory compensation to vary the amount of CO2 in the bloodstream, hydrogen ion absorption by tissue proteins and bone, and renal compensation through increased excretion of dihydrogen phosphate and ammonium ions. Prolonged excess of ketone bodies can overwhelm normal compensatory mechanisms, leading to acidosis if blood pH falls below 7.35.

There are 2 major causes of ketoacidosis:

• Most commonly, ketoacidosis is diabetic ketoacidosis (DKA), resulting from increased fat metabolism due to a shortage of insulin. It is associated primarily with type I diabetes and may result in a diabetic coma if left untreated.

• Alcoholic ketoacidosis (AKA) presents infrequently, but can occur with acute alcohol intoxication, most often following a binge in alcoholics with acute or chronic liver or pancreatic disorders. Alcoholic ketoacidosis occurs more frequently following methanol or ethylene glycol intoxication than following intoxication with uncontaminated ethanol.

A mild acidosis may result from prolonged fasting or when following a ketogenic diet or a very low-calorie diet.

The StatStrip ß-Ketone Hospital Meter is a hand-held, battery-powered, in vitro diagnostic laboratory instrument that works in conjunction with Nova Biomedical ß-ketone electrochemical test strips to measure ß-ketone in fresh capillary blood or venous whole blood samples.

The test strip has an electrode that measures ß-ketone levels. The blood is mixed with the reagent on the strip which in turn produces an electrical current. The amount of current produced is determined by the level of ß-ketone in the sample and is displayed as a numerical value on the meter.

2 Patient Preparation & Sample Requirements

. A fresh capillary or venous sample is required. Sample size is 0.8 µl.

- All human blood samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including lab coats, gloves and eye-protection must be worn when handling open blood samples or derivatives thereof.

	When performed according to the protocol detailed in this SOP, and in conjunction with adherence to Trust Policies and Good Laboratory Practice, the handling of patient samples represents minimal risk to staff.

Exposure to Bio-Hazardous Material

In the event of a needle stick injury or accidental blood splashes to eyes or mouth:

- If skin has been punctured encourage bleeding by gently squeezing. Wash with soap and running warm water then dry and dress the wound.
- Splashes to the eyes: irrigate eyes thoroughly with eye wash / saline
- Splashes to the mouth: gargle with drinking water (avoid swallowing)

Contact the Occupational Health Department / Emergency Department for guidance and report all adverse incidents to your line manager / complete a DATIX form.

Disposal of Patient Samples

Ensure compliance with the Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Samples: QM/POL/SHY-19.

3 Tasks, Responsibilities and Authorisations

- These procedures must only be carried out by staff who have received documented training on the use of the Ketone analyser. Training is documented in Aegis POC.
- All tasks should be performed under supervision of trained, competent colleague until staff member has passed competency and feels competent to perform tasks alone.

Tasks	Responsible	Authorised
Patient testing	Clinical staff who have received POCT training as above	Trained member of POCT staff or certified POCT link trainer
Maintenance tasks	POCT staff who have received training	Trained member of POCT staff

4 Equipment

Nova StatStrip handheld meter. This should be stored in the docking station to allow the battery to remain fully charged.

Nova Stat Strip docking station.

Nova Biomedical UK

Innovation House

Aston Lane South

Runcorn

Cheshire

WA7 3FY

Tel 01928 704040

If there are problems with the meter, please contact the POCT team on

York 772 5890

Scarborough 771 2659

Bridlington 771 3321

5 Chemicals and Reagents

- The Nova ketone StatStrips cat no 46951 are obtained via pharmacy. Store the container of strips between 15-30 C in a dry place. Do Not freeze the strips. The strips when stored correctly are stable for 90 days once opened and until the expiry date if unopened.
- QC material
- Level 1 cat no 46947- Obtained from POCT team Tel York 5890 Scarborough 771 2659 Bridlington 771 3321
- Level 3 cat no 46949- Obtained from POCT team Tel York 5890 Scarborough 771 2659 Bridlington 771 3321

6 Risk Assessment

For a full risk assessment please see PC/RA/YS-9

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.
- Include reference to table in 'chemicals and reagents' section for specific COSHH assessment.

Risk assessment must also evaluate the impact of work processes and potential failures on examination results as they affect patient safety, the procedure should incorporate any modifications taken to reduce or eliminate identified risks. The overall intention is to be able to leave the following text box in the SOP.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

Calibration is carried out by the manufacturer.

8 Quality Control

Two level of quality control samples must be analysed every 24 hours and under the following circumstances.

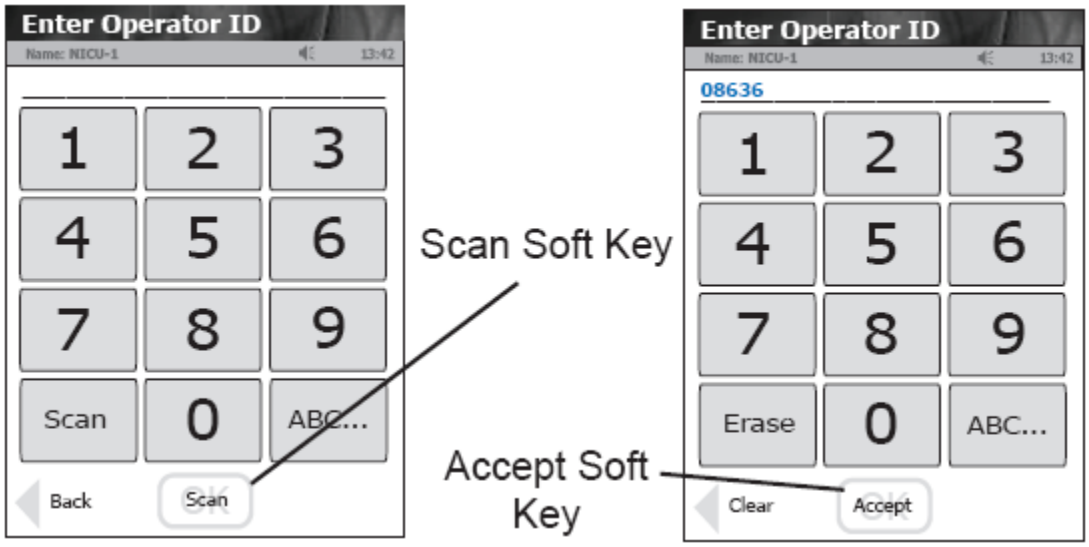
• If a patient test has been repeated and the blood results are still lower or higher than expected

• If there are other indications that the system is not working properly

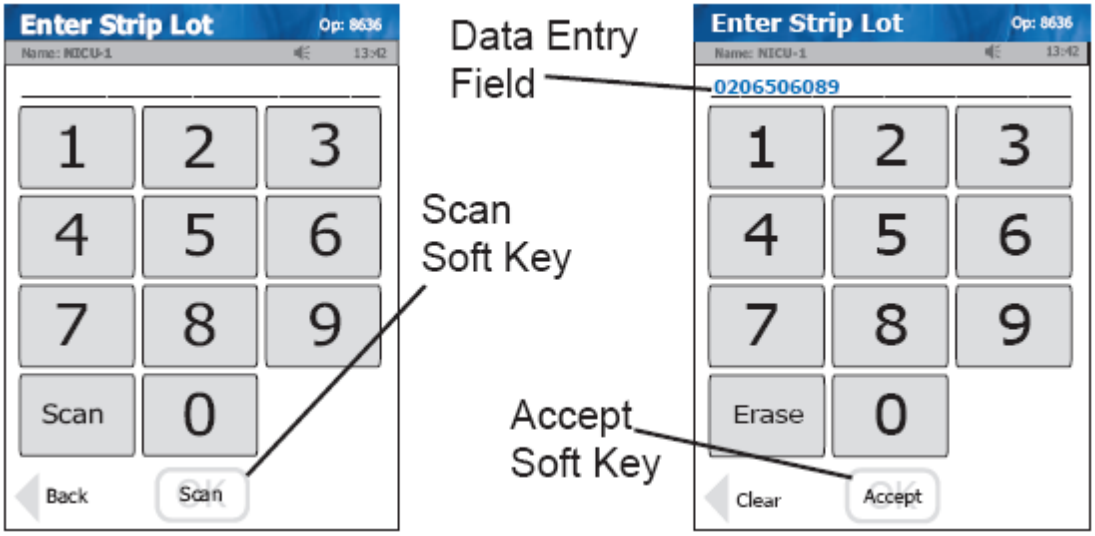
• Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

To run a control sample

- Log on to the meter by scanning or manually entering your operator ID and clicking ‘Accept’

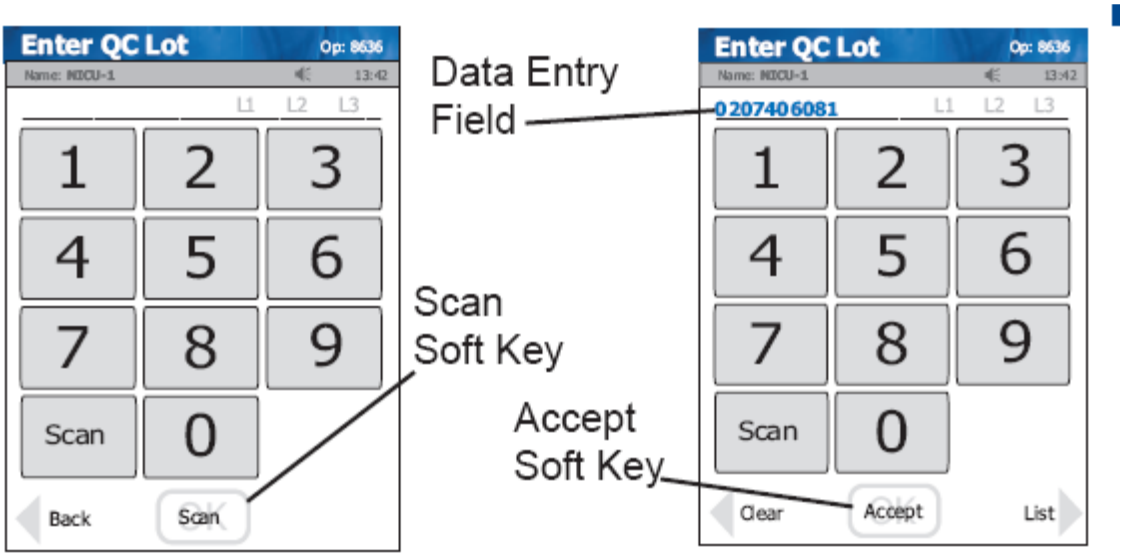


- From the Patient Test screen, press the QC soft key.
- The Enter Strip Lot screen displays. Barcode the Strip Lot number by clicking ‘Scan’ and then ‘Accept’.

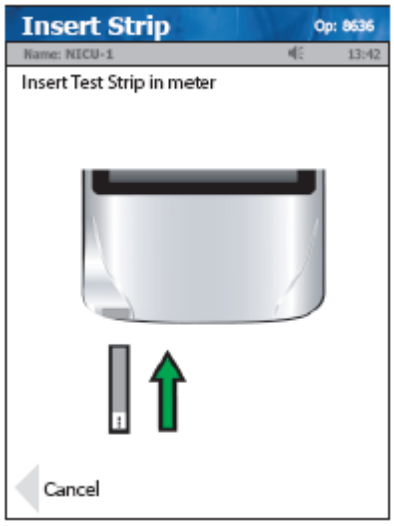


- The Enter QC Lot screen displays.

- Enter the QC lot number, by scanning the barcode. To scan the barcode, press the Scan soft key. Click 'Accept' to confirm.



- The Insert Strip screen displays.



- Insert a Test Strip into the port at the bottom left of the meter.
- With the test strip correctly inserted, the Apply Sample screen displays.
- Gently mix the control solution vial before each use.
- Discard the first drop of control solution from the bottle to avoid contamination.
- Place a drop of control solution from the bottle to the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, a clock appears and a 10 second count down begins.

- Recap the control solution.
- The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.
- When the meter completes the test, the QC Result screen displays with pass or fail.
- Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.
- To add a comment to the result, press the Comment soft key.
- To accept the results, press the Accept soft button.

If the quality control samples fail, please

- Check the dates on all the consumables/mix samples well clean top of the bottle.
- Repeat the control.

If the controls are still out, please quarantine the meter and contact the POCT team on

York	772 5890
Scarborough	771 2659
Bridlington	771 3321

The results are reviewed by the POCT coordinator and discussed at the POCT committee meeting.

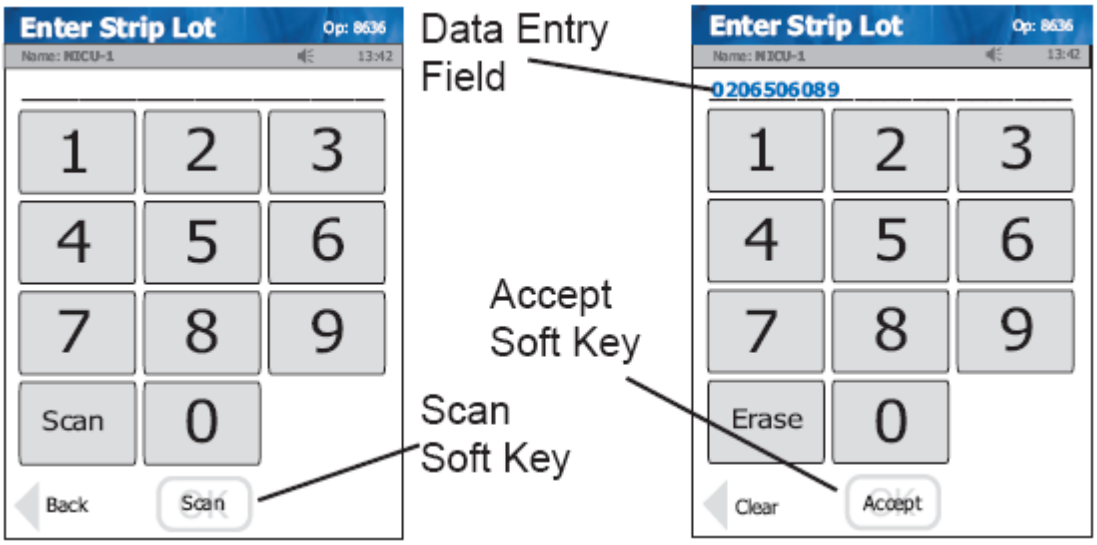
9 External Quality Assurance (EQA)

All Ketone meters in the Trust are enrolled in WEQAS EQA scheme.

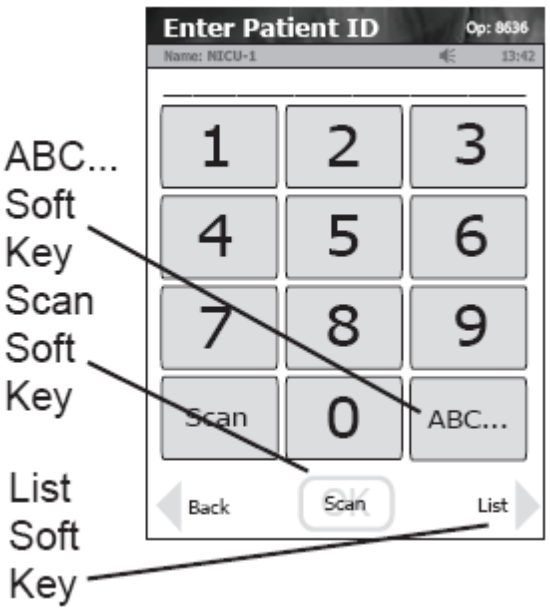
Samples are distributed in a bright yellow envelope every 2 months with instructions and reports are reviewed by a BMS from POCT.

10 Procedural Steps

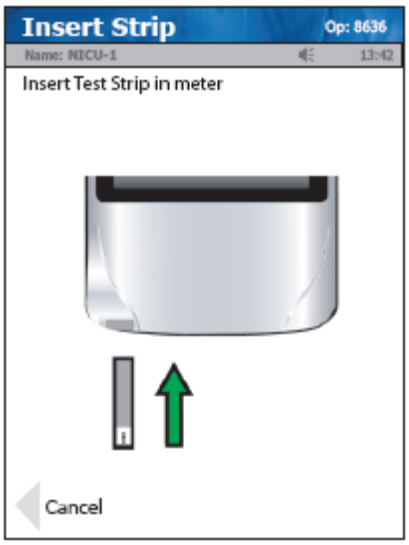
- Log on to the meter.
- From the Patient Test screen, press the Accept soft key.
- The Enter Strip Lot screen should be displayed.



- Scan the strip lot number by clicking ‘Scan’ From the Patient ID screen enter the Patient ID scanning the NHS number from the wrist band or if not available enter manually and press the accept soft key. If no NHS number is available, please use the full case note number.
- If the patient is not current on the system a message Patient ID is not valid –Try again/New patient override. If you have checked the NHS number has scanned correctly press the new patient override button and continue
- If the patient is live on the system a confirm Patient ID is visible. It will display the Name DOB and gender. If this is correct press the accept button. If the Patient is not live on the system a “new patient override” button will appear on screen. Double check that the correct NHS number has been entered, if it has press the new patient button to continue



- Insert the strip into the port at the bottom left-hand side of the meter



- Wash the patient's hand with water and dry thoroughly.
- Explain the procedure.
- Ask the patient which finger they want the sample taken from.
- Holding the hand downward use the safety lancet to puncture the finger on the side of the pad no lower than the nail bed.
- If no blood is visible massage the finger gently until a drop of blood appears
- The apply sample screen should be displayed. Touch the end of the strip to the blood. When the strip is full the meter will beep. The test strip must be filled in one go do not fill from a second drop.

- The result will appear on the meter after a 10 second count down
- Remove the used strip by using the eject button on the back of the meter and eject directly into the clinical waste.
- To accept the result, press the Accept soft key.

- If you wish to add a comment, press the comment soft key.
- The result must be documented in the patient's notes. The results are also stored indefinitely on middleware accessed by the POCT team and the patient's electronic record in CPD.

11 Reporting of Results

Results must be documented in the patient's notes and the following should be included

- Date and Time
- Result
- Operator Name

The reportable range of the meter is 0.1mmol/L-7.0mmol/L below 0.1 the meter will read <0.1mmol/L above 7.0mmol/L the meter reads Hi

12 Reference Intervals

Interpretation of the results

For diagnosis and monitoring of ketone levels in DKA please refer to DKA Protocol

Blood ketone levels	Action in patients with diabetes and blood glucose levels >16mmol/l who are at risk of DKA
>3.0 mmol/L	Monitor hourly and get urgent medical review to assess for DKA. See DKA guidelines.
1.6 - 2.9 mmol/L	Refer to medical team to assess for DKA, continue to monitor blood ketones and blood glucose 2 hourly.
0.6 -1.5 mmol/L	Monitor blood ketone and blood glucose 2 hourly and refer to medical team as patients treatment will need to be altered if levels are rising.
<0.6 mmol/L	Get insulin doses reviewed and treat hyperglycaemia. Re-check blood ketones in 2 hours if the blood glucose remain above 16 mmol/L.

Further information regarding testing and reporting results can be found on Staffroom.

Management of Diabetic Ketoacidosis (DKA) in Adults best practice guidance Jan 2017.cdr (yorkhospitals.nhs.uk)

13 Performance Characteristics and Known Limitation

- Should not be used on new-borns.
- Should not be used as a sole tool to diagnose DKA
- Should only be used with fresh capillary or venous blood
- Should only be used in humidity levels between 10-90%
- Should only be used on samples with a haematocrit between 25-60%

Inter batch precision

	Level 1	Level 3
Mean	0.1	3.06
SD	0.0	0.3
CV	0.0	9.8

Intra batch precision

Instrument	Level 1	Level 3
Mean	0.11	2.83
SD	0.04	0.30
CV	33.6	10.5

Assay detection limit.

The reportable range of the meter is 0.1mmol/L-7.0mmol/L below 0.1mmol/L the meter will read <0.1mmol/L above 7.0mmol/L the meter reads Hi

14 Related Forms/Templates and Documents

PC/RA/YS-9

PC/VV/YS-15

15 References

- Nova StatStrip- strip insert.
- Nova StatStrip user's manual. PC/ED/YS-6
- Evaluation carried out see PC/VV/YS-15