



CLINICAL GUIDELINES

Guidelines/Standard Operating Procedure

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Applies To:	All Certified Stat Strip Glucose and Ketone Meter Users at the IWK		

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STANDARD OPERATING PROCEDURES

PREAMBLE

Point of Care glucose meter testing is specifically indicated for use in a clinical setting by certified health providers as an aid to monitor the effectiveness of diabetes control. It is not for diagnosis of, or screening for diabetes.

The β -Ketone meter is intended to measure β -hydroxybutyrate in capillary and venous whole blood. The manufacturer indicates it should not be used to test newborns nor for the diagnosis of Diabetic Ketoacidosis (DKA).

POLICY STATEMENTS

1. Capillary blood glucose testing must not be used for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. It is recommended that a venous sample be collected and compared to a laboratory value in these cases. Examples include, but are not limited to:
 - Severe hypotension
 - Shock
 - Hyperosmolar-hyperglycemia (with or without ketosis)
 - Severe dehydrationCapillary glucose concentrations may be 3.9 mmol/L higher than a venous blood glucose concentration in a person who has recently ingested food or liquid.
2. StatStrip Glucose and Glucose/Ketone Meter testing requires Certification and recertification, on a yearly basis, of care providers who have been oriented and practicing in the IWK. Please refer to the POCT Policy (#3101) for a list of users who qualify for certification. Those operators requiring certification on the StatStrip Xpress Glucose meter, maintain their recertification via the StatStrip Glucose/Ketone meter process.

Demonstrated competence consists of:

- successfully completing the online training learning module system (LMS) for the Nova StatStrip Glucose/Ketone meter
- achieving greater than 80 percent on the quiz
- attending a hands on training session with a super user, Point of Care Coordinator (POCC) or laboratory designate.

Recertification requirements include:

- successfully performing two sets of quality control
- ten patient samples per year (as per information obtained from the Aegis software) prior to the operator's yearly expiry date.

NOTE: Noncompliance will result in the operator being inactivated until recertification is completed.

3. The meter should be designated to a single patient if possible. If this is not possible, the meter must be thoroughly cleaned and disinfected prior to use on another patient.

STANDARD OPERATING PROCEDURE (Nova StatStrip™ Meter)

EQUIPMENT/ MATERIALS

- StatStrip meter - (GLU and/or GLU/KET)
- StatStrip test strips - (GLU and/or KET)
- Hospital approved lancets
- Hospital approved antiseptic
- Isolation sleeves (if required)
- Quality Control Solutions (obtain from lab)
- Hospital approved disinfecting wipe

SPECIMENS

- Acceptable specimens for glucose meter testing include fresh capillary blood from finger stick or heel stick, venous, and arterial samples (including neonatal) requiring 1.2 µL (microliter) of whole blood.
- Acceptable specimens for ketone meter testing include fresh capillary and venous samples requiring 0.8 µL whole blood.

NOTE: Capillary glucose concentrations may be 3.9 mmol/L higher than a venous blood glucose concentration in a person who has recently ingested food or liquid (e.g. “Insta-Glucose”).

See Appendix B for Principles for the Nova StatStrip Meter

See Appendix C for Limitations/Interferences

See Appendix D for Nova StatStrip Meter Components, Test Strips and Control Solutions.

1. Powering up and Entering Operator ID

- 1.1 Press the power on/off button located on the top right side of the meter or touch the screen. The Welcome screen displays. This screen displays the meters' assigned location, date, time, status of battery charge (battery is fully charged when symbol is blue) and Login soft key.

- 1.2 Press the Login soft key on the screen and scan or manually enter your Operator ID **Bar Code Scanning:** Touch the Scan soft key on the touch screen. Position the scanning beam approximately 4-6 inches from your operator ID barcode.
- 1.3 **Manual Entry:** Input operator ID using the touch screen.
- 1.4 Press the Accept soft key on the touch screen to progress to the next screen. The Patient Test screen will appear.

NOTE: Follow instructions in the dialogue box at the top of the screen. The dialogue box for the GLU/KET meter is grey until the test strips are scanned or inserted into the meter. Glucose test strips will change the dialogue box to a blue color, the ketone test strips will change the dialogue box to a green color.

2. **StatStrip™ Control Solutions:** Two different levels of the StatStrip Glucose and Ketone Control Solution (QC) should be run each 24 hours, prior to testing a patient specimen, and under the following circumstances:
 - 2.1 When a new vial of test strips are first opened.
 - 2.2 If a patient test has been repeated and the blood glucose or ketone results are still lower or higher than expected.
 - 2.3 If there are other indications that the system is not working properly indicated by alerts on the screen or difficulties with the meter operation (See Appendix F for additional Troubleshooting recommendations).
 - 2.4 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).
 - 2.5 If meter infrequently used QC must be performed a minimum of twice a week.

Once QC is completed by clinical staff, the QC results will be stored electronically when the meter is docked on the docking station.

3. To run a QC:

- 3.1 Turn the meter on. The Welcome screen will indicate if the meter is locked out "Glu LOCKED" and or "Ket LOCKED"
- 3.2 Login with your operator ID (Press Accept soft key)
- 3.3 From the Patient Test screen, press the QC soft key. The meter will indicate the level(s) of QC required to unlock the meter.

- 3.4 The Enter Strip Lot screen displays. Press the Scan soft key and scan the barcode of the strip to be used for QC testing. Confirm the lot scanned successfully then Press Accept soft key.

NOTE: If the Strip Lot Number is invalid, the screen displays the invalid number with “is not a valid Strip Lot # Try again” .Touch the Back soft key to return to the Enter Strip Lot screen to rescan the lot number.

- 3.5 Press Accept or OK if the lot number is correct.
- 3.6 The Enter QC Lot screen displays. Scanning the barcode. Press the Scan soft key and scan the barcode on the QC vial. Press Accept soft key if the lot number is correct.

NOTE: If the QC lot Number is invalid, the screen displays the invalid number with “is not a valid QC Lot Try again” Touch the Back soft key to return to the Enter QC Lot screen to rescan the lot number.

- 3.7 The Insert Strip screen displays. Insert a test strip in the strip port. The Apply Sample screen displays.
- 3.8 Gently shake the StatStrip Control Solution before each use.
- 3.9 Discard the first drop of control solution from the bottle to avoid contamination.
- 3.10 Place a drop of control solution on the end of the test strip until the solution is drawn into the well of the test strip. When enough solution has been drawn into the strip, an audible beep is sounded by the meter and the second countdown begins.
- 3.11 Recap the control solution.
- 3.12 When the meter completes the test, a PASS or FAIL will appear on the screen. If PASS - Press Accept. If FAIL – a comment must be added to the results - Examples include: Procedure Error, Wrong Control, Repeat Control.
- 3.13 Remove the strip – Discard into sharps container.
- 3.14 Patient Test screen displays a reminder of the level of QC still required to be run – Repeat the above steps starting at 3.3 for the next level and other analyte (if applicable).

NOTE: Patient specimens cannot be tested until both levels of QC have passed

4. QC Troubleshooting (If QC FAILS)

- 4.1 Repeat QC test and be sure the correct QC level was used.
- 4.2 Mix QC solution gently and discard first drop ensuring there are no bubbles in the application.
- 4.3 If QC continues to fail try another vial of test strips
- 4.4 If the meter continues to fail, take the meter out of service and notify the POCC

See Appendix F Additional Troubleshooting for the Nova StatStrip™ Meter

5. Patient Testing using the StatStrip™ GLU or GLU/KET Meter

- 5.1 Put on gloves for patient testing as per *IWK Health Centre Policy #201.1 Application of Routine Practices*.
- 5.2 Put on personal protective equipment (PPE) if indicated based on identification of the need for additional precautions as per *IWK Policy # 301.1 Application of Additional Precautions*
- 5.3 Place meter in isolations sleeve if required
- 5.4 Turn on the Nova StatStrip™ Meter and Login by scanning or manually entering operator ID
- 5.5 Perform QC if necessary. *See section To run a QC.*
- 5.6 From the Patient Test screen press the Accept soft key
- 5.7 The Enter Strip Lot screen displays. Scan the strip lot number on the vial. Confirm lot number and press Accept.
- 5.8 The Enter Patient ID screen will display. Confirm patient ID using two unique identifiers. Scan the armband barcode (patient's accession number) or manually enter the patient's K number and press the Accept key
- 5.9 For patients that have not been assigned a K number or an account number (i.e. during Downtime, triage, newborns, out of country, or no patient identification), a unique identifier (HCN or name), must be manually entered.
- 5.10 The Insert Strip screen displays. Insert a test strip as shown on the screen.
- 5.11 Use a hospital approved antiseptic to cleanse the area to be punctured. Dry thoroughly.
- 5.12 Use an appropriate lancet to puncture the finger or heel. Gently squeeze the area to obtain a drop of blood. **Wipe away the first drop of blood (at minimum) with a cotton swab or gauze.**

Note: Failure to obtain good sample flow increases the risk of dilution and contamination with tissue fluid (more than one wipe may be useful).

- If collecting a specimen from an arterial line, observe hospital policy for Blood Specimens Collection from Arterial Lines. Inadequate flushing or improper amount of discard may lead to discrepant meter results.
- 5.13 Gently massage the area to obtain a drop of blood. Touch the **end** of the test strip to the blood drop until the well of the test strip is completely filled. The meter will beep (if the sound is turned on) and a countdown in seconds will begin.

Note: DO NOT touch the test strip to the blood sample a second time – a Flow error may occur. If the Flow error occurs, discard the test strip and repeat with a new strip.

- 5.14 The test results will appear in 6 seconds for glucose and in 10 seconds for ketone.
- 5.15 Comments may be added, from a predefined list, prior to accepting the result (Press comment, select from the list, press accept, then accept the result). Choose comments that pertain to the situation only.
- Patient Comments Include:
- Notify Doctor
 - Sample to Lab
 - Wrong Patient
 - Unit policy/Dr order
 - Repeat sample
 - Procedure Error
 - Train/Recert sample
- 5.16 To accept the result, press the Accept soft key.
- 5.17 Communicate patient results to doctor. Document results on patient chart indicating POC Glucose or POC Ketone result, unit of measure (mmol/L), collector's initials, the date and time of testing.
- 5.18 Log off the meter, remove isolation sleeve (if applicable), clean and disinfect the meter using the appropriate hospital approved disinfectant wipe ensuring appropriate contact time according to the manufacturer's instruction for use. More than one wipe may be required to ensure appropriate contact time or if heavily soiled.
- 5.19 Discard the test strip and poker in appropriate sharps container, the alcohol wipe, gauge and the isolation sleeve (if used) in the garbage.
- 5.20 Return the meter to the docking station.

See Appendix E – Isolation Sleeve, Cleaning and Disinfection, Maintenance

6. Measuring range:

- Glucose measuring range: 0.6 - 33.3 mmol/L. If the result is “LO” or “HI” it is outside the measurable range
- Ketone measuring range: 0.1 - 7.0 mmol/L. Results below 0.1 mmol/L will display as less than 0.1 (<0.1) and results above 7.0 mmol/L will display as “HI”

7. Resulting Glucose Ranges

- 7.1 Normal glucose range: 3.3 - 5.6 mmol/L. Results outside this range will display in red with one down (↓) or one up (↑) arrow
- 7.2 Critical limits for the glucose meter are set at: less than 2.5 mmol/L and greater than 20.0 mmol/L. Critical results will be displayed with two down arrows (↓↓) or two up arrows (↑↑). A Comment must be added to a critical result.
- 7.3 Please refer to unit policy for specific normal and critical glucose ranges if applicable
- 7.4 Based on assessment of the patient and review of patient history, a confirmation laboratory sample may be required for outside normal and critical ranges.
- 7.5 Glucose meter results may be generally lower than laboratory results by 20%, particularly at values below 2.2 mmol/L and above 20 mmol/L.

8. Resulting Ketone Ranges

- 8.1 Normal beta-hydroxybutyrate range: 0.1 – 0.4 mmol/L. Results outside this range will display with < 0.1 or one up (red) (↑) arrow
- 8.2 There are no critical limits for the ketone meters programmed.
- 8.3 Please refer to unit policy for specific normal and critical ketone ranges if applicable

NOTE: If clinically questioning a meter result, repeat the meter, and if required (according to unit practice or authorized provider) send a sample to the laboratory.

9. Review Results 400 results can be recalled and reviewed for 30 days

- 9.1 From the Patient Test screen, press Review soft key
- 9.2 The review Result screen displays
- 9.3 Select how to sort the results by pressing ID, Time/Date or Type
- 9.4 Press Page Down or Page Up to scroll through the stored results
- 9.5 Select the result that you want to review
- 9.6 Press View to view the selected result

10. StatStrip Xpress™ Meter SOP Operation Overview

- 10.1 The StatStrip Xpress meters are used only on the crash carts in specific locations.
- 10.2 There are automatic electronic function checks to verify proper meter operation.
- 10.3 A 3V coin cell battery (2450) provides power to operate the meter for approximately 600 tests. A low-battery warning on the meter display alerts the operator to change the battery. Meter will go to sleep after 1 minute of no activity.
- 10.4 See Appendix G Installing the Battery, Setting the Time and Date on the Xpress meter.
- 10.5 To keep-awake or to wake the meter press a button or insert a test strip
- 10.6 Quality Control Testing (QC) The Xpress meter has several quality control mechanisms that detect errors due to system failures and operator performance. Two levels of external liquid control material are used to verify the integrity of the Xpress glucose meter and test strips. Once the QC vial is opened the vial is good for 90 days.

11. Perform QC testing when

- 11.1 Once every 24 hours if patient being tested
- 11.2 Twice a week if the meter is not in use
- 11.3 When a new bottle of test strips is first opened
- 11.4 If a patient test results are higher or lower than expected
- 11.5 If there are other indications that the system is not working properly
- 11.6 Whenever problems (test strip storage, operator performance, and instrument) are identified or concern of the accuracy of the meter may have been affected by rough handling or dropping.

12. Testing a QC solution

- 12.1 Turn the meter on by inserting a test strip. Verify that all segments of the screen are displayed. If the meter display is incomplete discontinue testing.
- 12.2 A flashing blood drop is displayed.
- 12.3 Identify the sample as a Control by using the Right or Left arrow buttons to find the correct control level (C1 or C3).
- 12.4 Mix the control solution, discard the first drop and apply the next drop to the end of the test strip until the meter beeps.
- 12.5 Results will be displayed in 6 seconds.
- 12.6 Record results on the Quality Control Log for the Nova StatStrip Xpress™ Meter, indicate Pass or Fail in the Comment area.
- 12.7 Repeat above procedure for the next level of QC.

12.8 Both levels of QC must pass or fall within the expected range before a patient test can be performed.

Note: The Quality Control Log Form is to be sent to the laboratory monthly. QC values will be reviewed by the POCC or laboratory designate and signed off by the clinical Division Head of Biochemistry.

13. **Testing a Patient Sample using the StatStrip Xpress™ meter**

13.1 Turn the meter on by inserting a test strip. Verify that all segments of the screen are displayed. If the display is incomplete discontinue testing.

13.2 A flashing blood drop is displayed.

13.3 Use alcohol to disinfect the patient's finger. Air dry or wipe away the alcohol.

13.4 Use a single use, hospital approved lancet to poke the patient.

13.5 Obtain a blood drop, wipe away the first drop, use the second drop of blood for testing

13.6 Touch the end of the test strip to the blood drop until the strip fills with blood (1.2uL of sample required).

13.7 6 second countdown displays until the result is available on the meter screen. One long beep indicates the result is complete, 3 short beeps indicate the result is outside the measurable range of the meter (0.6-33.3 mmol/L).

13.8 Record or document results on the patient health record (if applicable).

13.9 Disinfect meter with a hospital approved disinfectant wipe after each patient sample. Other disinfectants that maybe used include: 10% bleach solution or 70% isopropyl alcohol.

****Note **** Result value of HI indicates meter reading above 33.3 mmol/L. Result value LO indicates meter reading below 0.60 mmol/L.

14. **Reviewing Results**

14.1 Press the MODE button once for less than 3 seconds.

14.2 The most recent test result is displayed first.

14.3 Use the Right or Left arrow buttons to scroll through results.

14.4 If you scroll past the first or last stored result, the screen will display END.

14.5 After 400 test results, the new result will override the oldest result in memory.

14.6 See Appendix H Troubleshooting for the Xpress Meter

REFERENCES

CLSI Guideline, C30-A2 Point of Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guidelines – Second Edition

CLSI Guidelines, POCT12-A3 Point of Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guidelines – Third Edition

Qmentum Program 2018 Standards Point of Care Testing

ISO 22870 Point-of-Care testing – Requirements for Quality and Competence
Nova StatStrip Glucose Test Strips package insert; Nova Biomedical; Waltham, MA 02454 U.S.A

Nova StatStrip β -Ketone Test Strips package insert: Nova Biomedical: Waltham, MA 02454 U.S.A

Nova StatStrip Glucose Hospital Meter Instructions for Use Manual, Nova Biomedical Corporation 2011, Waltham, MA 02454-1914

Nova StatStrip Xpress™ Glucose Hospital Meter Instructions for Use Manual; Nova Biomedical Corporation 2012, Waltham, MA 02454-9141

Nova Medical (2012). StatStrip Glucose/ β -Ketone Hospital Meter Instructions for Use Manual

RELATED DOCUMENTS

IWK Health Centre (2019) Point of Care Testing Policy # 3101

IWK Clinical Policy # 1100 - Patient Identification

IWK Clinical Policy #1900 – Unidentified (Unknown) Patients Identification Process

IWK Infection and Prevention and Control Services Policy # 201.0 - Application of Routine Practices

IWK Infection Prevention and Control Policy # 205.2 - Hand Hygiene

IWK Health Centre (2009). Blood Specimen Collection from Arterial Lines Policy #1753

Children's Health Program Clinical Policy Manual.

IWK Health Centre (2008). Umbilical Catheter Care and Maintenance Policy #8675

Women's and Newborn Health Program Clinical Policy Manual.

IWK Health Centre (2012). Arterial Catheter Insertion, Care and Management Policy #40005

IWK Health Centre (2010). Central Venous Access Device (CVAD) Care & Maintenance Policy #735

IWK Health Centre (2007) Capillary Blood Sampling in NICU Policy # 8530

APPENDICES

Appendix A - Definitions

Appendix B - Additional Principles for the Nova StatStrip Meter

Appendix C - Limitations/Interferences

Appendix D - Nova StatStrip™ Meter Components, Test Strips and Control Solutions

Appendix E - Isolation sleeves, Cleaning and Disinfection, Maintenance

Appendix F – Additional Troubleshooting for the Nova StatStrip™ Meter

Appendix G – Xpress meter: Installing the Battery, Setting the Time and Date

Appendix H - Troubleshooting for the Xpress Meter

Appendix A: Definitions

Nova StatStrip Glucose Hospital Meter is a hand held, battery powered, in vitro diagnostic instrument that works in conjunction with Nova Biomedical glucose electrochemical test strips to measure glucose in a whole blood sample, Quality Control solution, linearity, or proficiency solutions. The test strip is designed with an electrode that measures plasma equivalent glucose levels.

Nova StatStrip β -Ketone Hospital Meter is a hand held, battery powered, in vitro diagnostic instrument that works in conjunction with Nova Biomedical ketone electrochemical test strips to measure ketone in a whole blood sample, Quality Control solution, linearity, or proficiency solutions.

Nova StatStrip Xpress™ Glucose Hospital Meter is a small hand-held glucose meter, powered by a 3-volt coin battery, intended for in vitro diagnostic use by health care professionals at the point of care in the quantitative determination of glucose.

Point-of-Care Testing (POCT) is testing that is performed outside of the laboratory, by authorized health care personnel, near or at the site of the patient with utilization of the results leading to possible change in the care of the patient

Certified users for the Nova StatStrip Glucose and β -Ketone Meter are staff who have completed all training requirements to become certified.

Quality Control (QC) the set of procedures designed to monitor the test method and results to assure test system performance by detecting gradual or sudden changes.

Quality Control Solutions are external control material available from Nova Biomedical used to verifying the integrity of the Glucose and β -Ketone Hospital meters and test strips. Two levels (L1 and L3) of ready-to-use liquid controls are used.

Point of Care Coordinator (POCC) is a senior technologist in the Core Lab who works collaboratively with health professionals at the point of care to implement POCT testing safely, to help achieve/maintain staff competency, and adhering to the Department of Pathology and Laboratory Medicine quality management program

Operator ID Each operator will have a unique identifier. This identifier must be entered into the StatStrip meter before any testing can be performed. It is a breach of security to allow another person to use your operator ID. All results can be traced to the operator.

Patient ID Manually enter the patients' 6 digit K number or scan the barcode on the patient's armband (account number). Patient ID length must be between 5 and 20 characters long.

Appendix B: Additional Principles for the Nova StatStrip Meter

The Nova StatStrip™ Glucose and Glucose/Ketone Monitoring system is designed with an electrode that measures either glucose or beta-Ketone levels. The blood sample mixes with the reagent on the test strip to produce an electric current. The amount of current produced depends on how much glucose or beta-Ketone is in the sample.

The meter stores patient test data, QC test data, and other information relating to the patient test. The Docking Station is used to send results to the Aegis Software in the laboratory and recharge the meter battery. The docking stations are connected to designate PC's throughout the hospital to provide a route for transferring data to the laboratory. Currently at the IWK Health Centre, all results will be manually recorded by the operator. (The results will be clearly defined as a point of care test (POCT) signed and dated by the tester on the patient's chart according to unit protocol). Once the meter is interfaced with the Meditech system, results will flow into PCI.

All data for the StatStrip meters is held on the Aegis software (database) within the laboratory. The database allows for a complete audit trail of the Nova StatStrip™ Meter testing which includes but is not limited to dates, times, operators, patient results and Quality Control.

QC is reviewed by the POCC or laboratory designate. The clinical Division Head of Biochemistry reviews the QC results on a monthly basis or whenever problems occur.

Audits will be performed for QC and patient testing compliance. Certification may be revoked during audit reviews if there is a repeated non-compliance to policies and procedures.

All new meters will be validated with linearity, accuracy and precision studies prior to implementation.

Proficiency testing, linearity and patient correlation will be performed and results reviewed by lab.

Discrepant results may be investigated by laboratory personnel. Investigations may include quality assurance checks, SIMS events, proficiency testing and patient comparisons.

APPENDIX C: Limitations/Interferences

Glucose Interferences: The StatStrip Hospital meter and the StatStrip Xpress meter exhibits no interference for glucose from the following substances up to the following concentration levels:		Ketone Interferences: The StatStrip Glucose and β -Ketone Hospital Meter exhibits no interference for β -Ketone from the following substances up to the following concentration levels:	
Tested Substances Concentration Level		Tested Substances Concentration Level	
Acetaminophen	660 μ mol/L	Acetaminophen	1.32 mmol/L
Ascorbic Acid	0.57 mmol/L	Acetone	1.72 mmol/L
Bilirubin	260 μ mol/L	Acetoacetate	0.93 mmol/L
Cholesterol	12.9 mmol/L	Ascorbic Acid	1.14 mmol/L
Creatinine	530 μ mol/L	Bilirubin	0.18 mmol/L
Dopamine	0.53 mmol/L	Captopril	0.46 mmol/L
Ephedrine	0.055 mmol/L	Cholesterol	12.9 mmol/L
D(+) Galactose	19.4 mmol/L	Creatinine	0.53 mmol/L
Hematocrit (RBC)	0.20-0.65	Dopamine	0.53 mmol/L
Ibuprofen	2.33 mmol/L	Ephedrine	0.035 mmol/L
L-Dopa	5.07 mmol/L	Glucose	50.0 mmol/L
D(+) Maltose Monohydrate	6.66 mmol/L	Ibuprofen	2.33 mmol/L
D(+) Maltotetraose	3.6 mmol/L	L-Dopa	0.51 mmol/L
D(+) Maltotriose	4.76 mmol/L	Methyl-Dopa	0.042 mmol/L
Methyl-Dopa	0.042 mmol/L	N-Acetyl-L-Cysteine	0.61 mmol/L
Oxygen	All Concentrations	Tetracycline	0.62 mmol/L
Salicylate	1.87 mmol/L	Tolazamide	0.48 mmol/L
Tetracycline	0.62 mmol/L	Tolbutamide	1.67 mmol/L
Tolazamide	0.48 mmol/L	Triglycerides	8.47 mmol/L
Tolbutamide	1.67 mmol/L	Salicylate	1.87 mmol/L
Triglycerides	8.78 mmol/L	Uric Acid	1.05 mmol/L
Uric Acid	1050 μ mol/L		

APPENDIX D: Nova StatStrip™ Meter Components, Test Strips and Control Solutions

Nova StatStrip™ Meter Components

- On/Off Button: Located on the top right of the meter; powers the meter on
- Scanner: Infrared laser scanner for barcodes located at the top of the meter; avoid eye contact, scanner turns off in 5 seconds if not used
- Temperature sensor, located to the left of the scanner, will indicate errors outside the range of 15-40°C
- Touch Screen: Front panel of the meter – use soft key to scroll through the screens
- Test Strip Port: Located at the bottom of the meter where the strip is inserted; avoid exposure to liquids
- Battery Pack: Located in the back of the meter; allows the meter to hold its' charge
- Docking Station/Base Unit: Recharges battery and for downloading/uploading data; keep meter docked to keep battery fully charged and for data transferring, indicated by a green light

StatStrip™ Test Strips

- Always store unused test strips in their original container with the cap tightly closed
- Store at room temperature (<30°C), do not refrigerate or freeze
- Do not store in high heat and humidity
- **Always** date bottle when opened and include discard date
- Once opened the glucose strips are good for 180 days (6 months)/ ketone strips are good for 90 days (3 months)
- Discard expired strips
- Unopened strips can be used until manufacturer expiry date
- Discard test strips in the sharps container

StatStrip™ Control Solutions (Level 1 and Level 3)

- Store at room temp (15°- 30°C)
- QC Material is stable unopened until the expiry on the bottle
- **Always** date bottle with the expiry date when opened
- Once opened the QC is stable for 3 months
- Before each use the controls must be mixed gently, do not shake.
- If the tip becomes crystallized with the QC solution wipe with a tissue
- Distributed by the POCC or lab designate

APPENDIX E: Isolation sleeves, Cleaning and Disinfection and Meter Maintenance

Nova StatStrip™ Meter Isolation Sleeves Isolation sleeves are designed to fit the StatStrip meter and are used to provide an added barrier to help prevent excessive contamination. They must be used for all patients who require additional precautions. Meters are to be inserted into the isolation sleeves prior to entering the patient's room. The meter must be thoroughly cleaned and disinfected with a hospital approved disinfectant wipe after removing the isolation sleeve. Whenever possible, a meter should be dedicated to the patient requiring additional precautions.

CLEANING AND DISINFECTION:

- Always wear appropriate Personal Protective Equipment (PPE) when handling contaminated equipment
- Always clean and disinfect the meter after patient use (before placing in docking station)
- Clean the outside of the meter with a hospital approved disinfectant wipe ensuring cloth is damp, **not saturated** and allow to air dry for the appropriate contact time. Several wipes may be required if the meter is heavily soiled.

Note: Meter screen may need to be wiped with a damp gauze after cleaning with hospital approved wipe to avoid screen erosion/cloudiness

- **Avoid** getting fluid/moisture in the test strip port or base connector.
- Dispose of wipe and gloves
- Clean hands using alcohol based hand rub or soap and water

MAINTENANCE

- Meters that do not function correctly (i.e. don't turn on, battery issues, etc) are to be returned to the POCC. A replacement meter will be assigned to the unit if required.
- Additional cleaning of the strip port may be required if QC solution or blood enters the strip port. Use a Nova StatStrip wrapped in an alcohol wipe to clean the inside of the strip port. Allow to dry thoroughly and run QC.

Appendix F: Additional Troubleshooting for the StatStrip

Error	Resolution
Discrepant Results (meter vs lab)	Discard test strips used. Do a repeat patient comparison using a new vial of test strips.
Discrepant Results (meter results vs clinical indications)	Repeat meter results and send a sample to the lab (if applicable). Use a new test strip vial for testing.
Battery Low	Place on docking station to charge
Test Strip was Removed	Test has been cancelled, repeat with a new test strip. Leave the test strip in place until the results is displayed on the screen
Temperature	Operate within range 15°C to 40°C
Bad Sample	Remove and insert a new test strip. If error code persists, use a new vial of strips or another meter.
Replace Strip	Insert another strip and retest. If error code persists, perform using a new vial of strips or another meter.
Flow Error	The specimen was incorrectly drawn into the test strip due to either insufficient or incorrect sample application. Repeat the test with a new strip.
Transfer Failed	Dock meter after use. If error persists contact POCC as connection is lost.
Replace Wrong Strip	Incorrect strip inserted/scanned for testing (i.e. using a ketone strip for glucose test)

Appendix G: Xpress Meter Installing the Battery, Setting the Date and Time

- Order battery 2450 (3-volt coin battery)
- Remove the back battery cover on the meter
- Install the coin cell battery with the + side facing up
- Replace the battery cover. All segments flash 3 times. The software version and the default date and time will appear for 3 seconds then the screen will go blank.

**** The software version may be numerical, do not report as a patient glucose result ****

Setting the Time (From powered off or sleep mode):

- Press the MODE button for longer than 3 seconds.
- Select the 24hr format by pressing the Right/left arrow buttons.
- Press the MODE button to accept the Hour format.
- The meter will display the time with the hour digits flashing.
- Press the Right/Left arrow buttons to scroll from 0 to 23.
- Press the MODE button to accept the displayed hour choice.
- Next set the minutes (digits flashing). Press the Right/Left arrow buttons to scroll from 00 to 59 minutes.
- Press the MODE button to accept the displayed minute choice.

Setting the Date

- Press the Right/left arrow buttons to toggle between DD.MM and MM-DD. (we are using MM-DD, 1-31 2013).
- Press the MODE button to accept the displayed date format.
- Next the year will flash. Press the Right/Left arrow buttons to select the current year.
- Press the MODE button to accept the displayed year.
- The month should be flashing. Press the Right/Left arrow buttons to scroll through the 12 months.
- Press the MODE button to accept the displayed month.
- The day should be flashing. Press the Right/Left arrow buttons to scroll through the days of the month.
- Press the MODE button to accept the displayed day.

Beeper On or Off

- Press the Right/Left arrow buttons to toggle between Beeper ON or OFF.
- Press the MODE button to accept the displayed ON or OFF.

End is displayed with the entered date and time. Press the MODE button for 1.5 seconds to exit Setup or the meter will timeout in 1 minute

Appendix H: Troubleshooting for the Xpress Meter

Error	Resolution
Battery is Low	A full battery is capable of performing 600 tests. A flashing blood drop and battery icon will appear on the lower left corner of the screen to alert the user to replace the battery. Approximately 10 tests can be performed before replacing the battery.
E-0 Software Error	Perform test again. If the error continues return the meter to the Point of Care coordinator.
E-1 System Hardware Error	Perform test again. If the error continues return the meter to the Point of Care coordinator.
E-2 Operating Temperature Error	Move the meter to an area with temperature between 15°C and 40°C. Allow meter temperature to adjust, and then repeat the test.
E-3 Used Strip Error	Repeat test with an unused test strip
E-4 Short Sample Error	Repeat the test with a fresh test strip and ensure enough sample/control solution is drawn into the strip
E-5 Strip Not Recognized Error	Repeat with a new test strip.
E-8 Bad Strip Error	Test strip is defective or bad. Repeat with a new test strip.
E-9 Bad Sample Error	Problem with the sample was detected. Repeat with a new test strip.

District Health Authority/IWK Policies Being Replaced

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
NOTE this is the revision of the existing policy and includes major updates including ketone testing.	