Quick Reference Guide

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⚠️ *Refer to the StatStrip Glucose Hospital Meter Instructions for Use Manual and Package Inserts for complete instructions for use, indications, precautions, and limitations of the system.*

StatStrip®

Glucose Hospital Meter System

StatStrip Glucose Hospital Meter
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CLIA WAIVED

CLIA Complexity: This StatStrip Glucose Hospital Meter System is WAIVED under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) and all applicable state and local laws must be met. Facilities performing this test must have a Certificate of Waiver and must follow the manufacturer's instructions for performing the test. If a laboratory modifies the test instructions, the test will no longer be considered waived.

Intended Use

The StatStrip Glucose Hospital Meter System is also intended for point-of-care, *in vitro* diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens throughout

all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.

It is not intended for use with neonate cord blood specimens.

It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

Capillary Precautions

- Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.
- A capillary whole blood specimen relies upon an adequate, non-compromised capillary blood flow. The healthcare

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provider must be aware that a capillary whole blood specimen glucose result may not always be the same as an arterial or a venous whole blood glucose result, especially when the patient's condition is rapidly changing.

- If a capillary whole blood glucose result is not consistent with a patient's clinical signs and symptoms, glucose testing should be repeated with either an arterial or venous specimen on the StatStrip Glucose Hospital Meter System.

- When performing a capillary heel stick glucose test on a neonate, caution should be exercised to ensure adequate blood flow to the heel. Healthcare facilities should consider unswaddling the neonate, massaging and/or warming the heel prior to specimen collection.

Limitations

- The system has not been evaluated for use with neonate venous blood.
- Blood source - Use only whole blood. Do not use serum or plasma.
- Temperature and humidity extremes - Test results may be inaccurate when test strips are stored outside of the storage and handling conditions.
- Altitudes above 15,000 feet (4,500 meters) above sea level have not been evaluated.
- Specimens - Only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.
- Fluoride, EDTA, Sodium, and Ammonium blood collection devices should not be used for arterial and venous specimens.

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The StatStrip Glucose Hospital Meter System

Refer to this Quick Reference Manual only after you have become familiar with all of the instructions in the Instructions for Use Manual.

Laser Barcode
Scanner

Touch Screen

Test Strip Port

Barcode Scanning

A built-in barcode scanner provides automated data entry. Patient ID's and lot numbers may be scanned into the meter.

To scan a barcode, hold the barcode label parallel to and approximately 2 to 6 inches from the scanner. Press the scan button on the touch screen. If the information appears on the screen at the top (Screen Title), the barcode has been successfully scanned. Press the OK button.

WARNING: *Do Not stare into the laser light or point the light towards anyone's eyes while scanning a barcode.*

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Quality Control Test

The following section explains how to run a Quality Control Test with one of the three StatStrip Glucose Control Solutions.

⚠️ **Read the StatStrip Glucose Solution package insert sheet for complete instructions, indications, precautions, and limitations of the system.**

1. From the Patient Test screen, press the QC soft key.

2. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan 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."

3. Press the Accept soft key if the lot number is correct.


Data Entry Field

Scan Soft Key

Accept Soft Key

4. The Enter QC Lot screen displays. Enter the QC lot number, select from the QC Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key.

   NOTE: *If the QC Lot Number is invalid, the screen displays the invalid number with "is not a valid QC Lot # Try again."*

Data Entry Field

Scan Soft Key
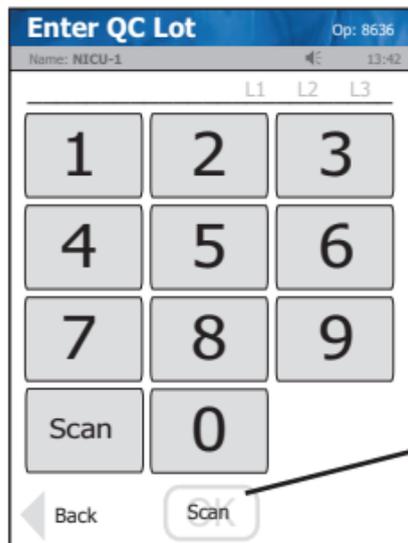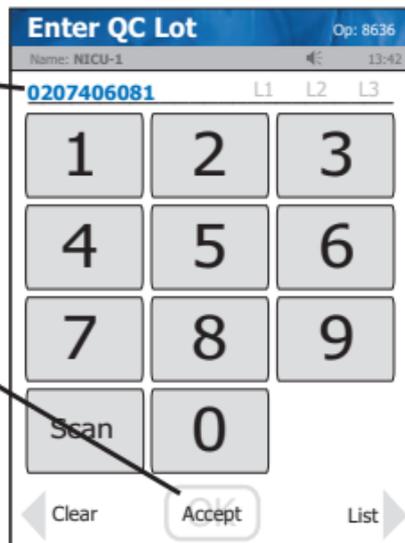
Accept Soft Key

5. Press the Accept soft key if the lot number is correct.

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6. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.

7. With the test strip correctly inserted, the Apply Sample screen displays.

8. Gently mix the StatStrip Glucose Control Solution before each use.

9. Discard the first drop of control solution from the bottle to avoid contamination.
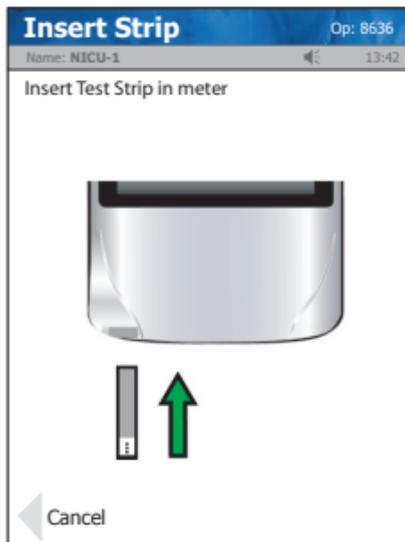
10. Place a drop of control solution from the bottle to the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter.

Apply Sample   Op: 8636

Name: **NICU-1**   13:42

Touch test strip to Level 1 QC drop

Remove test strip to cancel test

11. Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.

12. When the meter completes the test, the QC Result screen displays with the results in mg/dL (USA) or mmol/L (outside USA).

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QC Result — Op: 8636
Name: NICU-1 — 13:42
QC Lot: 0213806081
Level: **1**
Strip Lot: 0206806099
QC — Pending — 07/19 06:19

Glu

PASS

80 mg/dL

Range 72-86

Accept — Comment

QC Result — Op: 8636
Name: NICU-1 — 13:42
QC Lot: 0213806081
Level: **1**
Strip Lot: 0206806099
Patient — Pending — 07/19 06:19

Glu

PASS

4.4 mmol/L

Range 4.0-4.8

Accept — Comment

Glucose Result

Accept Soft Key

Comment Soft Key

NOTE: *Result is displayed with either PASS or FAIL, or only PASS or FAIL is displayed without the result.*

WARNING: *Do not test patient sample until a control solution test result is within expected range.*

13. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.

14. To add a comment to the result, press the Comment soft key.

15. To accept the results, press the Accept soft button.

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Add Comment to a Result (Patient, QC, Linearity)

To add a comment to a result, press the Comment soft key on the Result screen.

The Free Text Comment screen displays. Add a comment to this screen, e.g., Notified Dr. Smith or press the List soft key for list of comments.

Data Entry Field

List Soft Key

Accept Soft Key

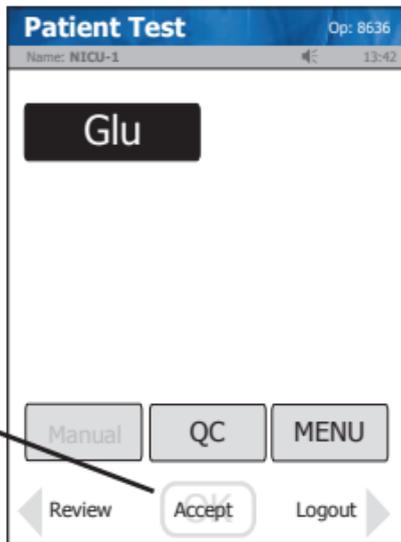To add the comment to the result and have it become part of the record, press the Accept soft key.

Running a Patient Sample

Read the Test Strip package insert sheet for complete instructions, indications, precautions, and limitations of the system.

1. From the Patient Test screen, press the Accept soft key.
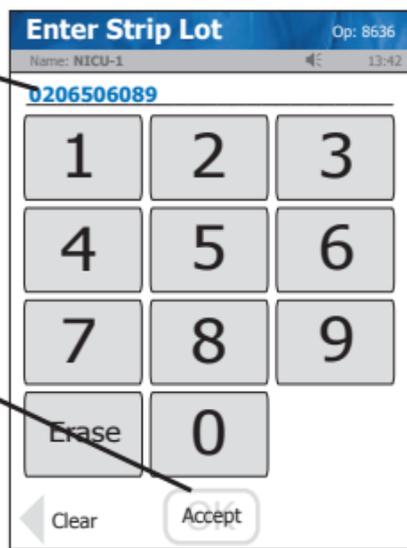
Accept Soft Key

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2. The Enter Strip Lot screen displays. Enter or scan the strip lot number.

3. Once the Lot Number has been added, press the Accept soft key.
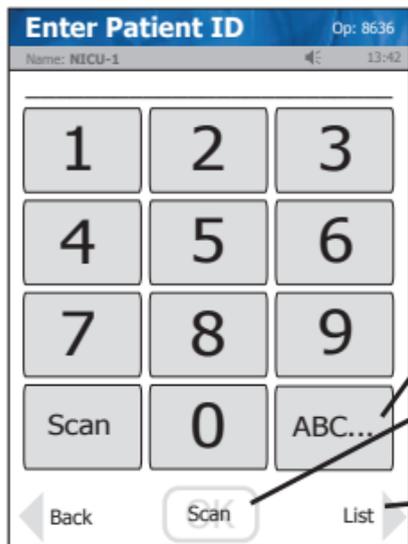
Data Enter Field

Accept Soft Key

Scan Soft Key

4. If the Physician's ID is enabled, the Enter Phys ID screen displays next. Enter the Physician's ID: from Phys ID List screen (press List soft key), by pressing numeric/ alphanumeric soft keys (press the ABC... soft key), or by scanning the barcode ID.

5. If the diagnosis code is enabled, the Enter Diagnosis Code screen displays next. Enter the code: from Diagnosis Code List screen (press List soft key), by pressing numeric/alphanumeric soft keys (press the ABC... soft key), or by scanning the barcode ID.

6. Depending on what is enabled to the meter, one of 3 screens will display: Enter Patient ID, Enter Accn Num, or Sample ID Type.

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7. If Sample ID Type is enabled, select (soft keys) Enter Accn Num (Accession Number) or Enter Patient ID: either the Enter Accn Num screen or the Enter Patient ID screen will display.

8. From the Enter Patient ID screen, enter the Patient ID: from Patient ID List screen (press List soft key), by pressing numeric/alphanumeric soft keys (press the ABC... soft key), or scanning the barcode ID.

9. From the Enter Accn Num screen, enter the Accession Number: by pressing numeric/alphanumeric soft keys (press the ABC... soft key), or by scanning the barcode ID.
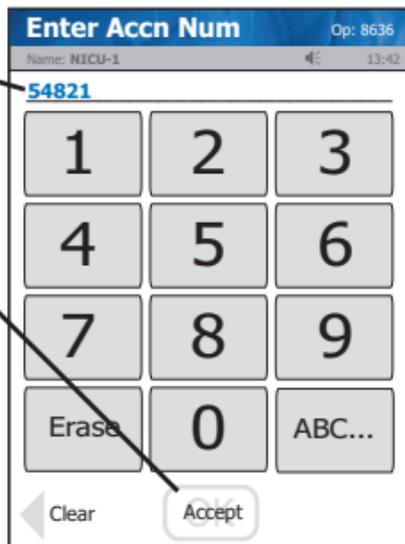
| Enter Patient ID | Op: 8636 |
| Name: NICU-1 | 🔊 13:42 |

1	2	3
4	5	6
7	8	9
Scan	0	ABC...

◄ Back   Scan   List ►

Data Entry Field

ABC... Soft Key

Accept Soft Key

Scan Soft Key

List Soft Key

| Enter Accn Num | Op: 8636 |
| Name: NICU-1 | 🔊 13:42 |

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1	2	3
4	5	6
7	8	9
Erase	0	ABC...

◄ Clear   Accept

NOTE: To scan the Patient ID, press the Scan soft key on the screen. Then scan the patient's barcode ID with the bottom of the meter.

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10. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.

11. The Insert Strip screen displays. Insert a test strip as shown on the meter screen.

Insert Strip   Op: 8636

Name: **NICU-1**   13:42

Insert Test Strip in meter

Cancel
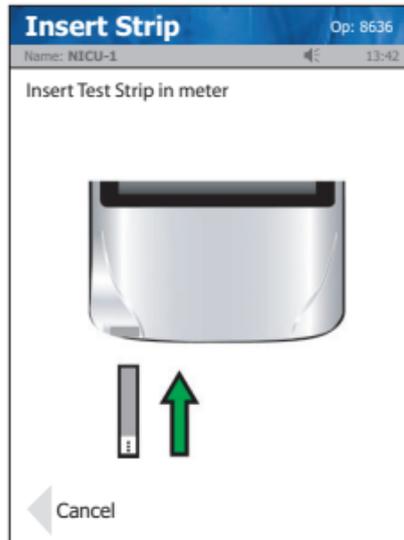
12. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.
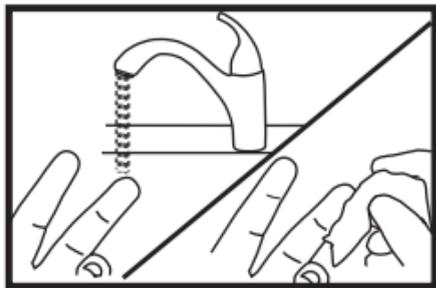
13. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

14. Use the single-use, auto-disabling Safety Lancet to puncture the finger.
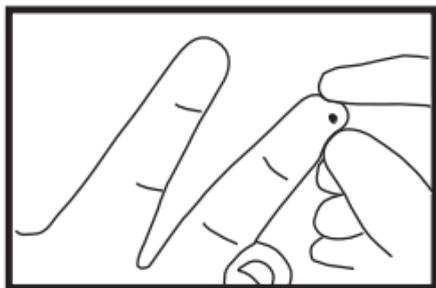
15. Squeeze the finger to form a drop of blood. Wipe away the first drop of blood, then squeeze the finger again to form a second drop of blood.

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16. The Apply Sample screen should be displaying. When the blood drop 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.

Apply Sample   Op: 8636

Name: **NICU-1**   13:42

Touch test strip to blood drop

Remove test strip to cancel test

*WARNING: The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, **do not touch the test strip to the blood droplet a second time.** Discard the test strip and repeat the test with a new strip.*
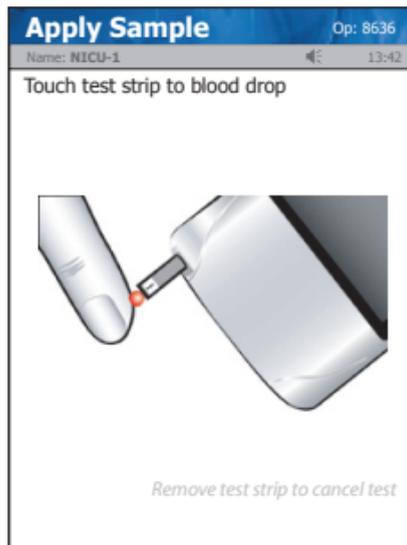
17. The test results will appear in 6 seconds.

NOTE: *Do not remove the test strip while the countdown is in progress.*

NOTE: *A single up arrow displays for abnormal high result and 2 up arrows for critical high value.*
A single down arrow displays for abnormal low result and 2 down arrows for critical low value.

18. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.

19. To accept the result, press the Accept soft key.
To reject the result, press the Reject soft key. To add a comment, press the Comment soft key (See *Section 2.4 Add Comment to a Result* in the Instructions for Use Manual.) All data are stored into memory.

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Review Result — Op: 8636
Name: NICU-1 — 13:42
Pt ID: 774615128
Patient Name
Strip Lot: 0206806099
Patient — Pending — 07/19 06:19
Glu
102 mg/dL
Normal 70-109
Reject — Accept — Comment

Patient Result — Op: 8636
Name: NICU-1 — 13:42
Pt ID: 194546646
Patient Name
Strip Lot: 0206806099
Patient — Pending — 07/19 06:19
Glu
5.7 mmol/L
Normal 3.9-6.1
Reject — Accept — Comment

Glu Result

Comment Soft Key

Accept Soft Key

Reject Soft Key

20. When patient testing is completed, the StatStrip Glucose Hospital Meter System should be cleaned and disinfected after use prior to testing with a new patient. For cleaning and disinfecting instructions, see page QR-30 or *Section 6.3* in the Instructions for Use Manual.

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Docking/Charging Station

When the meter is not in use, place it into the Docking/ Charging Station. This enables the meter to stay fully charged and connects the meter to the computer network. When the Battery LOW symbol displays on the screen, place the meter into the Docking/Charging Station. If you have a spare battery that is already fully charged, change the battery.

- The left, green light is on if the station is connected to the network.
- The middle, green light is on if data is transferring.
- The right light is green for fully charged or amber for charging.

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Changing the Battery

> *NOTE:* *Each StatStrip Battery has an expiration date printed on the outside of the battery case. A battery beyond its expiration date indicates the maximum charge of the battery may be less than 60% of its original capacity. The battery will function well beyond that date, but with lower maximum charge. Replace the battery when battery life is no longer acceptable for clinical use.*

If you have a spare fully charged battery, it can be changed to allow for continuous operation.

WARNING: *Replace the battery with Nova P/Ns 46827 or 50436 only. Using another battery may present a risk of fire or explosion. If discarding, dispose of the battery promptly. Keep the battery away from children.*

1. Press the Power button to enter the Sleep Mode. This will allow the operator approximately 20 seconds to change the battery and not lose date/time settings.

    NOTE: *If it takes longer than 20 seconds to change the battery, power up the meter, login, and set the date and time: see the Glucose Meter Instructions for Use Manual.*

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

3. Remove the drained battery.

4. Replace with a fully charged battery.

   NOTE: The battery is keyed to allow only insertion from bottom first then push in top.

5. Replace the battery cover.

6. Place the drained battery into the Charging Station.

Cleaning and Disinfecting the Meter

For Technical Support in the **USA dial (800)-545-6682.** Outside the USA, contact you local Nova dealer.

The StatStrip Glucose Hospital Meter should be cleaned and disinfected after each patient use to minimize the risk of transmission of blood-borne pathogens between patients and healthcare professionals.

Healthcare professionals and others should follow Good Laboratory Practice guidelines and these important safety instructions.

Healthcare professionals should ensure they are wearing protective gloves when disinfecting the meter and should sanitize their hands following approved guidelines after handling the meter.

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Acceptable Cleaning and Disinfecting Materials

Nova Biomedical recommends the use of Clorox Healthcare® Bleach Germicidal Wipes, EPA Registration #67619-12, or any disinfectant product with EPA Registration #67619-12, and Super Sani Disposable Wipes (Sani Wipes) EPA Registration #9480-4.

The disinfectants were validated separately; therefore, only one disinfectant should be used on the device each time it is cleaned and disinfected as the effect of using more than one disinfectant interchangeably has not been evaluated.

The StatStrip Glucose Hospital Meter cleaning and disinfection procedure was validated a total of 10,950 times to simulate a 3-year use life of 10 patient tests per day 365 days per year.

Meter Cleaning and Disinfection Procedure

Clean and disinfect after each patient use following this protocol to help ensure effective cleaning and disinfection. Cleaning is not the same as disinfecting. Disinfecting means to kill or prevent the growth of disease carrying microorganisms.

Prepare

Make sure the test strip is removed from the meter.

WARNING: *To ensure proper disinfection, it is important to clean the meter (Step 1) prior to disinfecting the meter (Step 2).*

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1. **Clean the Meter.**
   - Remove a fresh germicidal wipe from the canister.
   - Wipe the external surface of the meter thoroughly with a fresh germicidal disinfecting wipe. Discard the used wipe into an approved waste container.

2. **Disinfect the Meter.**
   - Using a new, fresh germicidal wipe, thoroughly wipe the surface of the meter (top, bottom, left, and right sides) for example, a minimum of 3 times horizontally and 3 times vertically, avoiding the bar code scanner and electrical connector.
   - Gently wipe the surface area of the test strip port making sure that no fluid enters the port.

3. **Observe surface contact time.**
   • Ensure the meter surface stays wet **for 1 minute (Clorox Wipes)** or **for 2 minutes (Super Sani Wipes)** then allow to air dry for an additional **1 minute.**

4. **Dispose of wipe and gloves.**
   • Dispose of used wipe and gloves in an approved waste container.

5. **Sanitize hands.**
   • Sanitize your hands thoroughly following approved guidelines and put on a fresh set of protective gloves before proceeding to perform testing on the next patient.

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Additional information

WARNING: *Do not allow liquid to enter the strip port connector or allow pooling of liquid on the touch screen. If liquid does get into the strip port or connector, immediately dry the components with a dry cloth or gauze.*

WARNING: *Do not spray the meter directly with solutions as this could cause the solution to enter the case and damage the electronic components.*

*WARNING:* *Do not immerse the meter or hold the meter under running water.*

WARNING: *Cleaning and disinfection may in rare cases damage the meter. Damage may include plastic housing cracks, cloudiness or frosting of the display, response issues with the display, battery compartment fluid leakage, or test port damage. Signs of meter performance deterioration may include failure to recover proper control solution results or the inability to perform a blood glucose test. If you observe damage due to cleaning and disinfection, stop using the meter and contact Nova Technical Support at 800-545-6682.*
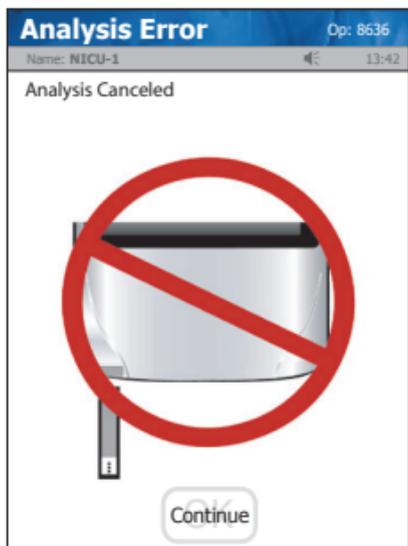
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Troubleshooting

The StatStrip Hospital Meter displays screen alerts.

1. **Battery Low:** Change the battery or place the meter into the Charging Station.
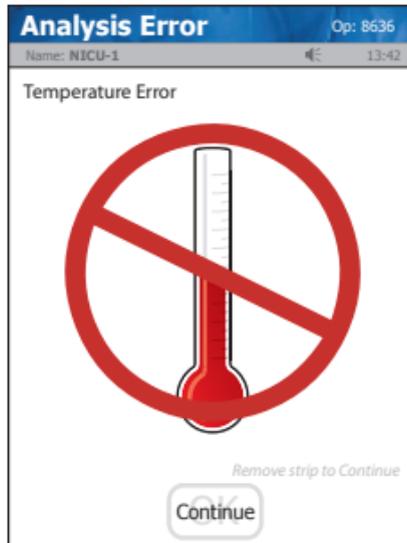
Battery Low Icon
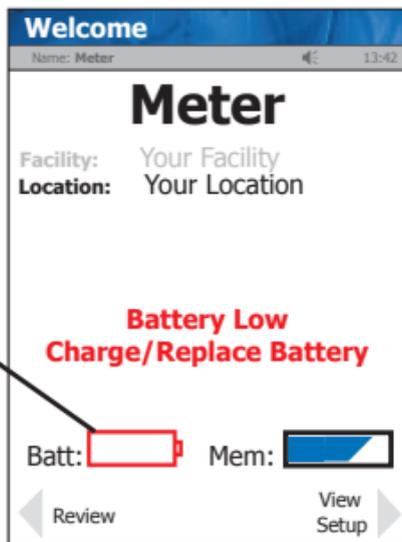
2. **Analysis Cancelled:** The test has been cancelled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.

3. **Temperature:** Meter will only work within the temperature range of 59°F to 104°F (15°C to 40°C). Return the meter to an environment within the specified temperature range of 59°F to 104°F (15°C to 40°C).

4. **Bad Sample:** Insert a new strip and rerun the test. If the error code persists, perform the test using an alternate test strip vial or alternate method.
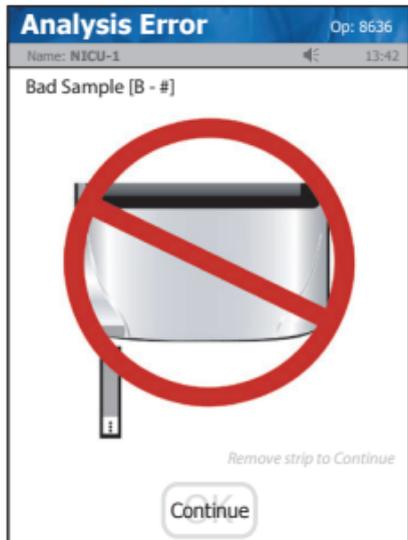
5. **Replace Strip:** Occurs after insertion of strip or occurs during analysis. Insert another strip and retest. If the error code persists, perform the test using an alternate test strip vial or alternate method.

6. **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. If the error code persists, perform test using an alternate method.
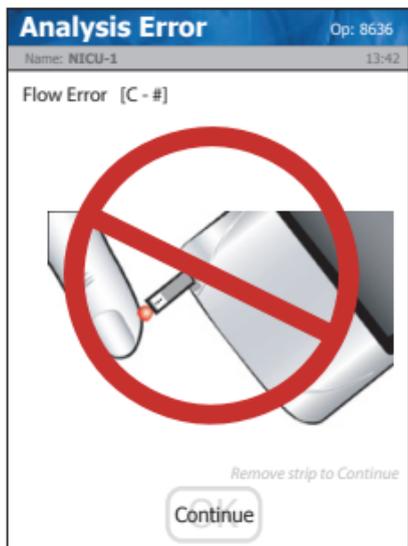
7. **Transfer Failed:** Server refuses to allow dialog with meter, or Connection to server was broken. Please check the network settings, status of your network, or contact your administrator for assistance.
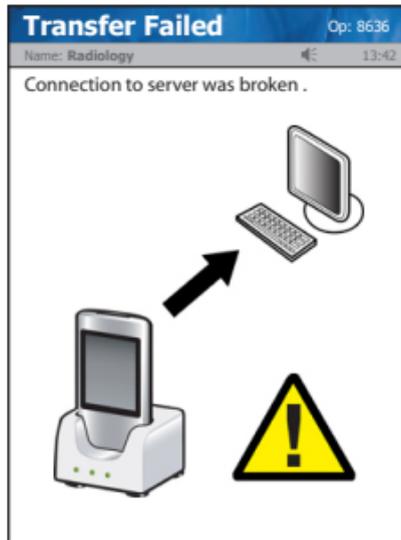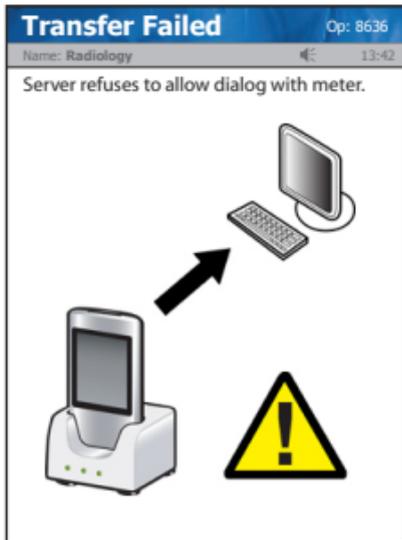
8. **Transfer Failed:** The meter was removed before data transfer was complete. Please re-dock the meter.

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For technical assistance outside the United States, call your local Nova subsidiary or authorized distributor.

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