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

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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 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.

The StatStrip Glucose Hospital Meter System includes the following components:

- StatStrip Glucose Hospital Meter
- StatStrip Glucose Test Strips

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 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 (4,572 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.
- It is not intended for screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
- The system has not been evaluated with alternative site testing (AST).

- The system has not been evaluated for use in Tight Glycemic Control protocols as reported in the Greet Van den Berghe or NICE-SUGAR (Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation) studies.[1,2,3,4]
- Glucose results from alternative sampling sites should not be used to calibrate continuous glucose monitoring systems (CGMS) or entered into insulin dose calculators for dosage recommendations.
- Only auto-disabling, single-use lancing devices may be used with this device.

1 Van den Berghe, G. et al. Intensive Insulin Therapy in Critically ill Patients. N Engl J Med. 2001; 345:1359-1367

2 Van den Berghe, G. et al. Intensive Insulin Therapy in the Medical ICU. N Engl J Med. 2006; 354:449-461

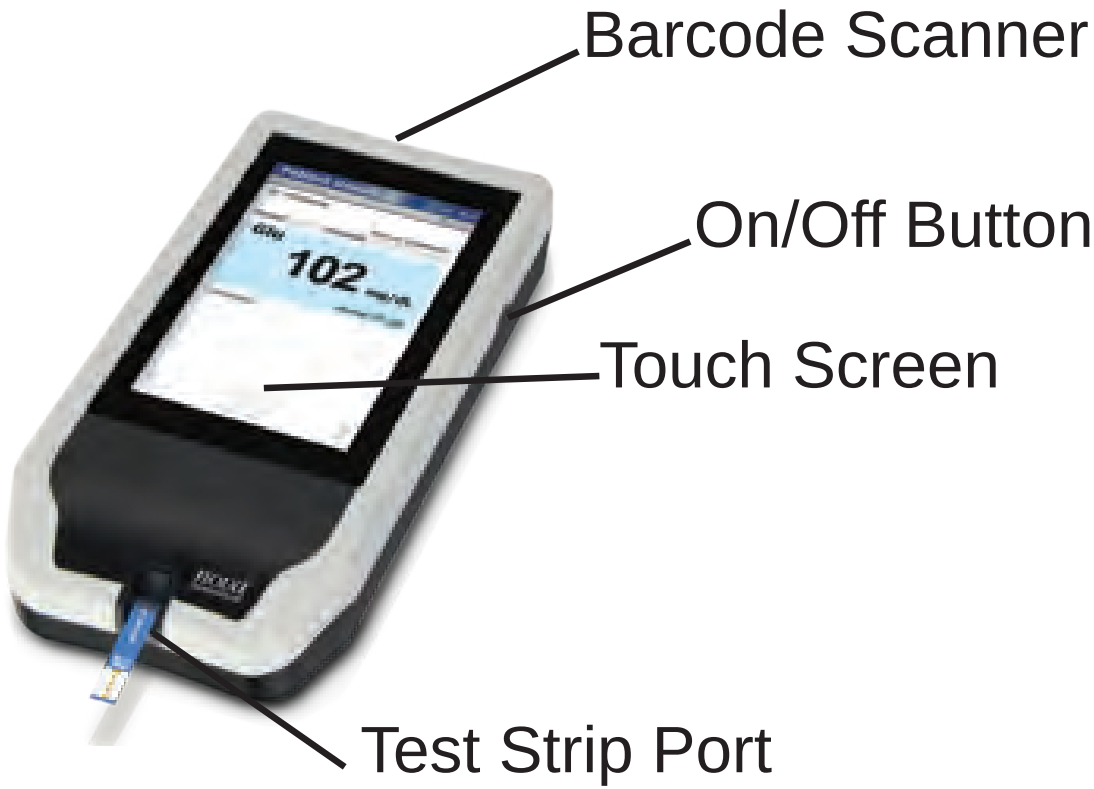
3 The NICE-SUGAR Study Investigators. Intensive versus Conventional Glucose Control in Critically Ill Patients. N Engl J Med. 2009; 360:1283-1297

4 Van den Berghe, G. et. al. Intensive Insulin Therapy in Critically Ill Patients: NICE-SUGAR or Leuven Blood Glucose Target. J Clin Endocrinol Metab. 2009; 94(9): 3163-3170

- Ranges for the StatStrip Glucose Hospital Meter using other commercially available glucose controls have not been established and may give erroneous results.

The StatStrip Glucose Hospital Meter System

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



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 light or point the light towards anyone's eyes while scanning a barcode.

Quality Control Test

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

When to Perform a Quality Control Test:

Run 2 different levels of the StatStrip Glucose Control Solutions during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

- During institutional training of each new operator
- Before using your meter for the first time
- If a patient test has been repeated and the blood glucose 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).
- As required by the institution's quality control policy or local regulatory requirements, state and federal guidelines.

The StatStrip Glucose Control Solution should produce results that fall within the range of results printed on the control vial. If a control test results are within the range, the meter will display PASS. If the control solution test result is outside the range (is either higher or lower), the meter will display FAIL. If the control test fails, the glucose meter and test strip may not be working as a system.

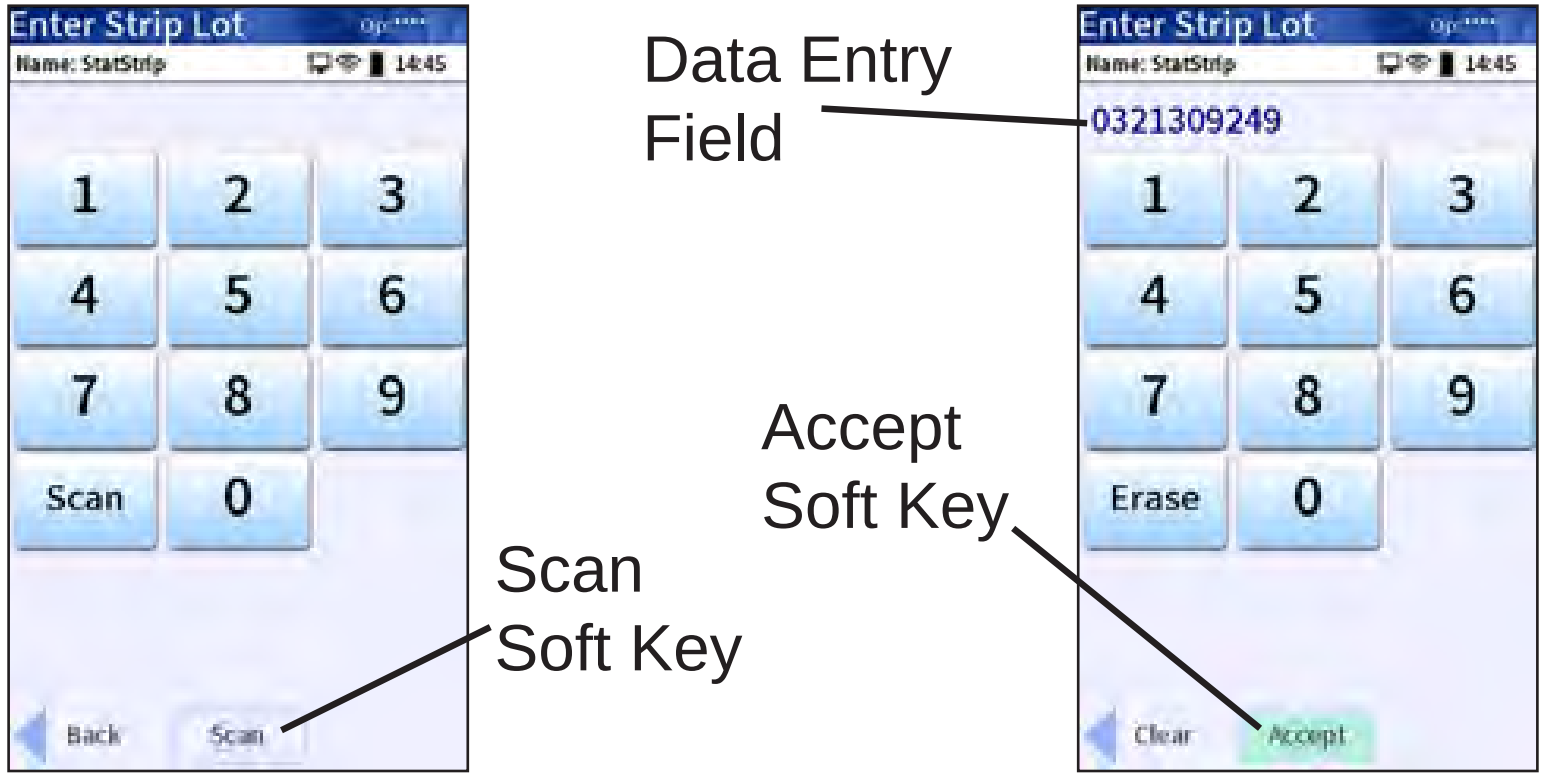
How to Perform a Quality Control Test

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."*

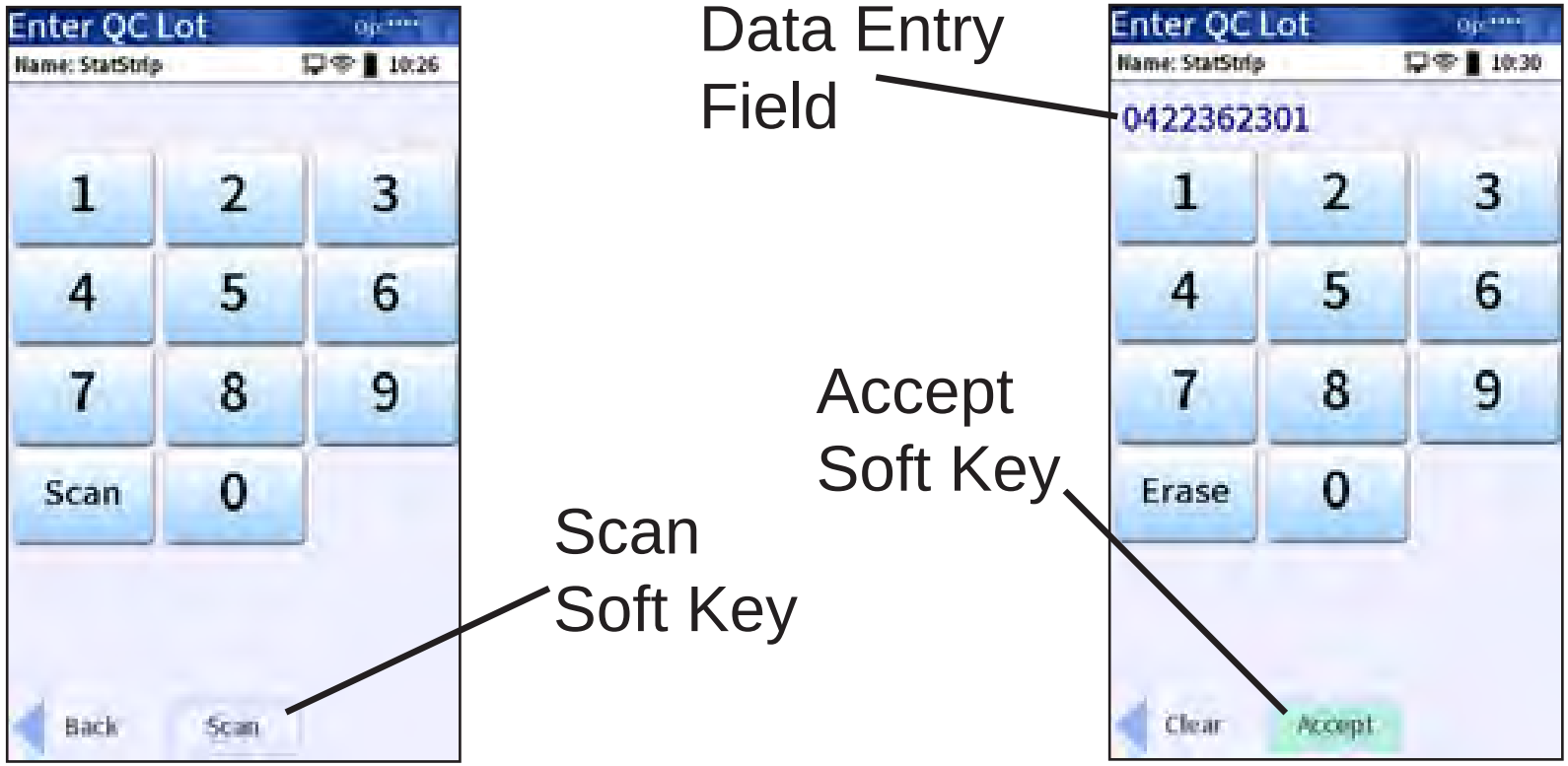
3. Press the **Accept** soft key if the Lot Number is correct.



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."*

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

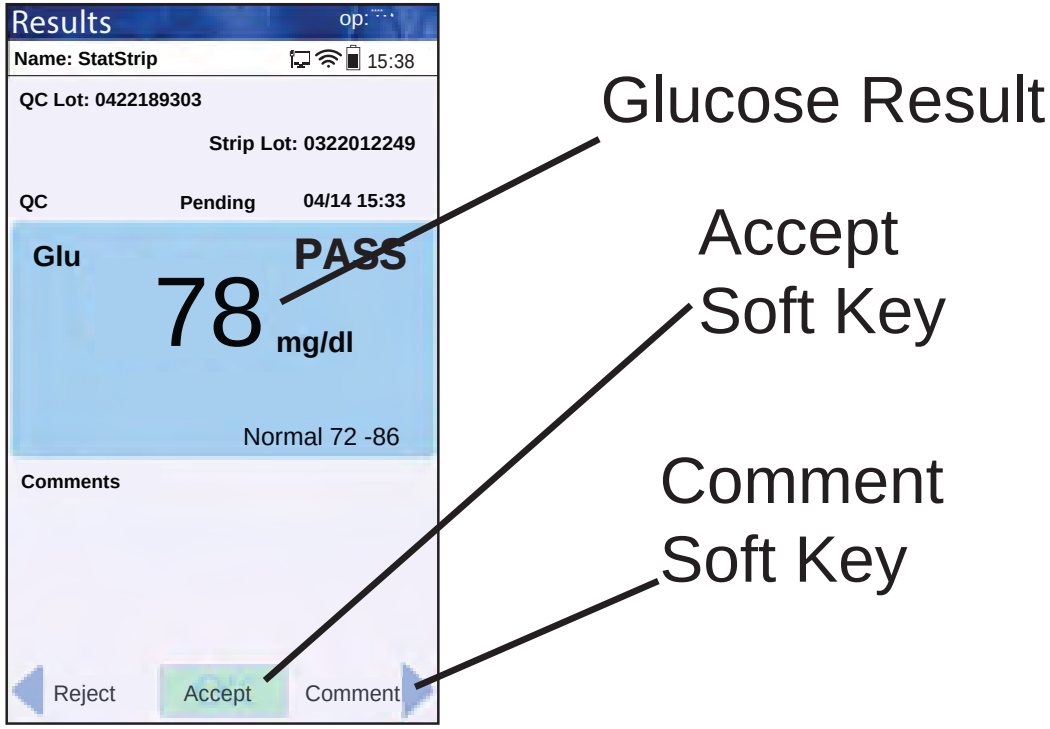


6. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.
7. With the test strip correctly inserted, the Apply Sample screen displays.
8. Gently mix the StatStrip Glucose Control Solution before each use.
9. Discard the first drop of the control solution from the bottle to avoid 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.
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).

NOTE: *The 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 the 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.

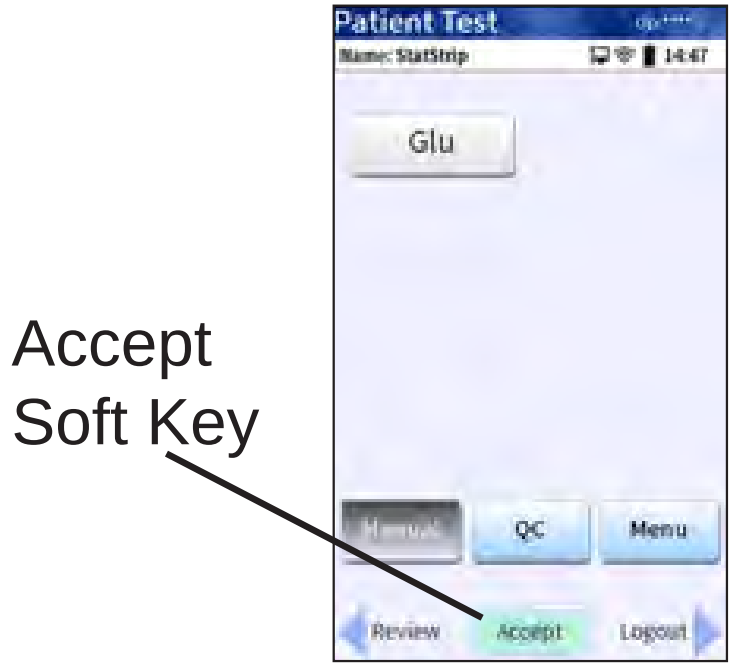
Add Comment to a Result (Patient, QC, Linearity)

1. To add a comment to a result, press the **Comment** soft key on the Result screen.
2. 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.
3. 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.

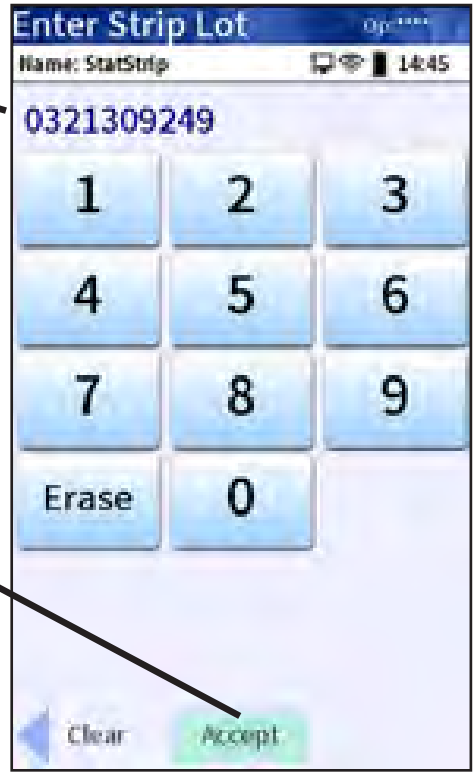


2. The Enter Strip Lot screen displays. Enter or scan the Strip Lot Number.
3. Once the Lot Number has been added, press the **Accept** soft key.

Data Enter Field

Accept Soft Key

Scan Soft Key

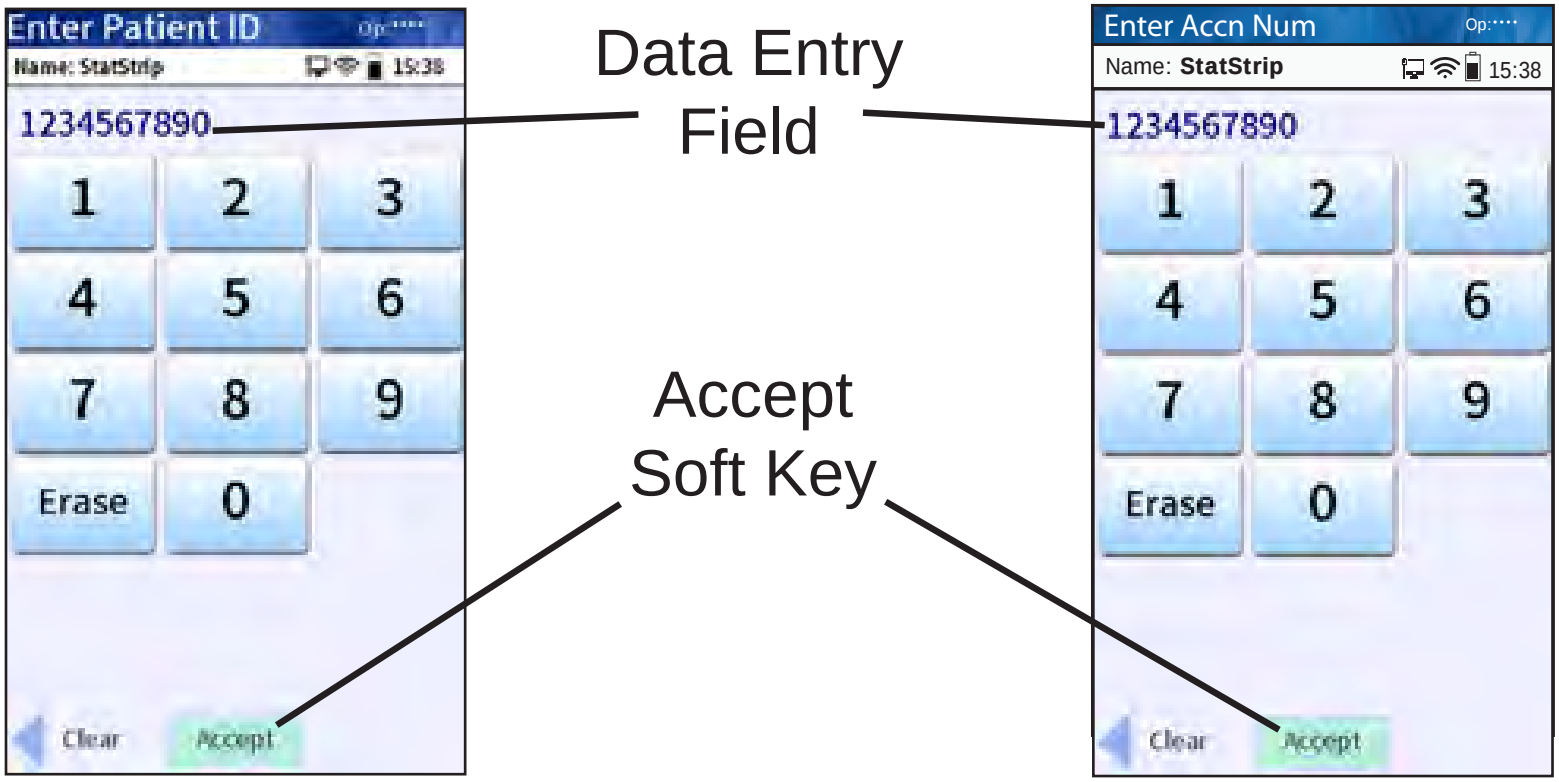


4. If the Physician's ID is enabled, the Enter Phys ID screen displays next. Enter the Physician's ID: from Phys ID List screen (press **List** soft key), by pressing numeric/ alphabetic soft keys (press the **ABC...** soft key), or by scanning the barcode ID.
5. If the diagnosis code is enabled, the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

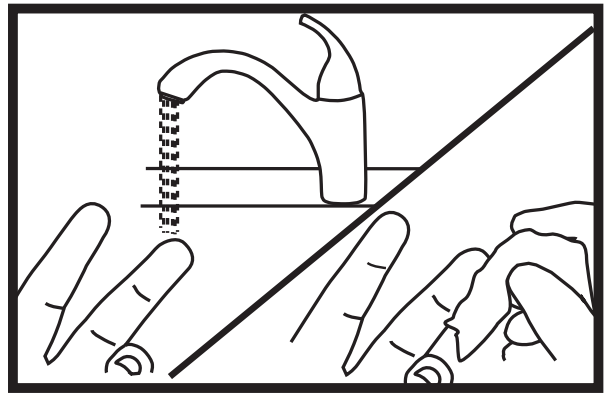
7. If Sample ID Type is enabled, select (soft keys) **Enter Accn Num** (Accession Number) or **Enter Patient ID**; either the Enter Accn Num screen or the Enter Patient ID screen will display.
8. From the Enter Patient ID screen, enter the Patient ID: from Patient ID List screen (press **List** soft key), by pressing numeric/alphabetic 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/alphabetic soft keys (press the **ABC...** soft key), or by scanning the barcode ID.

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

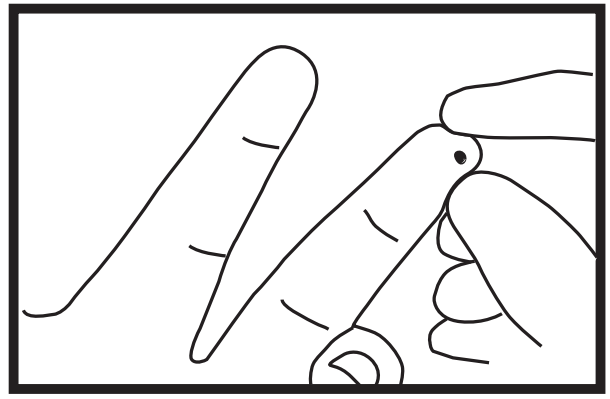
10. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.



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



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.

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.*

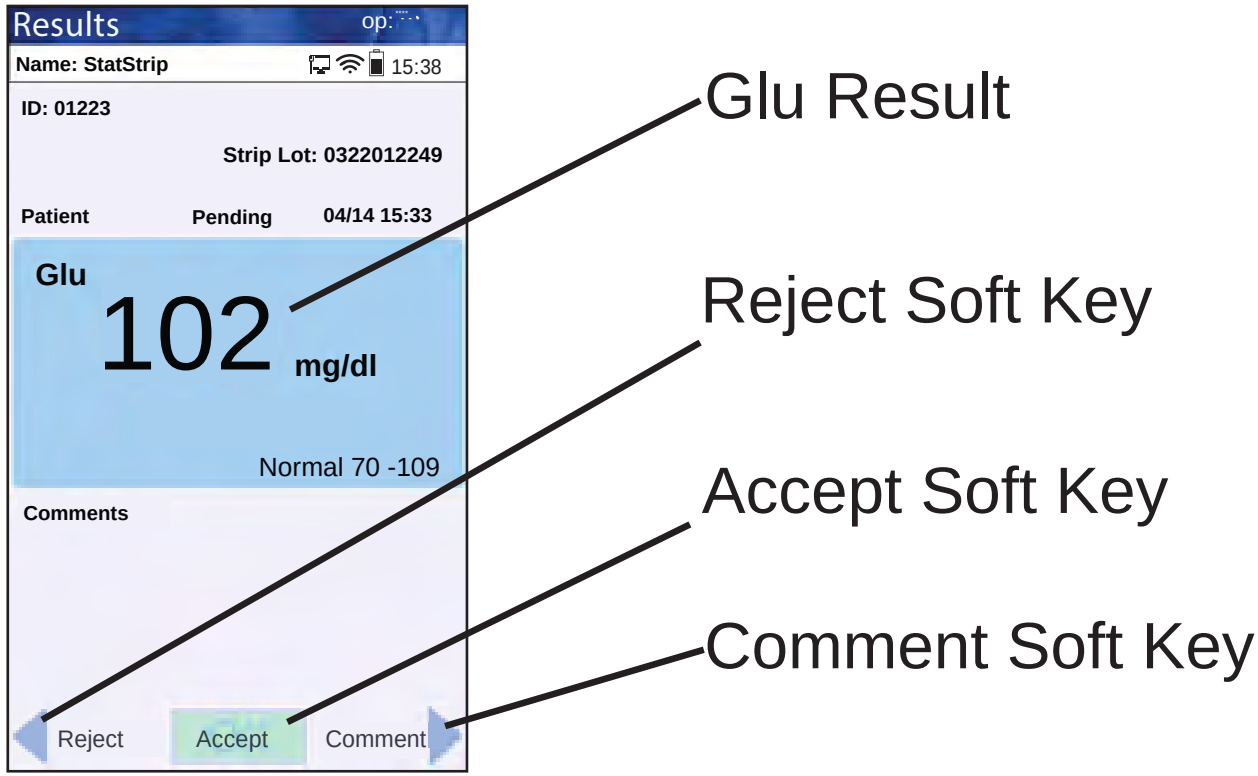
    NOTE: *A single up arrow displays for abnormal high result and 2 up arrows for critical high value.*

    NOTE: *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 Result in IFU Manual)*.

All data are stored into memory.



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

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.

- There is one LED light on the docking station. The green blinking light indicates that the meter is charging.

Battery Issues

In case of any issues with the battery, the users are requested to return the meter to Nova Biomedical for repairs and replacements.

This can be done by contacting Nova's Technical Support team to resolve the issues.

In the USA, please contact Nova Biomedical Technical Support at 1-800-545-6682. Outside the USA, contact your local dealer.

Cleaning and Disinfecting the Meter

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

WARNING: 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.

Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system

should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to *“2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings".*

The meter should be cleaned and disinfected following the manufacturer’s instructions after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer’s cleaning and disinfection procedures are followed.

Only auto-disabling, single use lancing devices may be used with this device.

Healthcare professionals should ensure they are wearing protective gloves when disinfecting the meter and should wash their hands thoroughly with soap and water after handling the meter.

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 may be used.

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.

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

Meter Cleaning and Disinfection Procedure

Clean and disinfect after each patient use by 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.

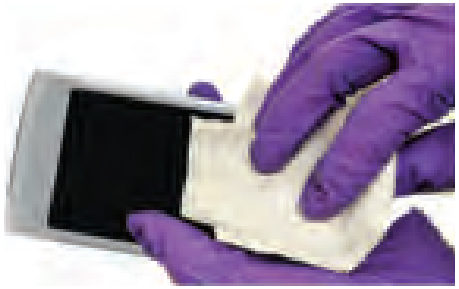
Prepare

Make sure the test strip is removed from the meter. Lay the meter on a flat surface prior to cleaning and disinfecting the meter.

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

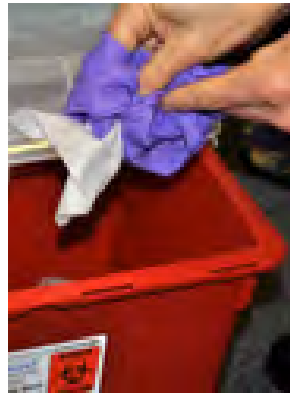
1. **Clean the Meter.**
   - Remove a fresh germicidal wipe from the canister.
   - Wipe the external surface of the meter thoroughly with a fresh germicidal disinfecting bleach wipe. Discard the used wipe into an appropriate biohazard container.

2. **Disinfect the Meter.**
   - Using a new, fresh germicidal bleach wipe, thoroughly wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 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)** and let air dry for an additional **1 minute**.



4. **Dispose of wipe and gloves.**
   - Dispose of used wipe and gloves in a standard biohazard container.
5. **Wash and sanitize hands.**
   - Wash your hands thoroughly with soap and water, and put on a fresh set of protective gloves before proceeding to perform testing on the next patient.

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.***

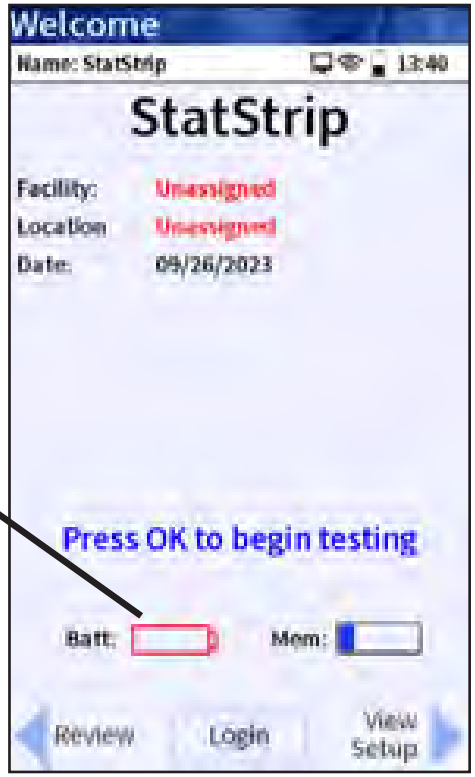
WARNING: ***Cleaning and disinfection may in rare cases damage the meter. Damage may include plastic housing cracks, cloudiness or frosting of the display, response issues with the display, battery compartment fluid leakage, or test port damage. Signs of meter performance deterioration may include failure 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.***

Troubleshooting

The StatStrip Hospital Meter displays screen alerts.

1. **Battery Low** - Place the meter into the Charging Station.

Battery Low Icon



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2. **Analysis Canceled** - The test has been canceled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.

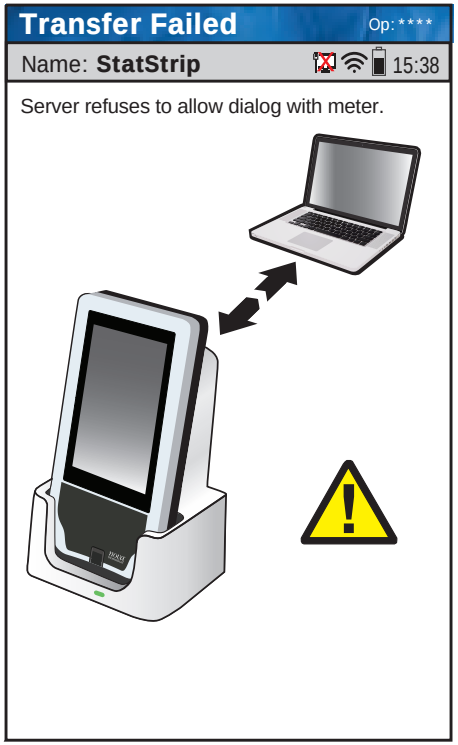
3. **Temperature** - The meter will only work within the temperature range of 59°F to 104°F (15°C to 40°C). **Return the meter to an environment within the specified temperature range of 59°F to 104°F (15°C to 40°C).**

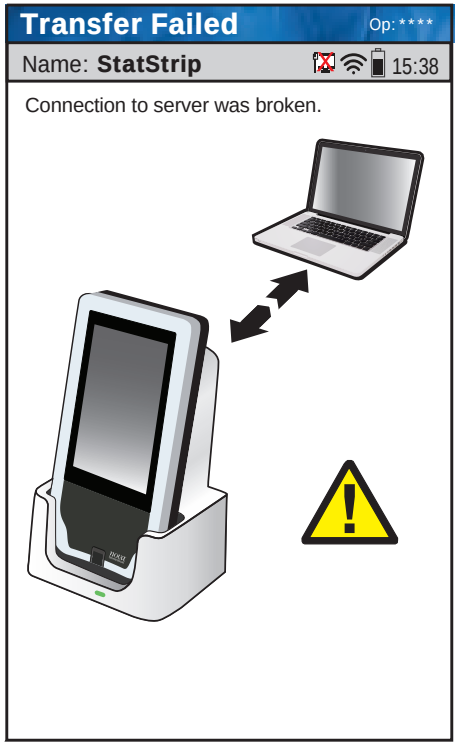
4. **Bad Sample** - Insert a new strip and rerun the test. **If the error code persists, perform the test using an alternate test strip vial or an alternate method.**

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 an 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 a 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, the status of your network, or contact your administrator or Nova Biomedical customer support if an administrator is not available.**





8. **Transfer Failed** - The meter was removed before the data transfer was complete. Please re-dock the meter.

Disposal Information

Disposal of Used Meters & Batteries

The meter may become infectious during the course of use. Discard in accordance with local regulations for biohazardous electronic waste.

Dispose biohazardous waste in accordance with institutional, local, state, and national regulatory guidelines.

NOTE: *Since the battery is internally part of the meter and not user-replaceable, it should be considered as part/component of the meter itself. Hence, the meter (including the battery) must be disposed as biohazardous* electronic *waste and not treated as household waste.*

Consider recycling the meter at an appropriate facility. Be aware the meter is potentially a biohazardous electronic waste and should be disposed of accordingly.

WARNING: Disinfect the meter before recycling or discarding.

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

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StatStrip® Glucose Hospital Meter

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