REF 41853

IVD CE

Instructions for Use Manual

Stat Strip®

Glucose Hospital Meter

nova® biomedical

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

Manufactured by

LOT — Batch code

CE — Product fulfills the requirements of Directive 98/79 EC (IVDD)

CONTROL — Control

SN — Serial Number

Caution, consult accompanying documents

LEVEL — Level

Temperature limitation

Consult instructions for use

EC REP — Authorized Representative in the European Community

Upper Limit of Temperature

Biological risk

Laser Radiation - Do Not Stare Into Beam
Class II Laser Product
Wavelength: 650 nm
Max. Output : 1.2 mW

Use by (last day of the month)
YYYY - MM

REF — Catalog number

Electronic Waste

StatStrip® Glucose Meter Instructions for Use Manual

Ordering Information

The *StatStrip® Glucose Hospital Meter Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Write or call:

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U.S.A.

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+1-781-899-0417 (outside the U.S.A.)
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EC REP Authorized Representative

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Trademark and Patents

StatStrip is a registered trademark of Nova Biomedical Corporation.
The Nova StatStrip Glucose Hospital Meter is patented by the following patents:
US Patent Numbers. 6,258,229; 6,837,976; 6,942,770;
CA Patent Numbers: 2,375,089; 2,375,092.

Copyright

Technical Assistance

For technical assistance inside the United States, call Nova Biomedical Technical Services at:

U.S.A.: 1-800-545-NOVA 1-781-894-0800 or
FAX: 1-781-894-0585

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Contents

1 Introduction

CLIA Complexity: This test is WAIVED for finger stick whole blood, venous, and arterial whole blood under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Laboratories with a Certificate of CLIA waiver can perform this test in a waived setting 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. (Refer to Appendix A.7, Results of CLIA Waiver Study.)

CAUTION: *Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.*

This manual provides all necessary instructions for the routine operation and maintenance of the StatStrip Glucose Hospital Meter. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Meter.

WARNING: Healthcare professionals and others using this system on multiple patients should be aware that all products or objects that come into contact with human blood should be handled as if capable of transmitting viral diseases, even after cleaning.

This section introduces the meter and covers requirements, tests performed, procedural limitations, clinical utility, and sample handling.

The StatStrip Glucose Hospital Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose electrochemical test strips to measure glucose in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. In addition to measuring glucose, the meter stores patient test data, QC test data, and other information relating to patient, patient sample, operator, reagents, and the meter. A user interface provides for a self-prompting environment via a color LCD. The Charging Station recharges the batteries of the meter.

1.1 About This Manual

This manual is for the Nova Biomedical StatStrip Glucose Hospital Meter.
Throughout this manual, *NOTE:* indicates especially important information, *CAUTION:* indicates information that is critical to avoid instrument damage or incorrect results, and *WARNING:* indicates possible hazard to the operator.

1.2 Safety

Personnel operating this meter must be proficient in the operating and maintenance procedures of the meter. The following safety procedures must be followed.

General Safety

1. Read the safety and operating instructions before operating the meter.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the meter and in the operating instructions.
4. Follow all operating and use instructions.
5. Place the meter away from heat sources.
6. Connect the meter to the Charging Station, as described in the operating instructions.
7. The meter should be cleaned only as recommended by the manufacturer.
8. The meter should be serviced by qualified service personnel.

Electrical Safety

1. Battery powered: 3.7 V Li Polymer battery (rechargeable/replaceable)
2. Desk-mount Charging Station
3. An LED indicator light to show the battery is charging: yellow indicates charging and green indicates fully charged.
4. Extra battery slot recharges and stores spare battery. An LED indicates the spare battery is charging or charged: amber indicates charging and green indicates fully charged.

WARNING: *The battery used in this meter may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate.*

Disposal of Used Batteries for customers in Europe.

- This symbol  on the battery label indicates that the battery provided with the meter should not be treated as household waste. To ensure the used battery is treated properly, remove the used battery from the meter and hand over the used battery to the applicable collection point for the recycling of electrical and electronic equipment.

Disposal of Used Meters for customers in Europe.

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

Chemical and Biological Safety

1. Observe all precautionary information printed on the original solution containers.
2. Operate the meter in the appropriate environment.
3. Dispose of all waste solutions according to standard hospital procedures.

Environmental

- The operating temperature range for Meter operation: 59˚F to 104˚F (15˚C to 40˚C)
- The relative humidity range for Meter operation: up to 90% non-condensing
- The maximum altitude for Meter operation: Up to 15,000 feet (4500 meters)

Dimensions:

Height: 153 mm (6.0 in)
Width: 82.5 mm (3.25 in)
Depth: 46 mm (1.8 in)

Weight:

360 g (0.8 lb)

1.3 Intended Use and Tests Performed

Intended Use

The Nova StatStrip Glucose Hospital Meter System is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of Glucose (Glu) in whole blood. Nova StatStrip Test Strips may be used to test capillary, venous, arterial, and neonate blood samples. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

Nova StatStrip Glucose Test Strips are intended for use only with the StatStrip Glucose Hospital Meter System for quantitative tests. The glucose meter is intended to quantitatively measure glucose (sugar) in whole blood. The Glucose Meter is calibrated to provide plasma equivalent results to laboratory methods. Nova StatStrip Glucose Test Strips are for testing outside the body (*in vitro* diagnostic use only).

Nova StatStrip Glucose Control Solution is intended for use with the Nova StatStrip Glucose Hospital Meter and Nova StatStrip Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls, (Level 1, Level 2, and Level 3). These solutions are offered for sale separately from the meter.

Nova StatStrip Glucose Linearity Kit solutions are used to check the linearity of the Nova StatStrip Glucose Hospital Meter System.

1.4 The Sample

- Capillary, venous, arterial, and neonate whole blood
- Plasma calibrated patient test results
- Sample size 1.2 µL
- Anticoagulants: sodium, lithium, and ammonium heparin

1.5 Interfering Substances

Glucose Interferences:
The StatStrip Glucose Hospital Meter exhibits **no** interference from the following substances up to the following concentration levels:

Tested Interfering Substances	Tested Concentration Level
Acetaminophen	10.0 mg/dL 0.66 mmol/L
Ascorbic Acid	10.0 mg/dL 0.57 mmol/L
Bilirubin	15.0 mg/dL 0.26 mmol/L
Cholesterol	500.0 mg/dL 12.9 mmol/L
Creatinine	6.0 mg/dL 0.53 mmol/L
Dopamine	10.0 mg/dL 0.53 mmol/L
Ephedrine	0.9 mg/dL 0.055 mmol/L
D(+) Galactose	350.0 mg/dL 19.4 mmol/L
Hematocrit (RBC)	20% - 65%
Ibuprofen	48.0 mg/dL 2.33 mmol/L
L-Dopa	100.0 mg/dL 5.07 mmol/L
D(+) Maltose Monohydrate	240.0 mg/dL 6.66 mmol/L
D(+) Maltotetraose	240.0 mg/dL 3.6 mmol/L
D(+) Maltotetriose	240.0 mg/dL 4.76 mmol/L
Methyl-Dopa	1.0 mg/dL 0.042 mmol/L
Oxygen	All Concentrations
Salicylate	30.0 mg/dL 1.87 mmol/L
Tetracycline	30.0 mg/dL 0.62 mmol/L
Tolazamide	15.0 mg/dL 0.48 mmol/L
Tolbutamide	45.0 mg/dL 1.67 mmol/L
Triglycerides	750.0 mg/dL 8.78 mmol/L
Uric Acid	20.0 mg/dL 1.05 mmol/L

1.6 Operation Overview

The meter uses a touch screen and 3-button keypad for menu navigation and data entry. An on-screen keypad allows manual data entry of alphanumeric characters. Pressing the Sleep button either places the meter into a power saving Sleep Mode or Wakes the meter for use. The Scan/Home buttons, one on each side of the meter, are used to scan in barcode data or return to the Welcome screen.

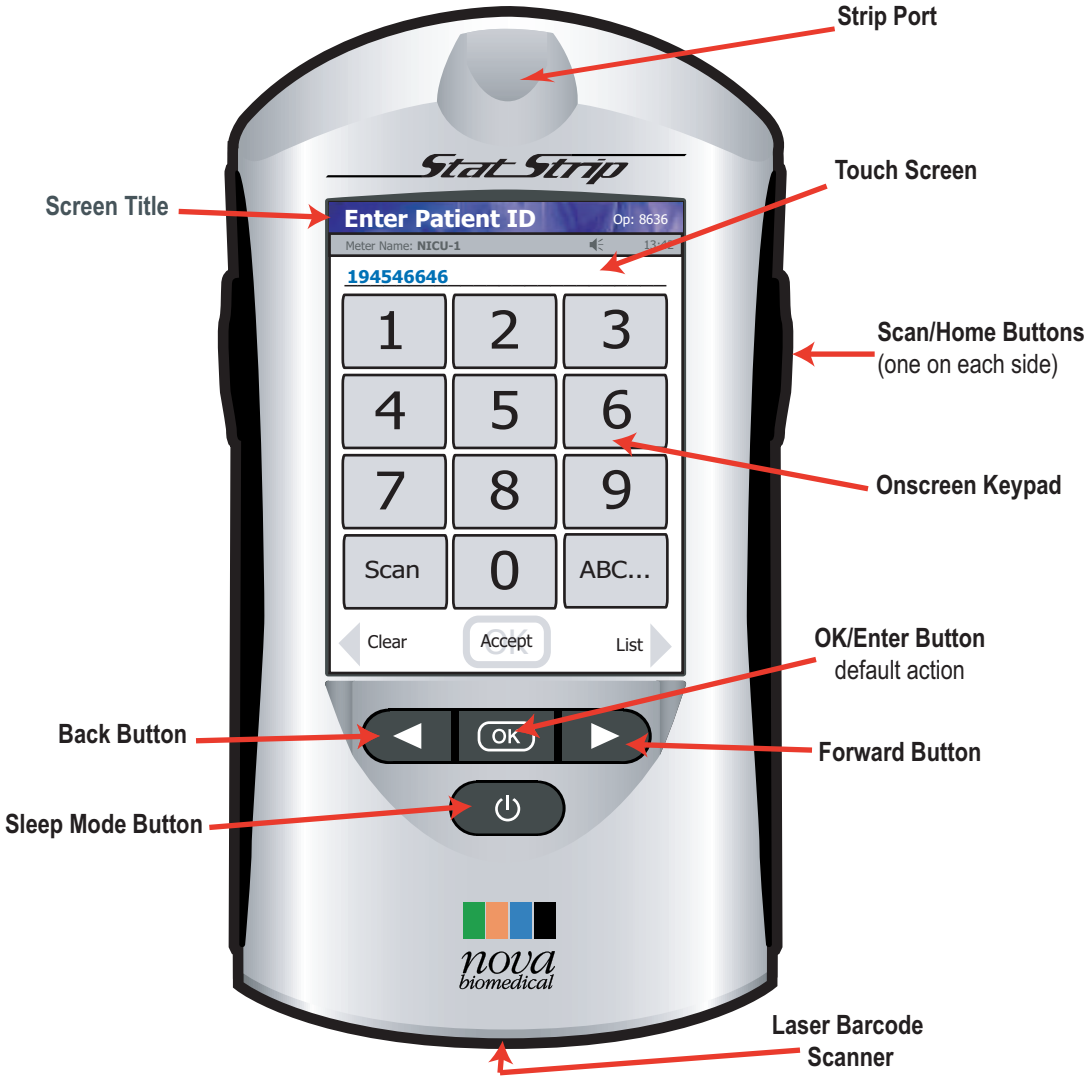


Figure 1.1 StatStrip Glucose Hospital Meter

The meter provides audible feedback of user inputs such as key presses and bar-code scans and audible and/or visual feedback for prompts and user alerts. A built-in barcode scanner provides automated data entry.

WARNING: Do not stare into the Laser light or point it towards anyone's eyes while scanning a barcode.

NOTE: *The Meter is designed such that the Operator uses his or her finger when dealing with the touch screen. A PDA-style pen may be used as a replacement for finger input. Any other type of implement with a sharp or abrasive end may damage or disable the Meter.*

- The meter stores patient test data, quality control test data, linearity test data, and other information relating to the patient, patient sample, and operator.

- Meter operation involves entering operator, patient, QC, and strip lot data, as needed. Insert a test strip into the meter. Present a blood sample onto the test strip. View the test result; and, if required, annotate the result by adding "comments" relating to the patient sample. QC and Linearity results can also be commented, if needed.

- The barcode scanner allows for scanning operator ID, patient ID, QC, Strip Lot Numbers, and Linearity Lot Numbers. These fields can be manually entered as well.

- The meter stores patient samples, quality control test data, and linearity test data on-board. The operator can recall and review test data stored in the meter.

- A rechargeable battery provides power to operate the meter. A low-battery warning on the meter display alerts the operator to recharge the battery. An auto sleep feature conserves power when the meter is not in use. Test data information are stored in a non-volatile memory to prevent data loss.

1.6.1 Using the Display Keypad

The Display Keypad has 2 formats: numeric and alphanumeric. To display the alphanumeric keypad from the numeric display, press the 'ABC...' key. To display the numerical display from the alphanumeric display, press the '0..9' key.

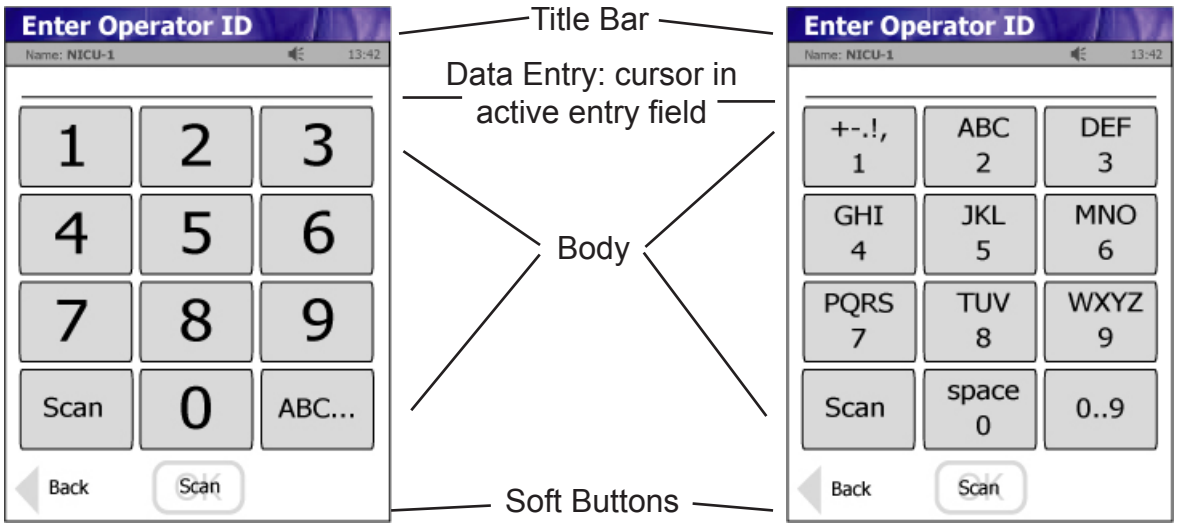


Figure 1.2 The Numerical and the Alphanumerical Keypad Screens

To use the alphanumeric keys, press the key with the letter of choice until it is displayed in the text display above the keypad.

The screen is composed of 3 sections:

1. A Title Bar (top) – the title of the screen, Time of day, logged-in operator ID, Sound status, Meter name

2. The Body – data entries, selections, and screens

3. The Soft Key Bar – confirmation of data entry and screen navigation
   The Soft Key Bar duplicates and labels the functionality of the Left, OK, and Right hard buttons.

The StatStrip Glucose Hospital Meter has the following operator input mechanisms:

- Hard buttons for menu navigation and menu prompt acknowledgement
- Soft buttons for menu navigation and menu prompt acknowledgement
- Soft keyboard for data input
- A power-on/sleep hard button
- A pair of scan hard buttons to trigger a barcode label scan

1.6.2 Hard Buttons

The following are the StatStrip Glucose Hospital Meter hard buttons:

- Right Button – when enabled has the same functionality as the right arrow soft key on the screen.
- Left Button – when enabled has the same functionality as the left arrow soft key on the screen.
- OK Button – when enabled has the same functionality as the **OK** soft key on the screen.
- Power Button – turns the Meter on or puts it into a sleep mode.
- Scan Buttons – when enabled trigger a barcode scan.

All the hard buttons are disabled when the Meter is in the Charging Station. Audible tones associated with the pressing of a hard button are not sounded when the Testing Sample screen is displayed.

Sleep Button

- Pressing the Sleep Button when the Meter is active normally causes the Meter to immediately go into the sleep mode. Pressing the Sleep Button when the Meter is powered off causes the Meter to wake up within 5 seconds.

- If the Meter is currently processing a sample (Testing Sample), the Power button is disabled.

Scan/Home Buttons

The Scan/Home Buttons are only active and will only trigger a scan for screens that accept barcode label scanned data. When not barcode scanning, pressing these buttons brings you back to the Home screen.

1.6.3 Soft Buttons

On-screen buttons, called "Soft Buttons," are used for menu navigation and screen menu choice. Soft buttons have the same functionality as the corresponding hard buttons.

Soft Keyboard

The soft keyboard functions in the following manner:

- An “ABC” soft key turns Alpha Mode ON (letters A-Z, space, +-.!,) to allow alphabetical character input to be inserted. A Punctuation soft key allows a plus (+), dash (-), period (.), exclamation (!) or comma (,).
- A "0..9" soft key turns Alpha Mode OFF to allow numeric character input only. A soft key is provided for numerals "0" through "9."

In Alpha Mode, most soft keys have multiple characters associated with them. For these soft keys, a particular character is selected by pressing the soft key multiple times, so as to scroll through the list of characters. Each character is displayed in the data entry field when it has been pressed.
In addition, barcode scan input can be enabled for those menu fields that support it to make data input easier and quicker.

Cursor

The cursor blinks in the active data entry field of a screen. Data entry fields have a 16-character fixed length. When an attempt is made to input more data than is allowed for a particular data field:

- The cursor remains at the right most position in the field.
- The pressed keys are not inputted.
- An audible tone is emitted.

Data entry fields are completed once the cursor moves to another field or once the OK Button or OK soft button is pressed.

1.6.4 Meter Sleep/Wake Up

The LCD display is turned off to conserve battery power (sleep mode) after an Operator defined time of no activity. Keep-awake activities include:

- Pressing a hard button
- Touching the screen
- Placing the meter into the Charging Station
- Inserting a test strip

If the meter is placed into the docking station, the following conditions should be expected:

- If Patient Result is the currently displayed screen when docking occurs, the results are auto-saved.
- If the currently displayed screen is a Setup screen, any unconfirmed input data or menu selection is discarded upon docking.

Wake Up

When in the sleep mode, the following conditions activate the meter: the meter displays the last screen it displayed before it went to sleep. To wake the meter, one of the following can be done:

- Pressing any hard button
- Touching the screen
- Inserting a strip (test/QC/Linearity)

1.6.5 Result Alerts

The result is displayed differently depending on whether it is in or out of the normal range for glucose measurement.

- Results within the normal range are displayed in Blue.
- Results outside the normal range are displayed in Red.
- If the value is outside the technical range of the meter, the low or high end of the technical range value displays as <XX or >YY (where XX-YY represents the technical range).
- A Single up arrow (↑) is displayed for a result if the value is higher than the upper end of the normal range but within the critical range.
- A double up arrow (↑↑) is displayed for a result if the value is higher than the upper end of the critical range.
- A Single down arrow (↓) is displayed for a result if the value is lower than the lower end of the normal range but within the critical range.
- A double down arrow (↓↓) is displayed for a result if the value is lower than the lower end of the critical range.

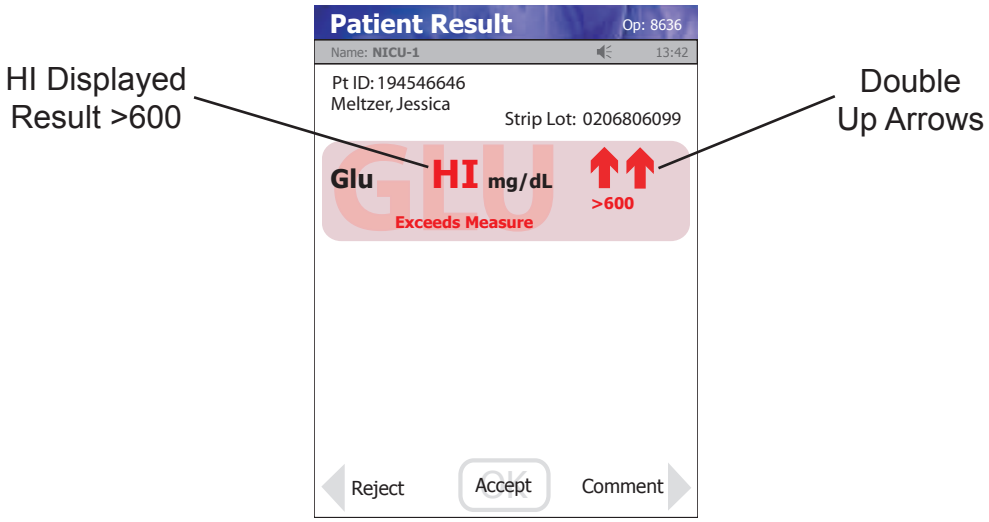


Figure 1.3 Patient Result: Exceeds Measure/HI screen

1.6.6 Multi-screen Menus

When a menu or a list is too large to be fully displayed on the LCD screen, or a menu item is one of many in a list, a Page Up (lower left side) and a Page Down (lower right side) soft keys display to navigate forward and backward amongst the screens. The Hard Arrow buttons can also be used to scroll to the previous or next page.

1.7 Installing the StatStrip Glucose Hospital Meter

Install a rechargeable Li battery. The Battery comes with a half charge thus the meter can be operated immediately. To fully charge the battery, place the meter onto the Charging Station. The Charging Station must be plugged into a 120 Volt AC outlet. The meter needs to be charged until the green light on the charging station lights up. At the same time, place the spare rechargeable battery into its place in the Charging Station.

A spare battery can be stored in a charging position in the Charging Station. The Charging Station recharges the battery of the meter when the meter is placed into the station. Indicator lights on the station provide feedback as to whether the meter battery is charging or fully charged.

The station must remain plugged into a wall outlet for power. The station is designed to reside on a desk or counter top.

1.7.1 Power Up Procedure

After initial power up or after battery replacement, the Boot screen appears and is displayed while the software loads. Once the software has loaded, the Welcome screen is displayed.

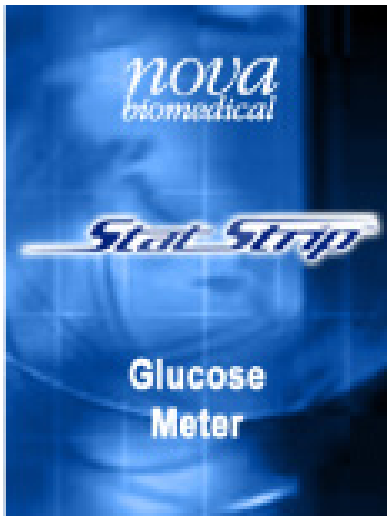


Figure 1.4 Boot Screen

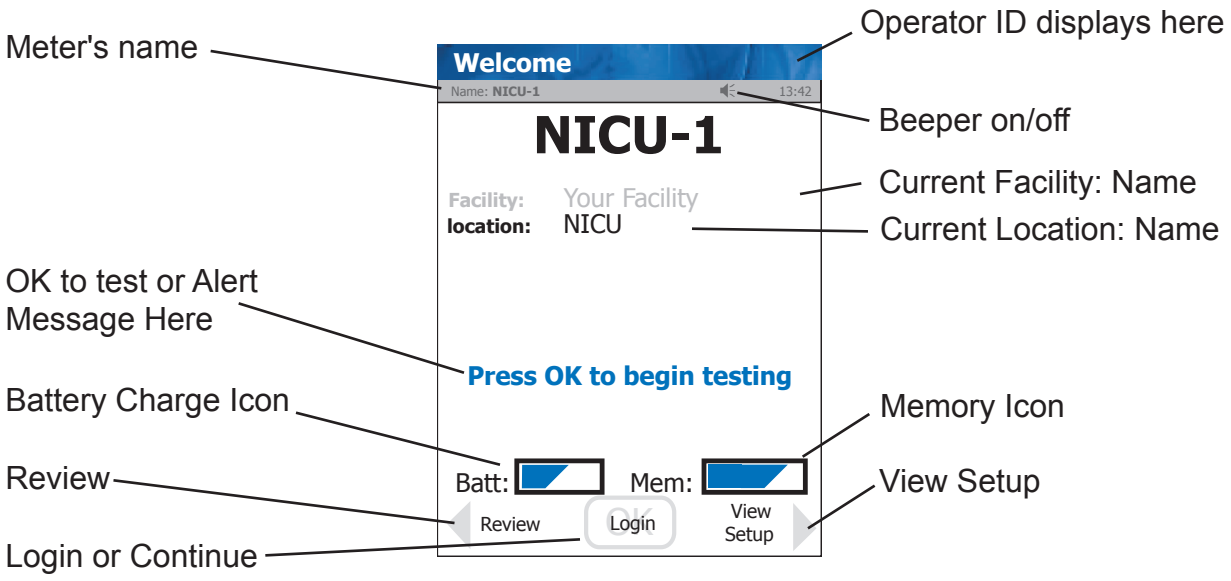


Figure 1.5 Welcome Screen

Messages or Alerts on the Home screen

- Press OK to begin testing
- Memory Full
  Dock Meter Immediately
- Battery Low
  Charge/Replace Battery
- QC Due: xx:xx hrs.
- Download Due: xx:xx hrs
- LOCKED
  Perform QC before Patient Testing
- QC Required
- Linearity Required
- Testing Not Allowed
  Assign Unit
- Dock Required
- Please return meter
  to dock for transfer
- Memory Low
  Need to Dock Soon
- LOCKED
  With a message

1.8 Operator Login

After initial power up, an operator can login to have access to all the assigned functions of the meter. To login, proceed as follows:

1. From the Home screen, press the Login soft key at the bottom middle of the screen.

2. The Enter Operator ID screen displays.
   a. To enter alphanumeric ID's, press the ABC soft key on the touchscreen keypad. An alphanumeric keypad will display.
   b. To return to numeric keypad, press the 0-9 soft key.
   c. To use the barcode scanner, press the Scan soft key on the Enter Operator ID screen or one of the side buttons to scan your badge with the bottom of the meter.

NOTE: *When an invalid ID is entered, the screen displays the invalid ID number with a message "is not a valid ID Try again."*

3. Press the Accept soft key at the bottom of the screen..

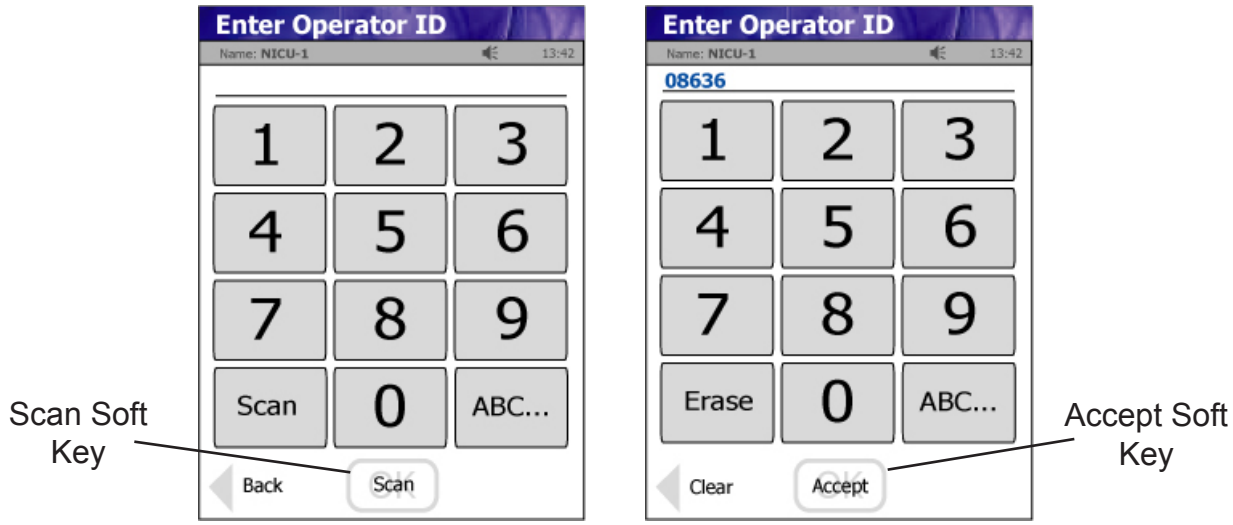


Figure 1.6 Enter Operator ID Screens

4. After the Operator ID is accepted, the Patient Test screen displays. The meter is now ready to run Patient tests, QC tests, Linearity tests, review results, set the time, etc.

1.9 Administration (Admin) Screen

This screen has soft keys to perform a number of non-patient functions: give the meter a name, set the time and date, reset the facility, etc. From the Patient Test screen, press the Menu soft key then the Admin soft key: the Admin screen displays.

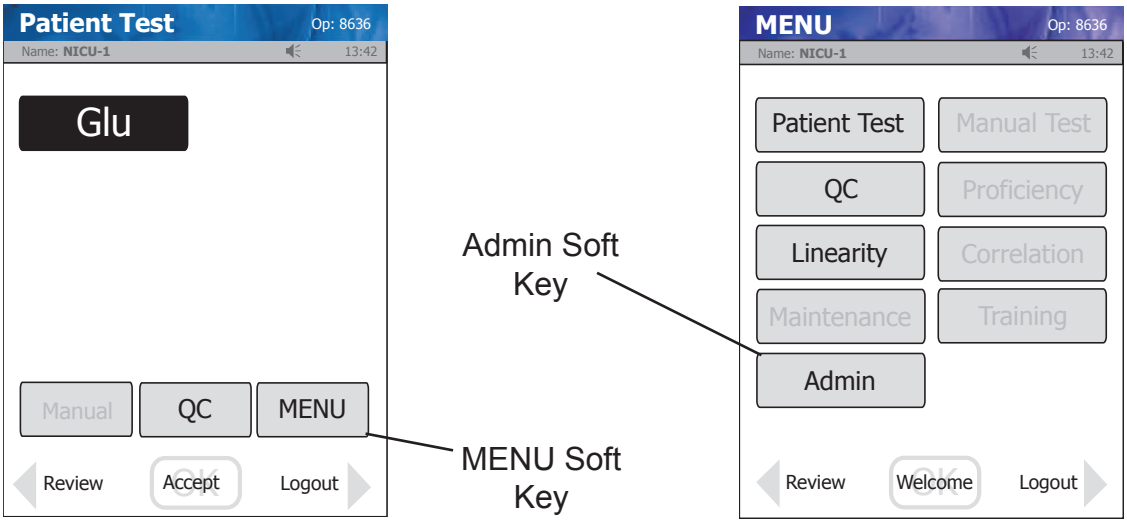


Figure 1.7 Patient Test Screen and MENU Screen

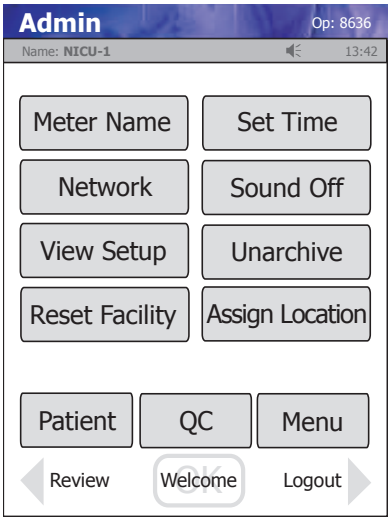


Figure 1.8 The Admin Screen

1.9.1 Naming the Meter

The meter can be given a name with respect to where it will be used: i.e., NICU-1.

1. From the Patient Test screen, press the Menu then the Admin soft button.

2. The Admin screen displays. Press the Meter Name soft key.

3. The Enter Meter Name screen displays. To add or change the name, enter the name onto the soft keypad on the screen.

NOTE: *Maximum number of characters is 10.*

4. When done, press the Accept soft key. The meter name appears on the Meter Name header of the screen.

1.9.2 Setting the Time/Date

Once you have logged in, the meter's time and date can be set.

1. From the Patient Test screen, press the Menu then the Admin soft button.
2. The Admin screen displays. Press the Set Time soft key.
3. The Set Time screen displays. To change the hour, press the drop down arrow. Then press the up/down scroll arrow to the current hour. Do the same for the minutes.
4. Do the same for the Month, Day, and Year.
5. If Date and Time are now correct, press the Accept soft button.

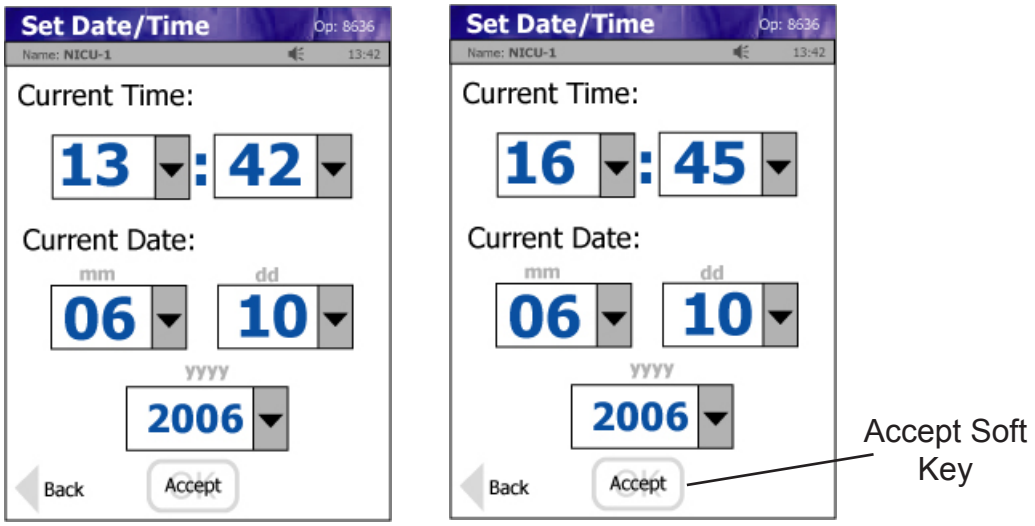


Figure 1.9 The Set Time (and Date) Screens

1.9.3 Sound On/Off

To turn the sound on or off, press the Sound On or Sound Off soft key.

1.9.4 View Setup

To view the meter settings, press the View Setup soft key on the Admin screen.

1.9.5 Unarchive

Once the data are transferred to the host computer, the data become archived and cannot be transferred again. If there is a need to retransfer data because it did not transfer or was lost on the host computer, the data must first be unarchived. Performing this task unarchives all data.

1. From the Patient Test screen, press the Menu then the Admin soft button.
2. The Admin screen displays. Press the Unarchive soft key.
3. The Confirm screen is displayed: Do you want to UNARCHIVE all results?
4. Press the Accept soft key.

1.9.6 Resetting the Facility

The meter's facility name can be reset.

1. From the Patient Test screen, press the Menu then the Admin soft button.
2. The Admin screen displays. Press the Reset Facility soft key.
3. The Confirm screen is displayed.
4. Press the Accept soft key.
5. The Meter displays the Welcome screen.

1.10 Assign Location

The Location can be assigned or changed. If there is no location assigned, the screen displays Unassigned.

1. To assign or change a location, first log on the meter.
2. Press the Menu then the Assign Location button and select a location from the displayed list.
3. With the new location selected, press the Accept soft button.
4. Press the Accept soft button again to confirm the location.
5. Dock the meter to upload the new location configuration.

1.11 Meter Transport Case

The meter transport case is a light, rugged case to transport the Nova hand-held meter, test strips, control solutions, and supplies. The case can hold:

- POC Meter
- Test Strips
- Alcohol swabs
- Gauze pads
- Lancets
- Control solutions
- Quick reference guide

2 Quality Control

2.1 When to Perform a QC Test

The Nova Stat Strip Glucose Hospital Meter includes several quality control mechanisms that detect errors due to system failures and operator performance. External controls materials are available from Nova Biomedical for verifying the integrity of the Nova Stat Strip Glucose Hospital Meter. These Stat Strip Glucose Control Solutions consist of 3 levels of ready-to-use liquid controls. They are formulated at clinically relevant levels. The controls can be used as part of a laboratory quality control program. Run the controls according to the procedure in Section 2.3 Quality Control Test.

2.2 StatStrip Glucose Control Solution

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

Only the Nova Stat Strip Glucose Control Solutions are recommended for use with the Nova Stat Strip Glucose Meter and the Nova Stat Strip Glucose Test Strips. Ranges for the Nova Stat Strip Glucose Meter using other commercially available glucose controls have not been established and may give erroneous results. Run 2 different levels of the Stat Strip Glucose Control Solutions during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

- Each new operator
- Before using the StatStrip 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

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about the test system integrity or operator technique.

2.3 Quality Control Test

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

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.

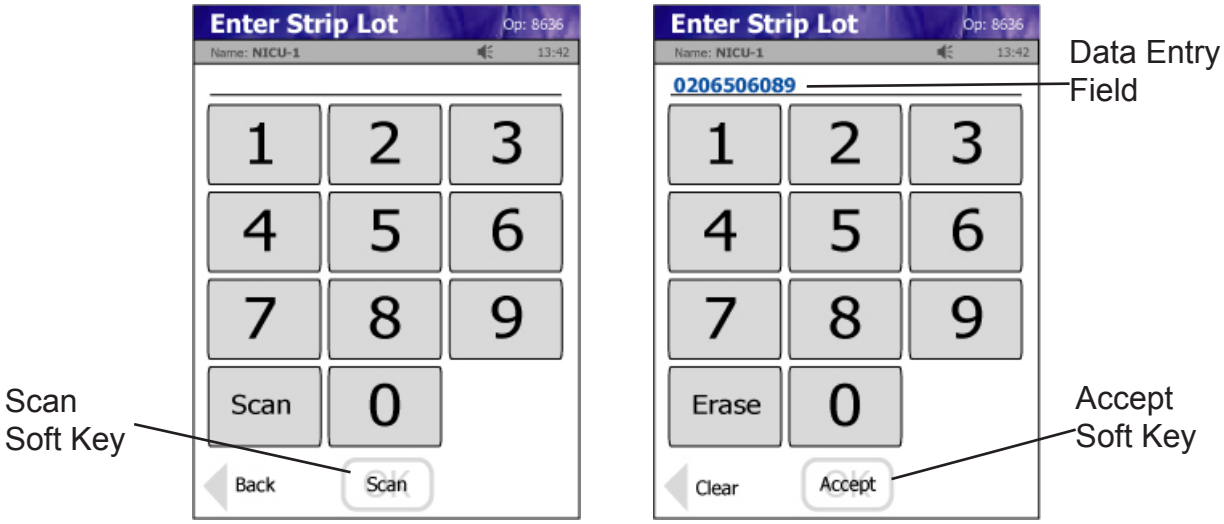


Figure 2.1 Enter Strip Lot Screens

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.

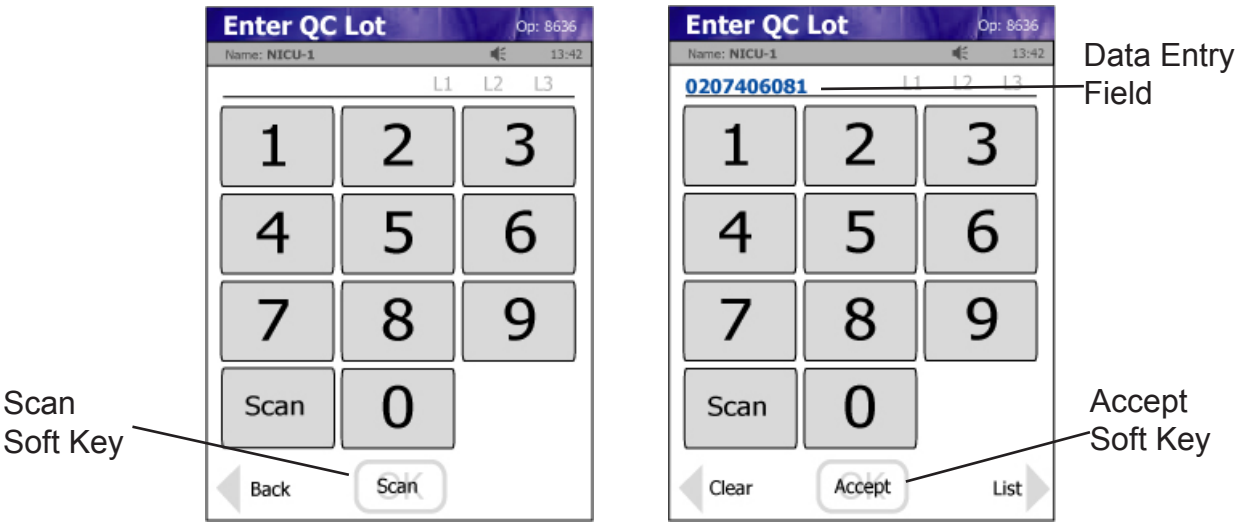


Figure 2.2 Enter QC Lot Screens

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

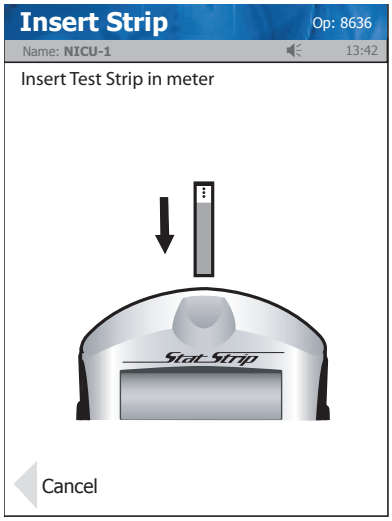


Figure 2.3 Insert Strip Screen

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 at 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.

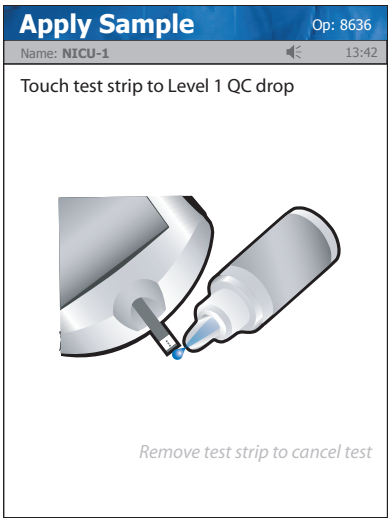


Figure 2.4 Apply QC Solution to Test Strip Screen

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 or mmol/L.

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.*

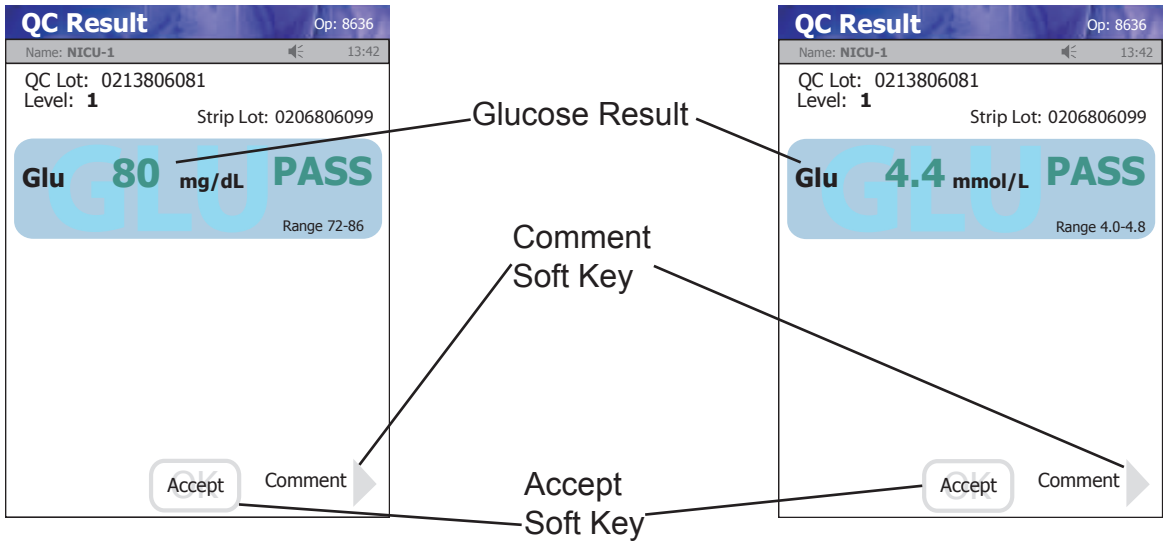


Figure 2.5 QC Result Screen

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

14. To accept the result, press the Accept soft key.

NOTE: *Acceptable control assay ranges are printed on the Nova Glucose Control Solutions vial label. If a QC test does not fall within the specified range, verify that the Nova Glucose Stat Strips and Control Solutions are not past their expiration dates. Repeat the test with a new strip. If the second test fails, inspect and clean the meter according to Section 6.3, Cleaning the Meter. If the third test fails, contact Nova Biomedical Technical Support toll free at 1-800-345-NOVA.*

2.4 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 Add Comment screen displays with preformed comments.

1. If appropriate, select one of the comments from the comments list on the Add Comment screen.

2. There are Page Up and Page Down soft keys to scroll through the comments.

3. Once selected, press the Accept soft key to place the comment onto the QC result.

There is also a Free Text soft key to add a unique new comment.

1. From the Free Text Comment screen add a comment, i.e., Notified Dr. Smith, Repeat Level 1, Operator Error Repeat, etc.

2. Press the Accept soft key to place the comment onto the QC result.

All comments to the result are transferred to the data manager.

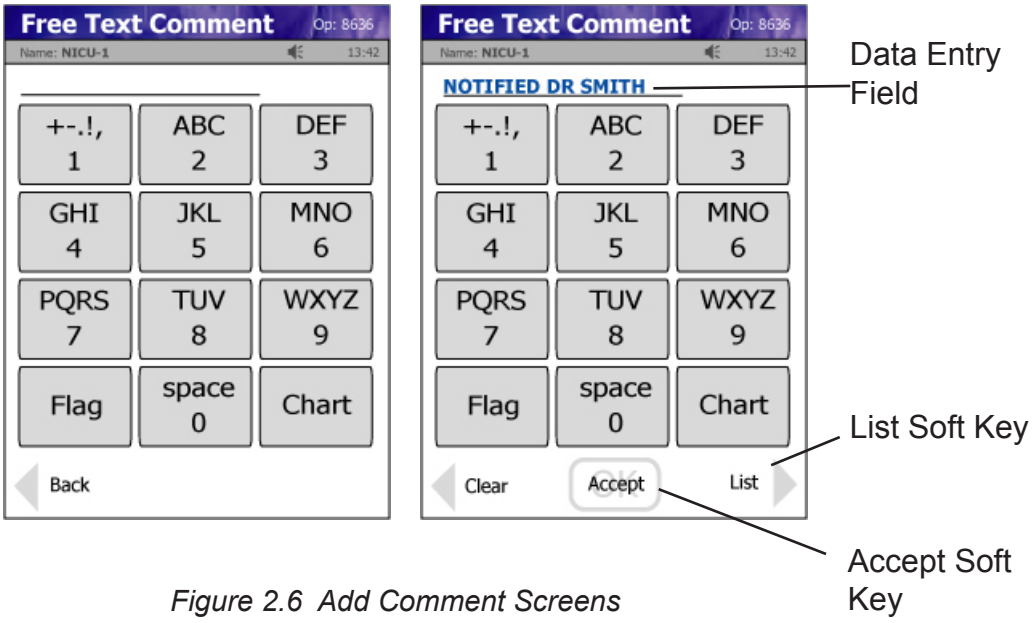


Figure 2.6 Add Comment Screens

3 Operation

This section describes how to perform tests with the StatStrip Glucose Hospital Meter.

3.1 Running a Patient Sample

The meter shows graphically a step-by-step procedure to run a glucose test.

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.

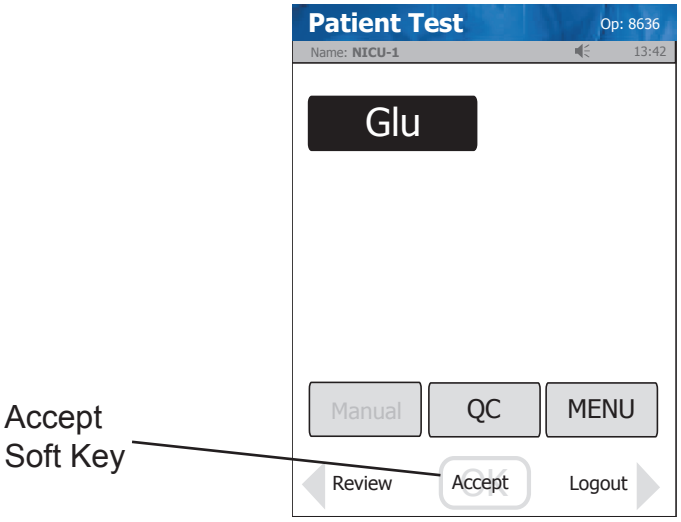


Figure 3.1 Patient Test Screen

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.

Figure 3.2 Enter Strip Lot Screens

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 three 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/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.

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

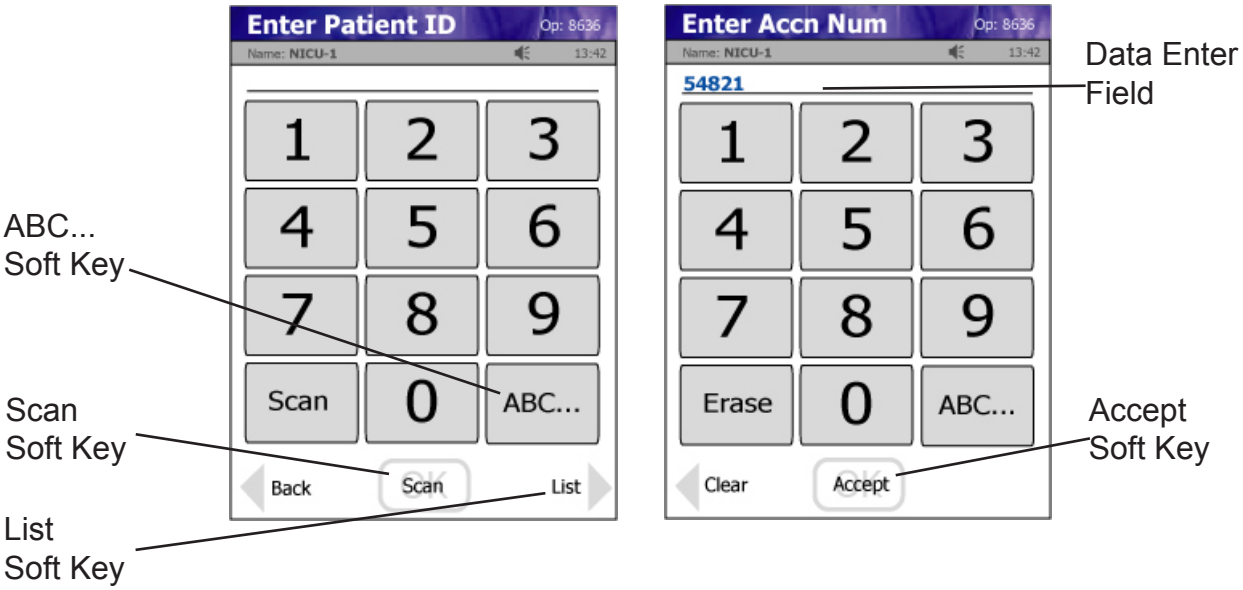


Figure 3.3 Enter Patient ID or Enter Accn Num Screens

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.

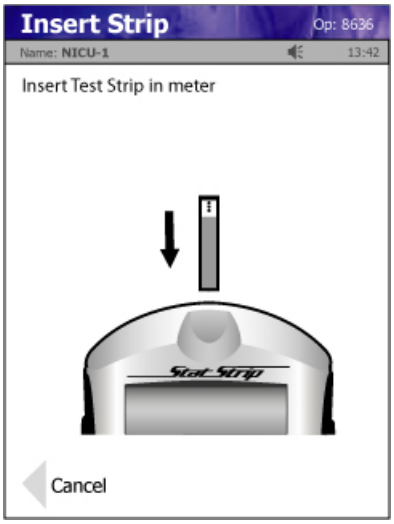


Figure 3.4 Insert Strip Screen

12. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.

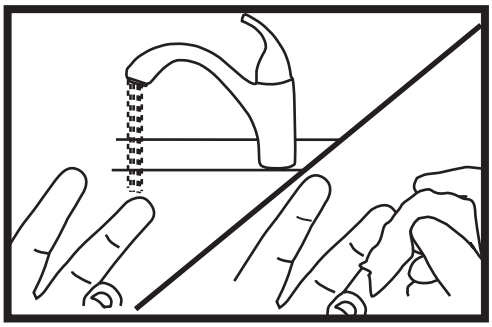


Figure 3.5 Wash the Patient's Finger

13. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

14. Use the Safety Lancet to puncture the finger.

15. Squeeze the finger to form a drop of blood.

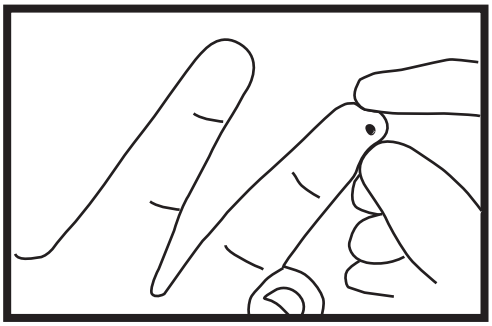


Figure 3.6 Squeeze the Finger to Form a Drop of Blood

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.*

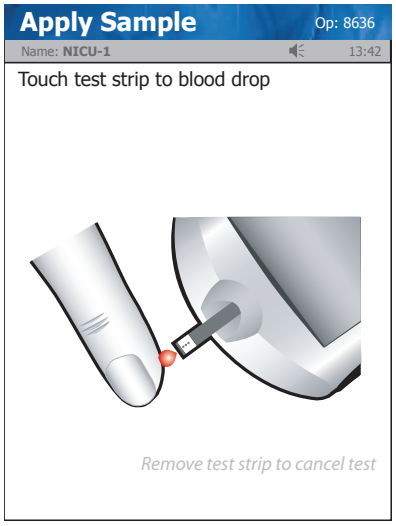


Figure 3.7 Touch Test Strip to Blood Drop Screen

17. The test results will appear in 6 seconds.

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

18. 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.)
    All data are stored into memory.

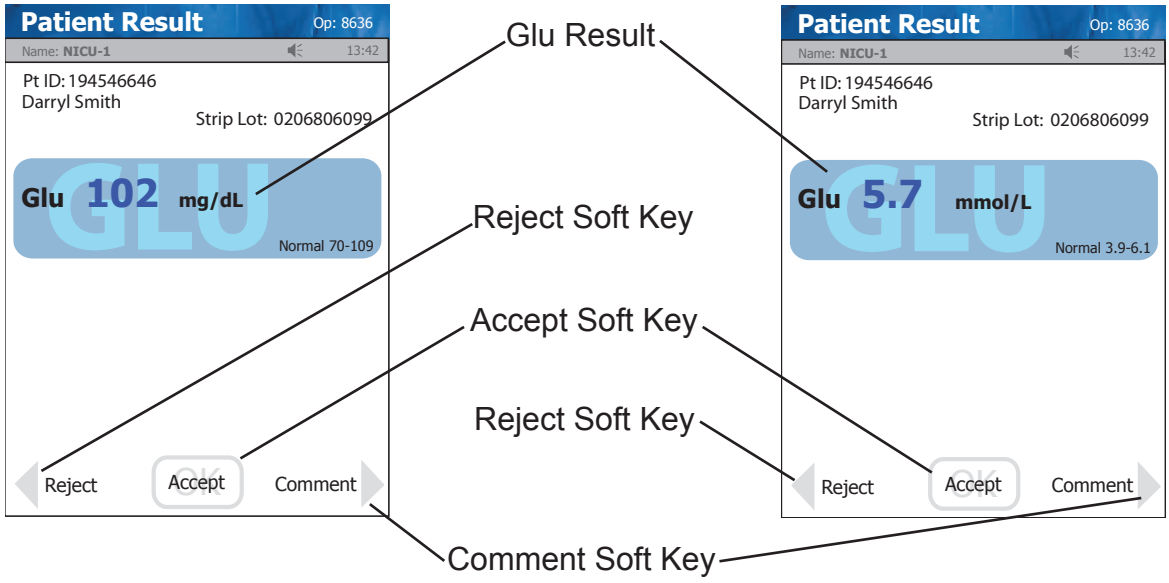


Figure 3.8 Glucose Results Screen

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.

3.2 Review Results

All results can be recalled and reviewed: Patient Results, QC Results, and Linearity Results. The Review Results screen can be sorted by ID, Time/Date, or Type.

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

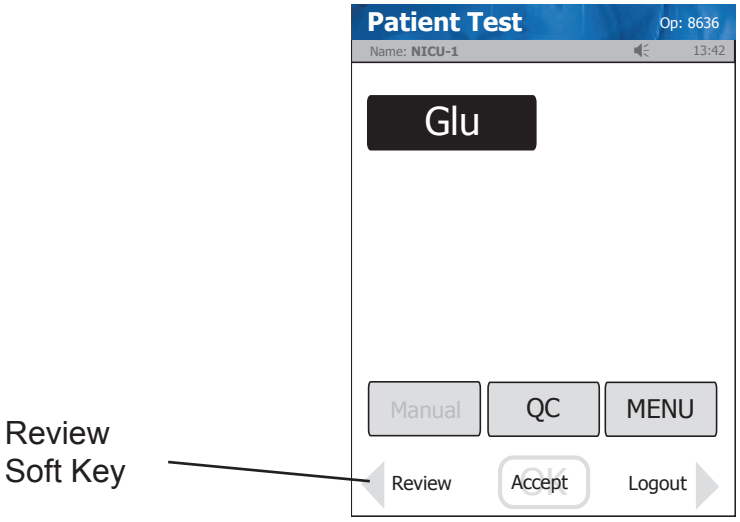


Figure 3.9 Patient Test Screen: Review Soft Key

2. The Review Result screen displays.
3. Select how to sort the results by pressing ID, Time/Date, or Type.
4. Select the result that you want to review.

NOTE: *The scroll bar shows the position in the results field: beginning, middle, end.*

5. Press the Page Down or Page Up soft key to scroll through the stored results.
   Press the View soft key to view the selected result.
   Press the Previous soft key to view the previous result.
   Press the Next soft key to view the next result.

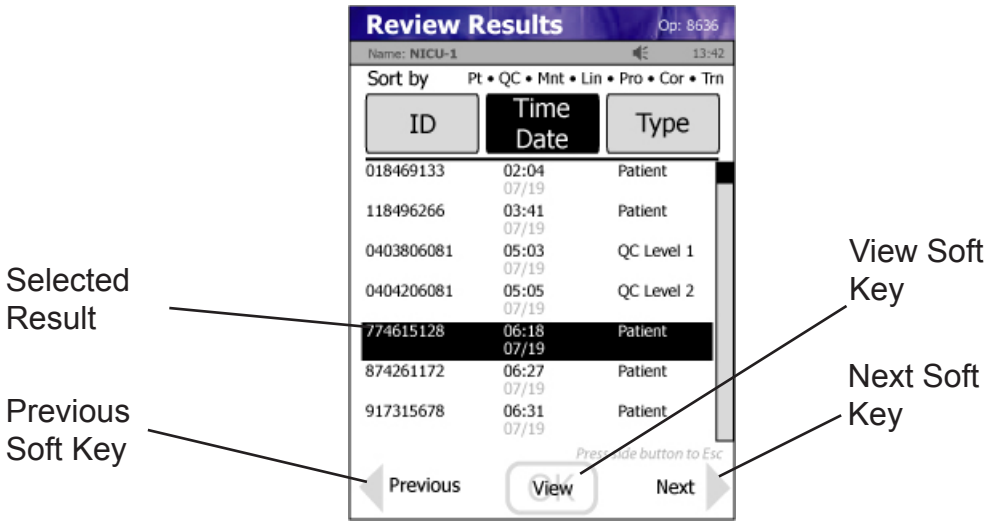


Figure 3.10 Review Results Screen: Result Selected

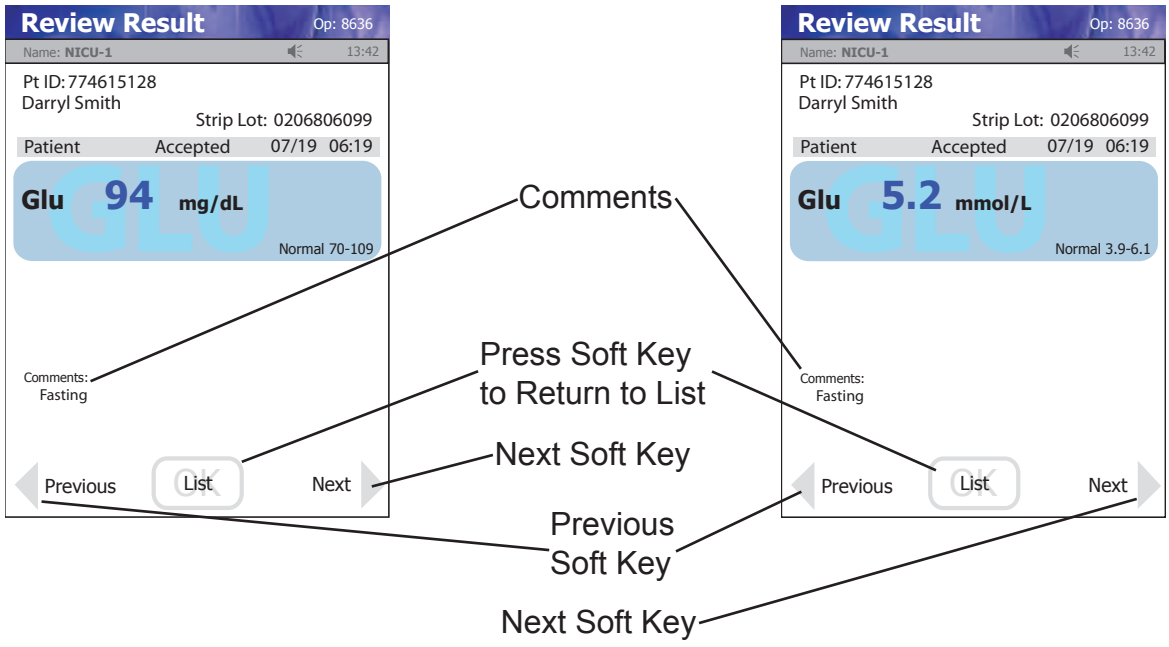


Figure 3.11 Review Result Screen: Selected

4 Docking/Charging Station

When the meter is not in use, place it into the Docking/Charging Station. This will enable the meter to stay fully charged. The Docking/Charging Station is connected to a power source and to the computer network as follows:

1. Plug the fixed power cord from the power supply into the back of the Charging Station.

2. Plug the 2-prong plug of the wall plug cord into the power supply.

3. Plug the 2-prong plug into a wall outlet.

4. Place the meter and/or spare battery into the Charging Station.

5. Connect the Docking/Charging Station to the network through the Ethernet connection at the back of the station. The connection is marked with the Ethernet <•••> symbol.

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

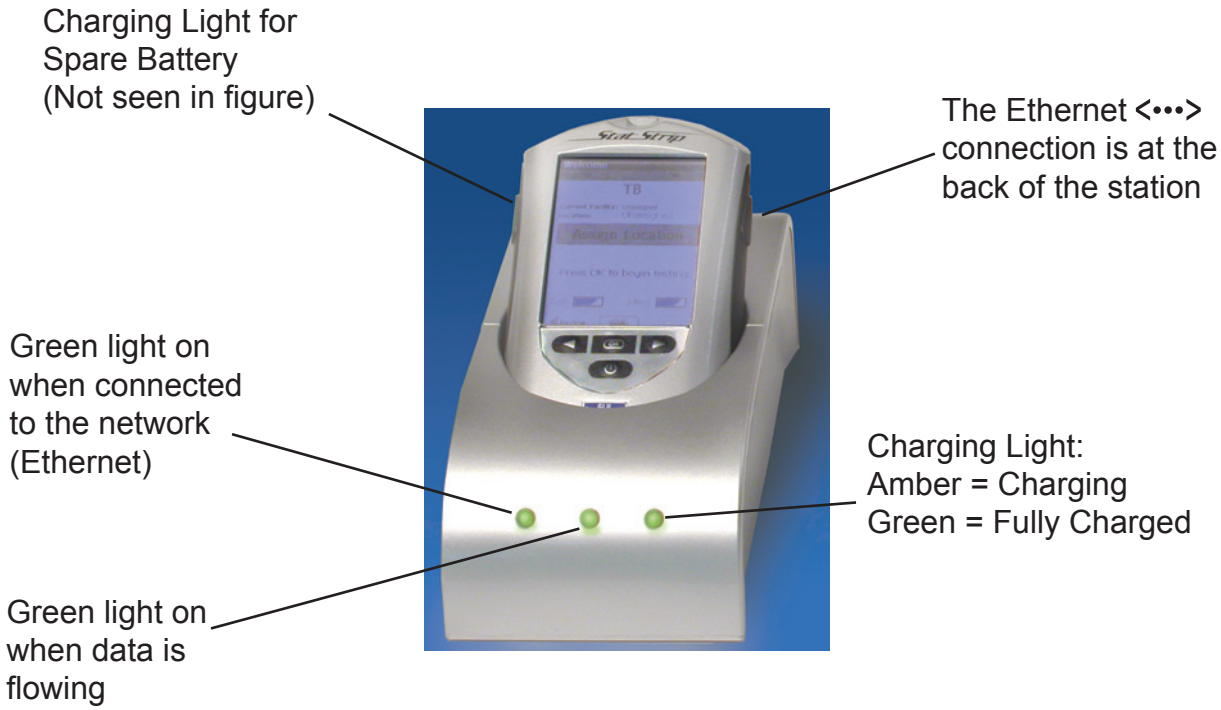


Figure 4.1 The Meter in the Docking/Charging Station

5 Linearity Test

For CLIA Moderate Settings only: This section describes how to perform Linearity tests with the StatStrip Glucose Hospital Meter. There are 5 levels in the StatStrip Glucose Linearity kit.

Refer to the StatStrip Linearity Kit package insert sheet for complete instructions, indications, precautions, and limitations of the system.

5.1 Running a Linearity Test

1. From the Patient Test screen, press the Menu soft key.
2. From the Menu screen, press the Linearity soft key.
3. 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."*

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

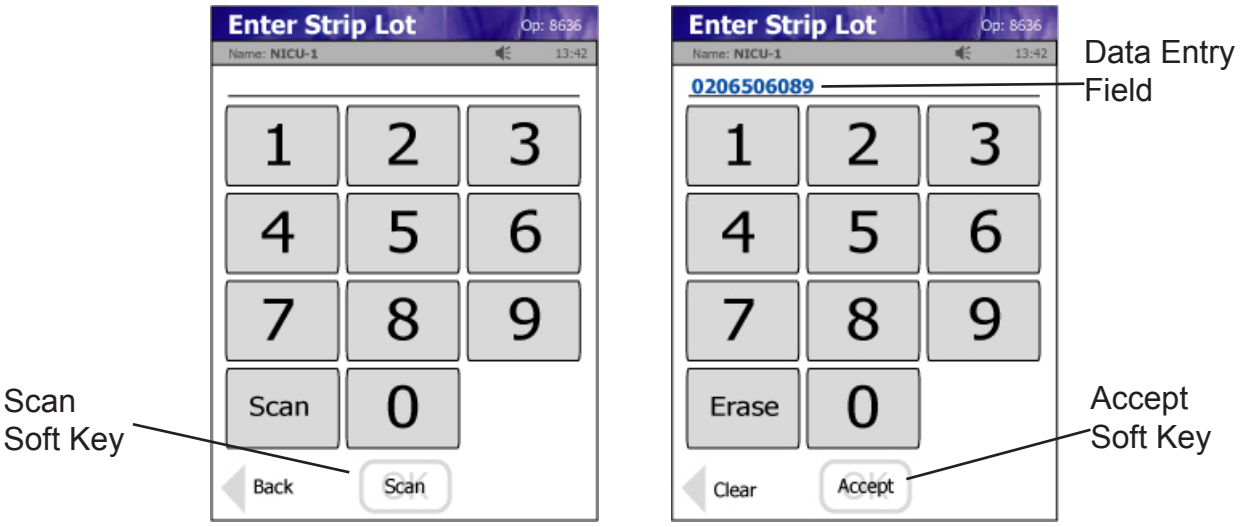


Figure 5.1 Enter Strip Lot Screens

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

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

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

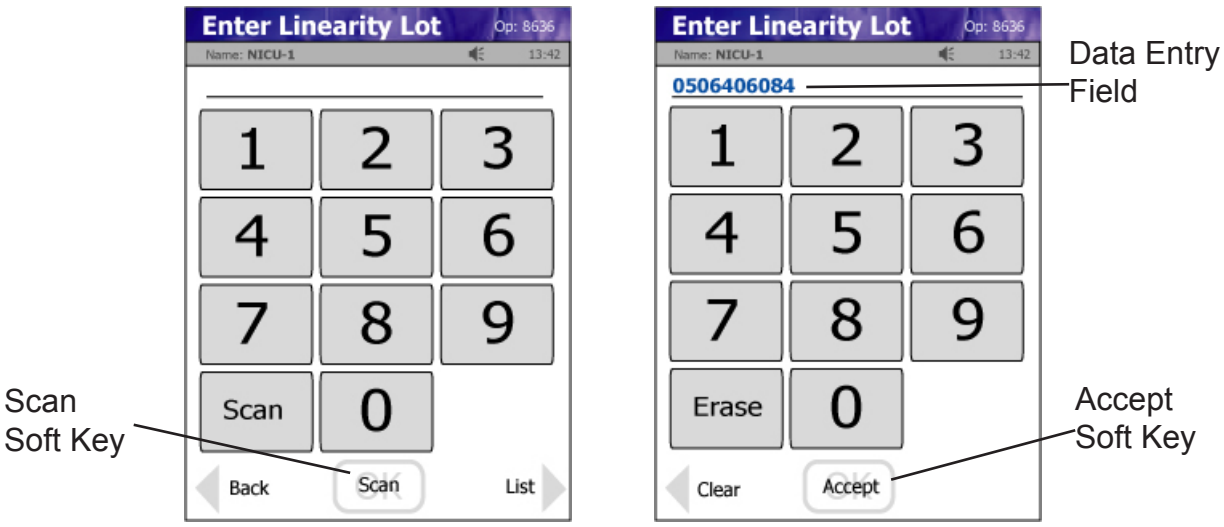


Figure 5.2 Enter Linearity Lot Screens

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

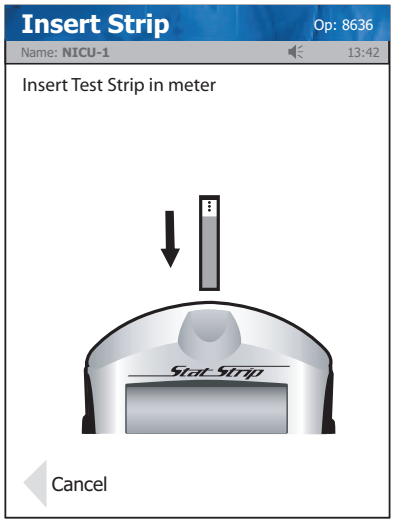


Figure 5.3 Insert Strip Screen

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

9. Gently mix the StatStrip Linearity Solution before each use.

10. Discard the first drop of linearity solution from the bottle to avoid contamination.

11. Place a drop of linearity solution from the bottle at 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.

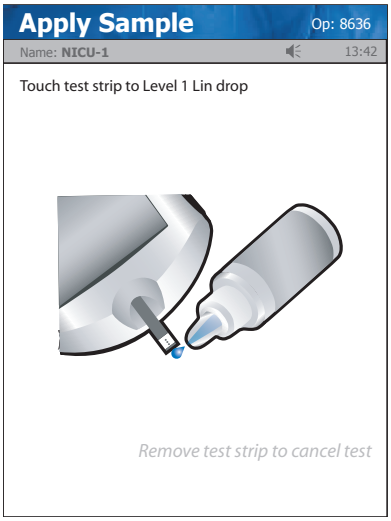


Figure 5.4 Apply Sample (Linearity Solution) to Test Strip Screen

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

13. When the meter completes the test, the Linearity Result screen displays with the results in mg/dL or mmol/L.

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

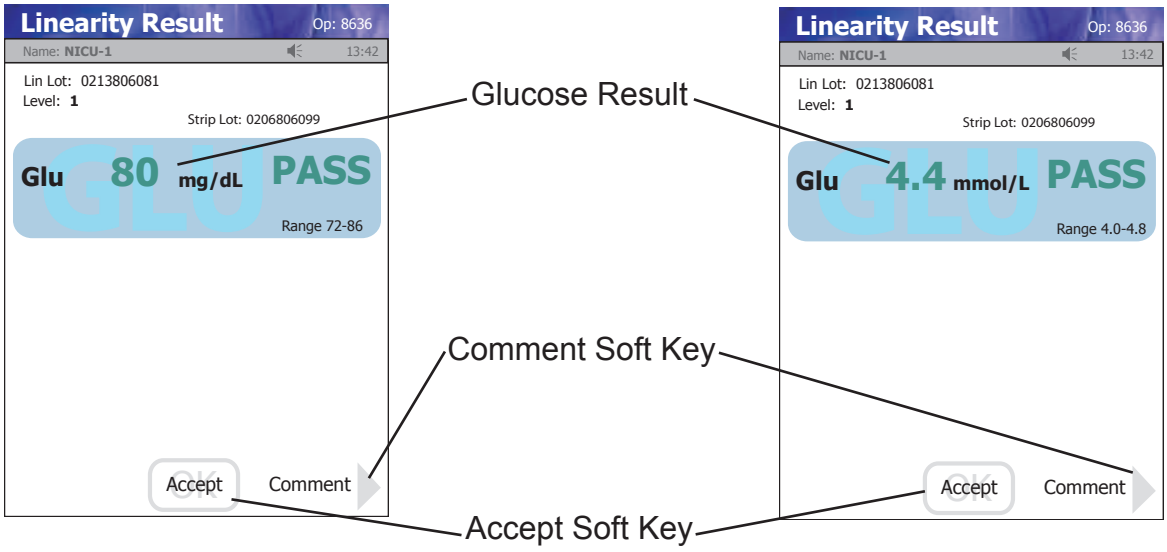


Figure 5.5 Linearity Result Screen

14. To add a comment, press the Comment soft key. (See Section 2.4 Add Comment to Result.)

15. To accept the result, press the Accept soft key.

6 Maintenance

The meter is very low maintenance. The meter needs to have the battery charged in the Charging Station, battery replaced, or its surface cleaned/disinfected.

6.1 Charging the Meter

When the Battery LOW symbol displays on the screen, place the meter into the Charging Station. If you have a spare battery that is already fully charged, change the battery.

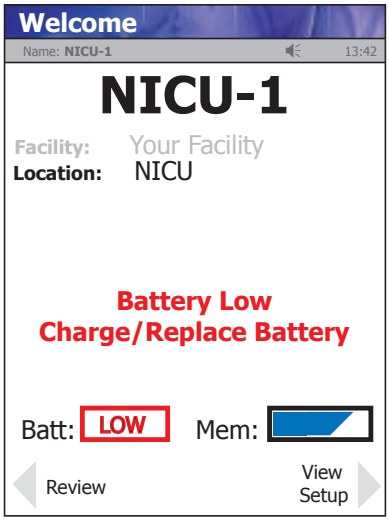


Figure 6.1 Battery Low: Charge/Replace Battery Screen Alert

Figure 6.2 Meter placed into Charging Station

6.2 Changing the Battery

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

WARNING: *Replace the battery with Nova Biomedical Part Number 46827 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, relogin, and set the date and time: see Section 1.7.1 Power Up Procedure, Section 1.8 Operator Login, and Section 1.9 Setting the Time/Date.*

2. Push down on the 2 cover latches to release the cover. Take the battery cover off the back of the meter.

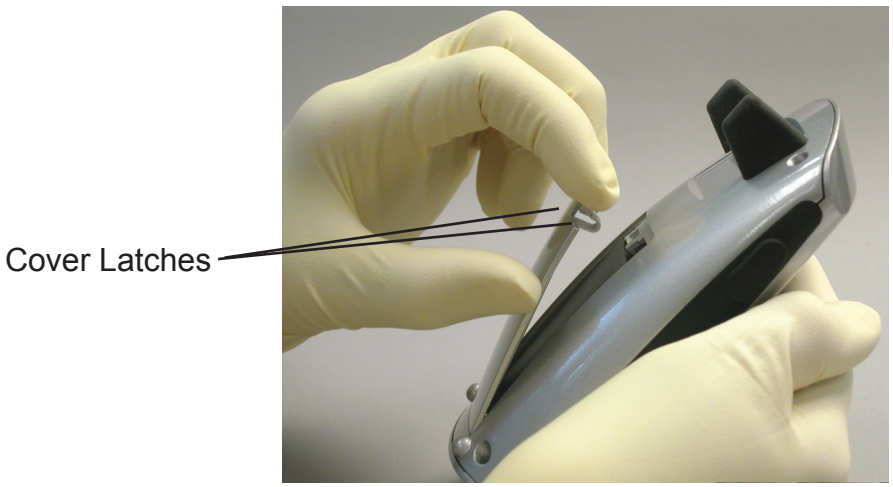


Figure 6.3 Removing the Battery Cover

3. Push up on the battery latch. Remove the drained battery.

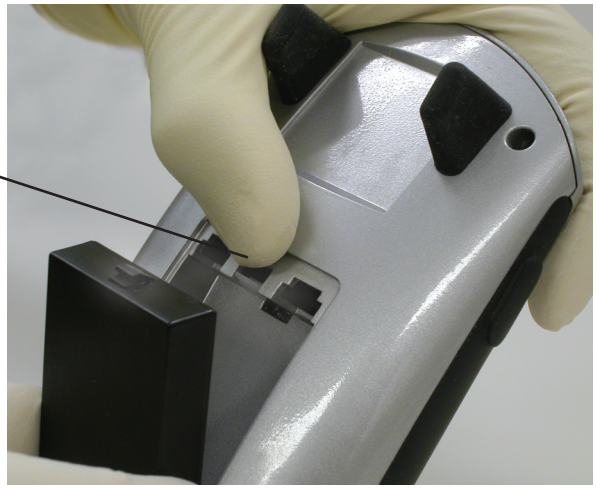


Figure 6.4 Removing the Battery

4. Replace with a fully charged battery.

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

Figure 6.5 Replacing with a Fully Charged Battery

5. Replace the battery cover.

6. Place the drained battery into the Charging Station.

6.3 Cleaning the Meter

The meters should never be immersed in any cleaning agent. Always apply the cleaning agent to a soft cloth to wipe the meter surface. Once complete, immediately dry thoroughly. When cleaning the meter, please follow the guidelines listed below:

- Dilute Bleach. A 10% solution of household bleach (Sodium Hypochlorite) may be used.
- 70% Isopropyl (rubbing) Alcohol may be used.
- Commercial surface decontamination preparations that are approved for use by your facility can be used. Apply to a small test area first to ensure surface finish integrity.
- Avoid harsh solvents such as benzene and strong acids.

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

7 Troubleshooting

7.1 Meter Screen Alerts

The meter displays a number of alerts:

1. **Battery Low** - Change the battery or place the meter onto the Charging/ Docking Station.

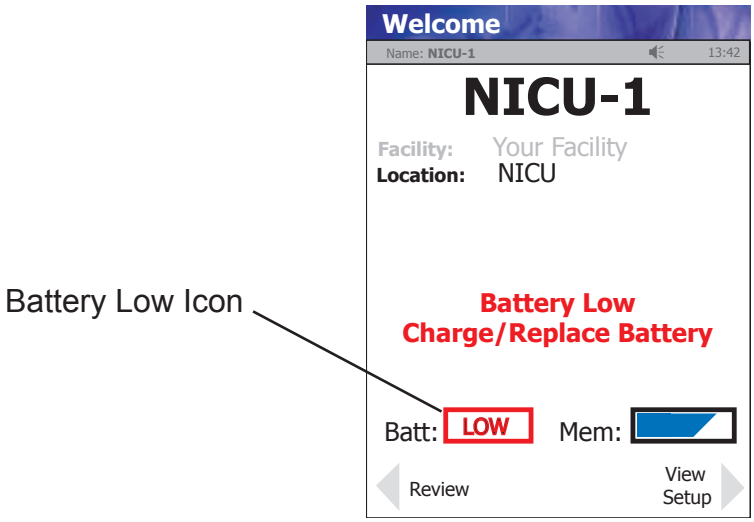


Figure 7.1 Battery Low: Charge/Replace Battery Screen Alert

2. **Test Strip Was Removed** - 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.

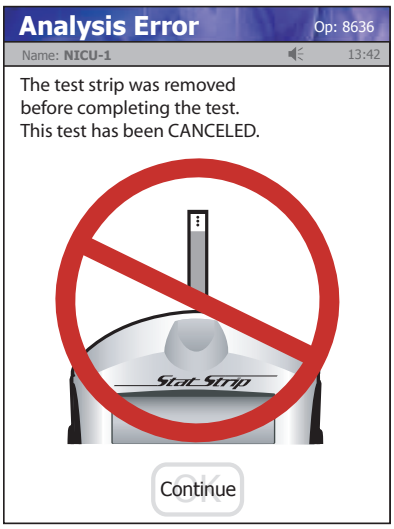


Figure 7.2 Analysis Error - The Test Strip Was Removed Before Completing the Test

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).

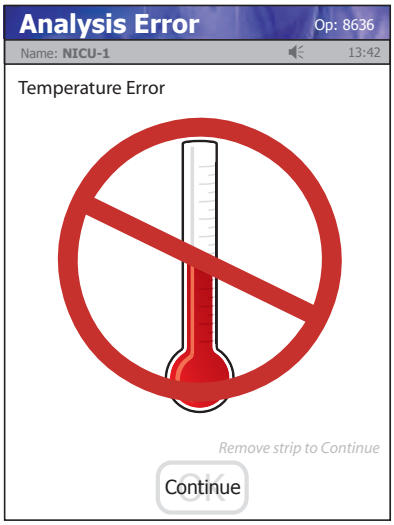


Figure 7.3 Analysis Error - Temperature Error Screen Alert

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.

Figure 7.4 Analysis Error - Bad Sample Screen Alert

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.

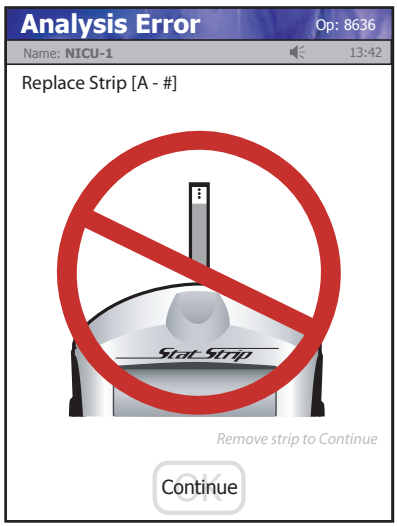


Figure 7.5 Analysis Error - Replace Strip Screen Alert

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.

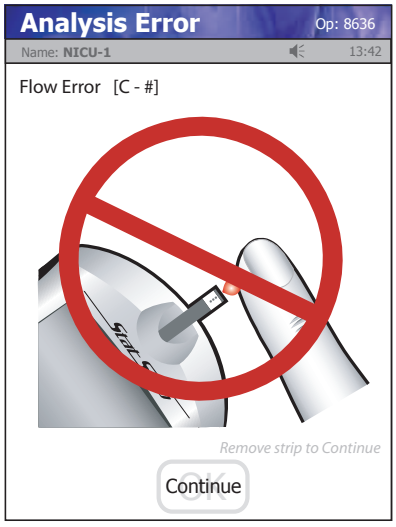


Figure 7.6 Analysis Error - Flow Error Screen Alert

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.

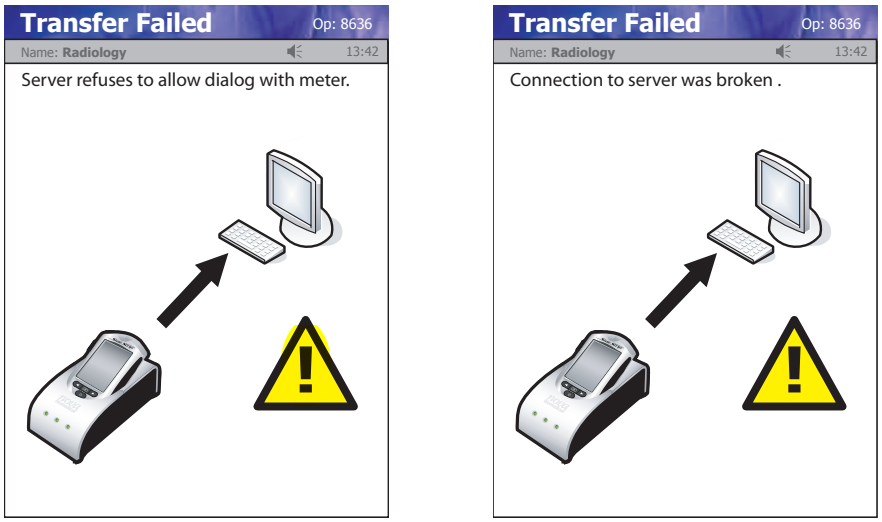


Figure 7.7 Transfer Failed - Connection Not Allowed or Connection Broken

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

Figure 7.8 Transfer Failed - Transfer Incomplete

A Appendix

Appendix A includes analyzer specifications, solutions and reagents, consumable lists, reference information, and warranty for the StatStrip Glucose Hospital Meter.

A.1 StatStrip Glucose Hospital Meter Specifications

Measurement Range: Glu	10 - 600 mg/dL or 0.6 - 33.3 mmol/L
Acceptable Samples:	Whole Blood: Capillary, Venous, Arterial, and Neonate
Measuring Technology:	Enzyme, Amperometric Glucose Enzyme (Aspergillus sp., >1.0 IU)
Analysis Time:	6 seconds
Sample Volume:	1.2 µL
Meter Memory:	1000 patient tests 200 QC tests 4000 Operators
Docking/Charging Station:	Desk mount Input 100-240 V ~, 50-60 Hz, 0.6 A Output +12 V ===, 0.85 A
Data Output Port:	RJ-45 Ethernet (10 Mbit)
Connectivity:	Protocol TCP/IP Ethernet Standard POCT1-A Compliant
Battery:	Rechargeble Li-polymer 3.7 V 1800 mAh
Electrical Compliance:	Conforms to UL and CSA Standards: IEC 61010-1:2001 and IEC 61010-2-101:2002
Dimensions:	153 mm (6.0 in) x 82.5 mm (3.25 in) x 46 mm (1.8 in)
Weight:	360 grams (0.8 lb)
Power:	3.7V Li Polymer battery (Rechargeable/Replaceable)

Environmental:

Temperature range	59°F - 104°F (15°C - 40°C)
Altitude	Up to 15,000 feet (4500 meters)
Relative Humidity	up to 90% (noncondensing)

Chemistry Measurement

The typical imprecision for glucose both for within-run and day-to-day

Glucose Levels (mg/dL)	Glucose Levels (mmol/L)	CV%
50	2.8	8%
150	8.3	6%
400	22.2	4%
600	33.3	4%

A.2 Controls/Linearity Solutions

This section covers the solutions required for the StatStrip Glucose Hospital Meter.

Solutions to be used by the Meter:

1. Three levels of Nova QC Solutions:
   Level 1, Level 2, and Level 3
2. Five levels of Nova Linearity Solutions (values for the full reportable range of meter linearity): Levels 1, 2, 3, 4, and 5

A.3 Barcode Scanner

1. The barcode scanner is a one-dimensional scanner and is able to interpret the following ID formats
   a. Code 39 Extended
   b. Code 93
   c. Code 128
   d. Interleaved 2 of 5
   e. Codabar
2. The barcodes must be black and white images only.
3. The barcodes must have a 1/8-inch border surrounding the barcode symbol.
4. Barcode character length must be 1 – 16 characters, including alphanumeric and special characters.
5. The barcodes must have a medium density (X dimension of 0.012 inches) or high density (X dimension of 0.0075 inches). Density is measured as the number of characters per inch, and X dimension is the width of the narrowest element in the symbol.

A.4 Reference Values

Each laboratory should establish and maintain its own reference values. The values given here should be used **only as a guide.**

Table A.1 Reference Values Serum and Plasma

Test	Value	
Glucose[1]	60 - 100 mg/dL (3.33 - 5.55 mmol/L)	(Child)
	70 - 105 mg/dL (3.89 - 5.83 mmol/L)	(Adult)

References:

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1999. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.

A.5 Ordering Information

Supplies and parts for the StatStrip Glucose Hospital Meter are available from Nova Biomedical.

DESCRIPTION	Part #
Battery for StatStrip Meter, 4-Pack	46827
Carrying Case for Meter & Supplies	42234
Docking Station with AC Adapter	42225
Instructions for use manual, printed	41853
Instructions for use manual, CD	41855
Quick Reference Guide	41854
Safety Lancets, 28-Gauge, 100 per box	41224
StatStrip Glucose Control Solution, Level 1, One vial	41741
StatStrip Glucose Control Solution, Level 2, One vial	41742
StatStrip Glucose Control Solution, Level 3, One vial	41743
StatStrip Glucose Linearity Kit, 5 levels, 1 vial of each level	42173
StatStrip Glucose Test Strips, 1800 test strips, 72 vials, 50 per vial	42214

A.6 Theory

A.6.1 Glucose

The glucose measurement is based on the following methodology:

Glucose + Enzymes(oxidized form)——>Gluconic Acid + Enzymes(reduced form) Equation 1

Enzymes(reduced form) + Ferricyanide—>Enzymes(oxidized form) + Ferrocyanide Equation 2

$$\text{Ferrocyanide} \xrightarrow[\text{Electrode}]{-e^-} \text{Ferricyanide} \qquad \text{Equation 3}$$

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

A.7 Results of CLIA Waiver Study

A clinical study was conducted at five sites located in two regions of the United States. A hospital in Florida performed studies at three sites (Site1: Medical Surgical unit; Site2: Cardiac, Pediatric, Oncology unit; and Site3: Progressive Care unit) and two sites in Northeast region (Site4: Nova Biomedical, Waltham, MA, and Site 5: Consumer Product Testing company, Fairfield, NJ). There were a total of 28 operators distributed as follows; site1 through site 5 had 3, 4, 5, 12, and 4 operators, respectively. The study involved running 493 specimens (124 fingertip; 183 venous; 13 spiked venous; 169 arterial; and 4 spiked arterial) across over 15 days for sites 1 through 3 and three days for sites 4 and 5.

The comparative method (CM) was Dade for venous and arterial whole blood and Yellow Springs Instrument (YSI) Model 2300 STAT Plus for capillary whole blood. Discarded whole blood samples ran by hospital personnel and then immediately centrifuged by a health care professional to obtain a plasma sample to be analyzed on a central laboratory chemistry analyzer (Dade RxL). Each sample was tested in duplicate by YSI and the average of two results was calculated. Three replicate samples (one from each finger) per subject were tested by Nova StatStrip. For systematic bias checking, mean of YSI and mean of StatStrip was used. For allowable total error (ATE) zones and zones of Limits for Erroneous results (LER) analysis, the proportion of results fallen into these zones was assessed including a 95% confidence interval that adjusted for multiple observations per specimen.

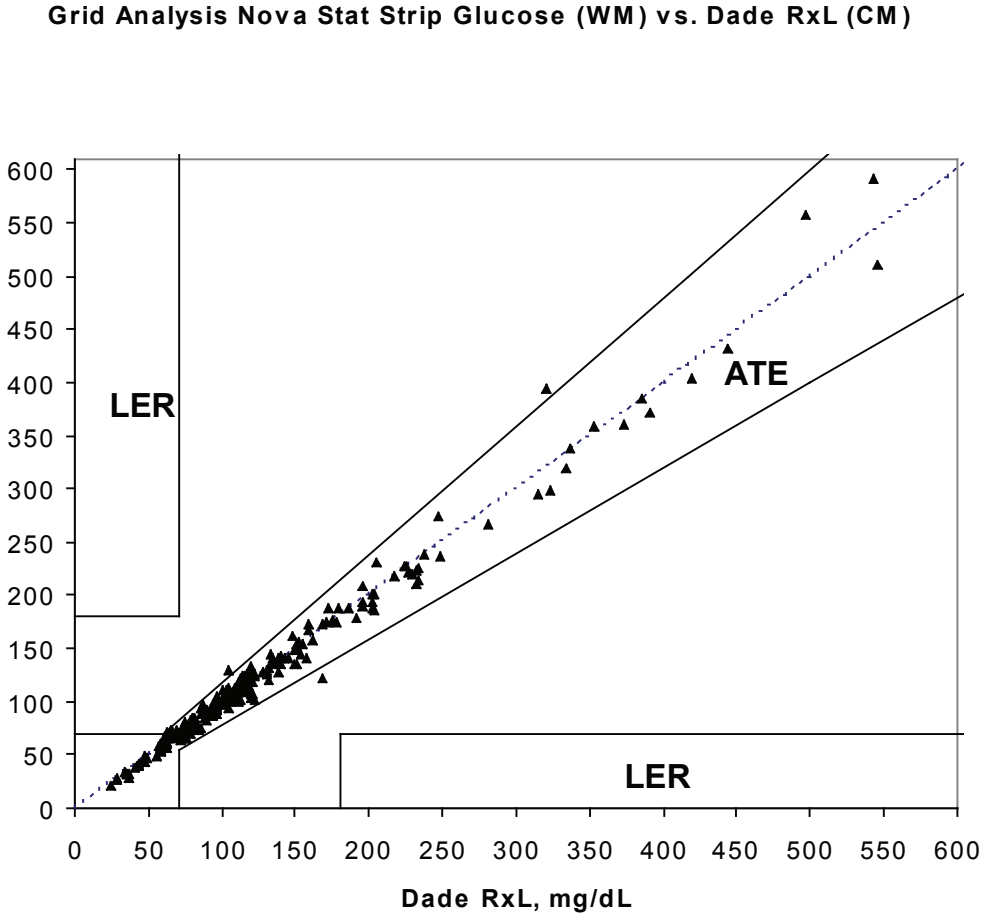
The study was intended to demonstrate that after reading only the test instructions, participants were able to get results on the Nova StatStrip that were as accurate as those obtained on comparative methods using the following performance limits: Allowable Total Error (ATE) encompasses values of (CM result ± 15 µg/dL) for CM results ≤75 µg/dL and (CM result ± 20%) for CM results > 75 µg/dL (International Standard Organization recommendations for blood glucose monitoring).

The results of the study for venous and arterial samples were following:

Range of Dade values (µg/dL)	Total number of samples	Number of samples within of ATE	Percent of samples within of ATE
20 to 97	168	168	100%
97.1 to 114	55	54	98%
114.1 to 650	146	144	98.6%
20 to 650	369	366	99.2%

The percentage of the arterial and venous samples over the entire range that fell within the ATE zone was 99.2% (366/369) with a lower bound of 95% confidence interval of 97.6%. In the study, none of the results were in the LER zone (0% with an upper bound of 95% confidence interval of 0.5%).

The scatter plot of the study results with ATE and LER zones is presented by the figure below:



The descriptive statistics of the differences between Dade glucose and Nova StatStrip results of arterial and venous samples are presented by the table below:

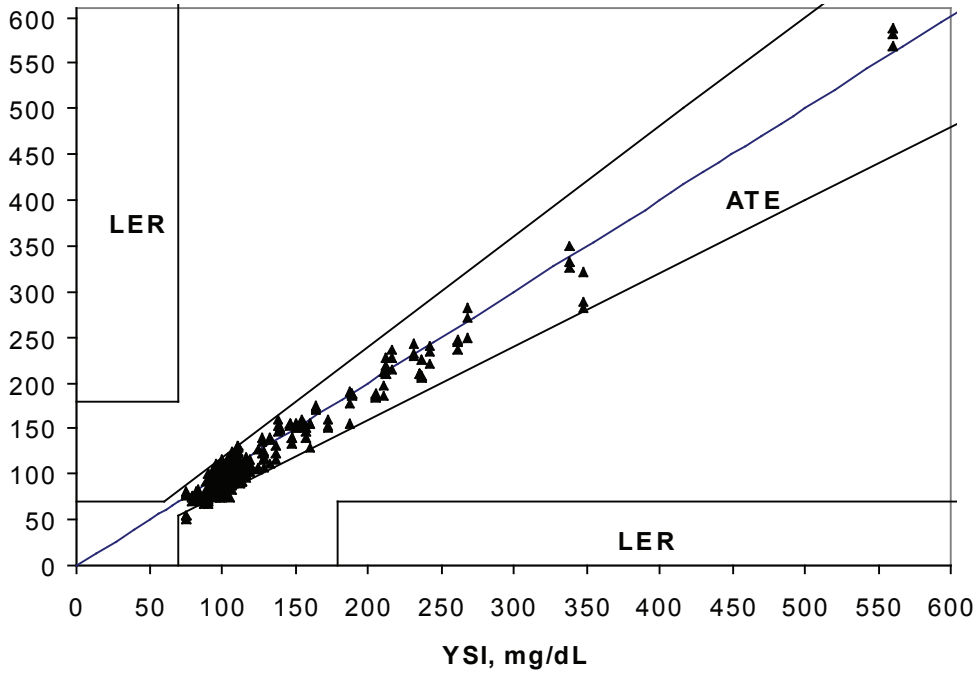
Range of Dade values (mg/dL)	Average Difference	2.5th percentile of relative differences	97.5th percentile of relative differences
20 to 75	1.37 mg/dL	-7.63 mg/dL	9 mg/dL
75.1 to 97	-1.1%	-12.3%	11.74%
97.1 to 114	0.35%	-10.15%	9.54%
114.1 to 650	-1.31%	-11.98%	10.86%

The results of the study for capillary samples were as follows:

Range of YSI values (µg/dL)	Total number of samples (including 3 replicates per subject)	Number of samples within of ATE	Percent of samples within of ATE
< 97	87	79	90.8%
97.1 to 114	168	158	94%
> 114	117	117	100%
Total	372	354	95.2%

The percentage of the capillary samples over the entire range that fell within the ATE zone was 95.2 % (354/372) with a lower bound of 95% confidence interval of 93%. These 124 sets of triplicate results were bootstrapped 1000 times to get 95% confidence bound for the percent of observations fallen within the ATE. In the study, none of the samples were in the LER zone (0% with an upper bound of 95% confidence interval of 0.5%).
The scatter plot of the study results with ATE and LER zones is presented by the figure below:

Grid Analysis Nova StatStrip Glucose (WM) vs, YSI Glucose (CM)



The descriptive statistics of the differences between YSI glucose and Nova StatStrip results of capillary samples are presented by the table below (124 sets of triplicate results were used):

Range of YSI values (µg/dL)	N	Average Relative Difference (%)	2.5th percentile of relative differences (%)	97.5th percentile of relative differences (%)
< 97	87	-7.56	-27.65	13.17
97.1 to 114	168	-4.99	-24.38	14.98
> 114	117	-3.79	-17.91	8.86

A.8 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails under warranty after delivery to the customer because of defective material or workmanship. This warranty does not include (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. Contact Nova for specific information. The following exceptions apply:

- Consumable items, including quality control solutions, are warranted to be free of defects until the end of the expiration date or 90 days after the date opened. Glucose Test Strips are warranted to be free of defects until the end of the expiration date or 180 days after the date opened. These items must be placed into use prior to the expiration date printed on the packaging.
- Freight is paid by the customer.

This warranty is invalid under the following conditions:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranty on a StatStrip Glucose Hospital Meter if used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.