

REF 65965

Rx Only IVD






















Instructions for Use Manual



nova[®]
biomedical

Stat Strip[®]
Glucose Hospital Meter System

NOVA BIOMEDICAL SYMBOL DIRECTORY

	<i>In vitro</i> diagnostic medical device		Batch code
	Caution, consult accompanying documents		Serial Number
	Consult instructions for use		Temperature limitation
	Biological risk		Upper Limit of Temperature
	Catalog number		Number of Tests
	Manufacturer		Use by
	Date of Manufacture		This device complies with Part 15 of the FCC Rules and with RSS-247 of industry Canada
	Control		The system complies with the electrical and safety requirements.
	Level		
	Do not reuse		
	Glucose		
	Power supply connection		Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Revision History

Rev.	Release	Description
A	01-2023	Initial Release
B	06-2024	Interfering Substances

StatStrip® Glucose Hospital 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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Waltham, MA 02454 USA		(in the USA)
		1-978-439-3763
		(USA and International)
		1-781-891-9718
		(International Only)
	Web:	www.novabiomedical.com

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

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1 Introduction

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.

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

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 or a Quality Control (QC) solution. 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.

In the USA, the StatStrip Glucose Hospital Meter is hard-coded to display glucose results in mg/dL units only.

1.1 About This Manual

This manual is for the StatStrip Glucose Hospital Meter System from Nova Biomedical.

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 Important Safety Instructions

Blood-Borne Pathogens Safety



1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the StatStrip Glucose Hospital Meter System.
2. Healthcare professionals should be aware that all parts of the StatStrip Glucose Hospital Meter System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
3. The StatStrip Glucose Hospital Meter System may only be utilized for testing on multiple patients when Standard Precautions are followed and when the system is cleaned and disinfected after use on each patient following the procedure in Section 6.3. Healthcare professionals should wear a new pair of protective gloves before testing each new patient.
4. Only auto-disabling, single-use lancing devices may be used with this system.
5. For more information, refer to the following references:
 - "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
 - Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmbl5/>.

- "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition," Clinical and Laboratory Standards Institute (CLSI) M29-A3.
- "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication." (2010) <http://www.fda.gov/Medicaldevices/Safety/AlertsandNotices/ucm224025.html>.
- "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens." (2010) <http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>.

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 serviced by qualified service personnel.

Electrical Safety

1. Battery powered: 3.7 V Li Polymer battery (rechargeable)
2. Desk-mount Wireless Charging Station with Power Adapter
3. An LED indicator light to show the battery is charging: green blinking light indicates meter 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.

Disposal of Used Meter and Battery



- 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.
- 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.
- Disinfect the meter before recycling or discarding.

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: 10% to 90% non-condensing
- The maximum altitude for Meter operation: Up to 15,000 feet (4572 meters)

Dimensions:

Height: 158 mm (6.23 in)

Width: 77 mm (3.04 in)

Depth: 28 mm (1.11 in)

Weight: 215 g (0.47 lb)

1.3 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

1.4 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 before specimen collection.

1.5 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 (4572 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 for use with neonate venous blood.
- 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
- Ranges for the StatStrip Glucose Hospital Meter using other commercially available glucose controls have not been established and may give erroneous results.

References:

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

1.6 General Precautions

- Before use, read the Instructions for Use Manual.
- DO NOT reuse test strips. Test strips should be disposed after a single use.
- Discard used test strips according to local regulations.
- Remove the test strip from the vial only when ready to test.
- Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
- Do not tamper with the test strip.
- If the test result is higher or lower than expected, run a control solution test to confirm test strip performance.
 1. If the control solution result is out of range, remove the test strip vial from the point of use and repeat the control solution test with the new test strip vial.
 2. If the control solution test is within the expected range, repeat the patient test.
 3. If the patient test result is higher or lower than expected, perform the glucose test on an alternate method and consult the healthcare professional.

1.7 The Sample

- Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonate heel stick, and neonate arterial whole blood specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.
- Sample size 1.2 μ L

1.8 Operation Overview

The meter uses a touch screen for menu navigation and data entry. An on-screen keypad allows manual data entry of alphabetic and numeric characters.



Figure 1.1 StatStrip Glucose Hospital Meter

The meter provides audible feedback of user inputs such as key presses and barcode 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 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.

1.8.1 Using the Display Keypad

The Display Keypad has 2 formats: numeric and alphabetic. To display the alphabetic keypad from the numeric display, press the 'ABC...' key. To display the numerical display from the alphabetic display, press the '123' key.

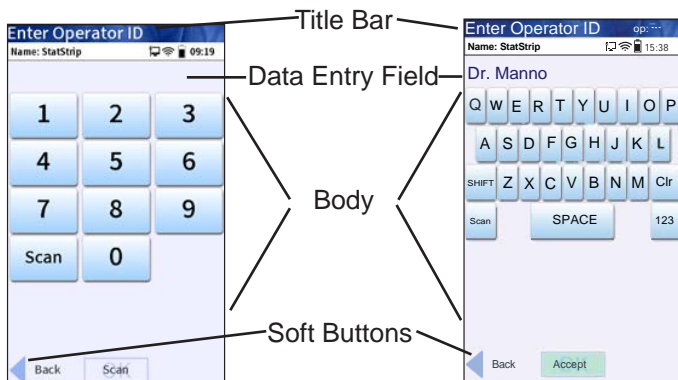


Figure 1.2 The Numerical and the Alphabetic Keypad Screens

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

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, and WIFI status
2. The Body – data entries, selections, and screens
3. The Soft Key Bar – confirmation of data entry and screen navigation

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

- Soft buttons for menu navigation and menu prompt acknowledgment
- Soft keyboard for data input

1.8.2 Soft Buttons

On-screen buttons, called "Soft Buttons," are used for menu navigation and screen menu choice.

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 "123" 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, 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.

1.8.3 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:

- 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:

- Touching the screen
- Inserting a strip (test/QC/Linearity)

NOTE: *Press the button provided on the side of the meter and hold it for 5 seconds to enter sleep mode and 8 seconds to reboot/restart the Meter.*

1.8.4 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.

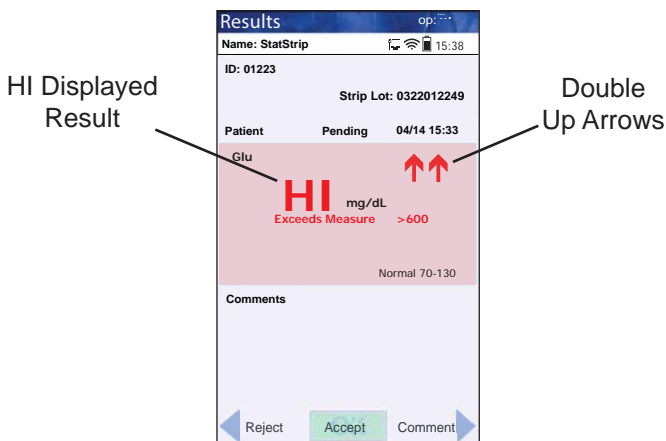


Figure 1.3 Patient Result: Exceeds Measure/HI screen

1.8.5 Multi-Screen or List Screen Menus

When a menu or a list is too large to be fully displayed on the LCD screen, the user can either scroll up or down to navigate through the complete list of screen/menu.

1.9 Installing the StatStrip Glucose Hospital Meter System

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.

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.

1.9.1 Power Up Procedure

After the initial power-up, 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

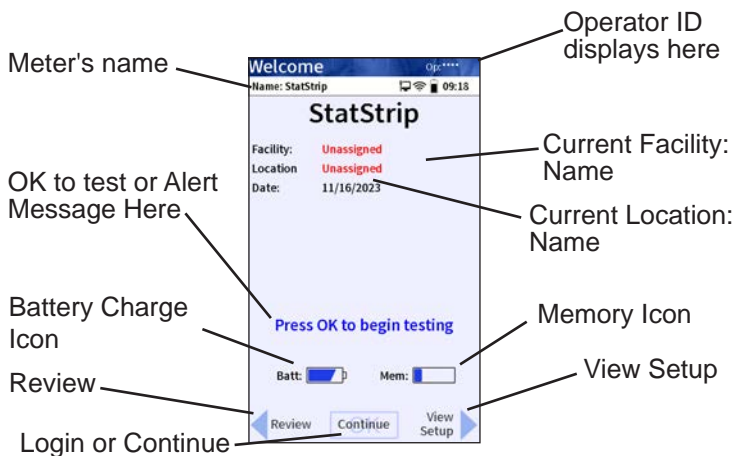


Figure 1.5 Welcome Screen

Messages or Alerts on the Home screen

- Press OK to begin testing
- Memory Full
Dock Meter Immediately
- Battery Low
Charge 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

**While CLIA-Waived users may encounter the "Linearity Required" alert, linearity testing is not expected to be done by CLIA-Waived users.*

1.10 Operator Login

After the initial power-up, a CLIA-Waived 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 the numeric keypad, press the '123' soft key.
 - c. To use the barcode scanner, press the Scan soft key on the Enter Operator ID screen.

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

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

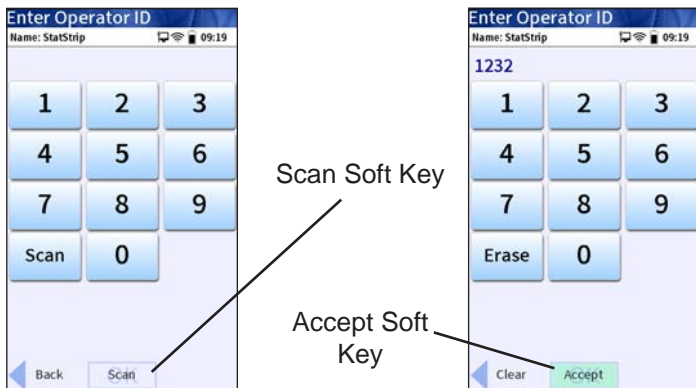


Figure 1.6 Enter Operator ID Screens

4. After the Operator ID is accepted, the Patient Test screen displays.

The meter is now ready to run Patient tests, QC tests, review results, set the time, etc.

1.11 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, scroll the numbers up or down to set the time 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.

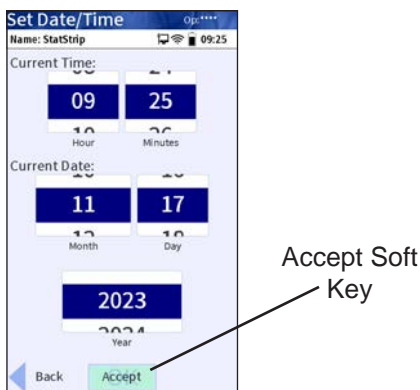


Figure 1.7 The Set Time (and Date) Screen

1.12 Sound

This feature can be accessed from the admin screen. The next screen would take you to the volume adjust page.

Set the volume level to '0' to mute (or) have no sound and the level '3' for the highest volume.



Figure 1.8 The Sound Screen

1.13 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 StatStrip 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 StatStrip Glucose Hospital Meter. These StatStrip 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.

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

- During institutional training of 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, 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 result is 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.

2.2 StatStrip Glucose Control Solution



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

Only the StatStrip Glucose Control Solutions are recommended for use with the StatStrip Glucose Meter and the StatStrip Glucose Test Strips. Ranges for the StatStrip Glucose Meter using other commercially available glucose controls have not been established and may give erroneous results.

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.

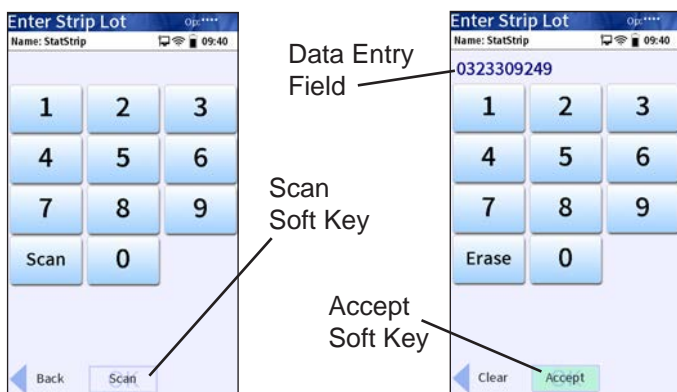


Figure 2.1 Enter Strip Lot Screens

- 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."

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

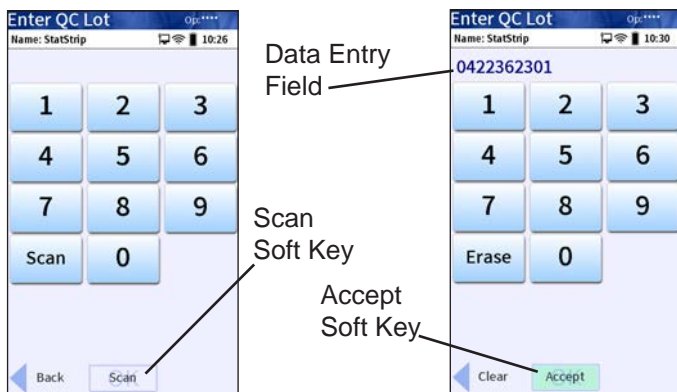


Figure 2.2 Enter QC Lot Screens

- 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.

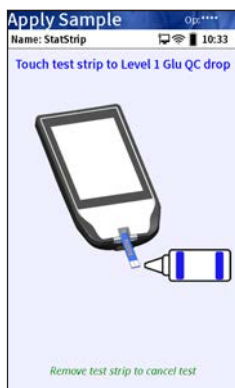


Figure 2.4 Apply QC Solution to Test Strip Screen

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.
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.

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.

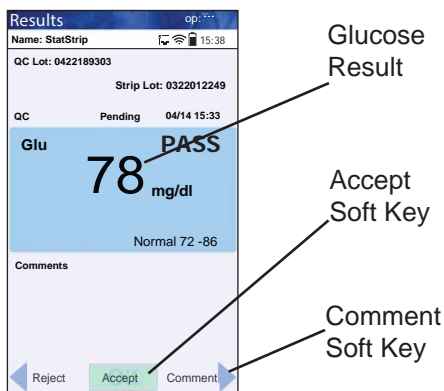


Figure 2.5 QC Result Screen

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

NOTE: Acceptable control assay ranges are printed on the Glucose Control Solutions vial. If a QC test does not fall within the specified range, the meter will display FAIL. If the control results are within the range, the meter will display PASS. If the control test fails, the glucose meter and test strip may not be working as a system.

NOTE: *Verify that the StatStrip Glucose Hospital Meter Test Strips and Control Solutions are not past their expiration dates. If they are expired, immediately discard. Repeat the test with a new strip. If the second test fails, repeat the test with a new test strip vial, discard the previous vial if the test strip from the new vial passes. If the third test fails, contact Nova Biomedical Technical Support toll free at 1-800-545-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. 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.

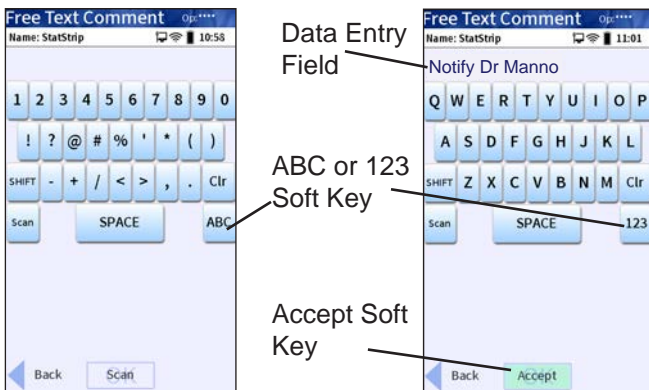


Figure 2.6 Add Comment Screens

2. QC

3 Patient Samples

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

3.1 Important Safety Instructions

Standard Precautions should be adhered to when handling or using the StatStrip Glucose Hospital Meter System to reduce the risk of disease transmission.

All parts of the StatStrip Glucose Hospital Meter System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.

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

The StatStrip Glucose Hospital Meter System may only be utilized for testing on multiple patients when Standard Precautions are followed and when the system is cleaned and disinfected after use on each patient following the procedure in Section 5.2.

Healthcare professionals should wear a new pair of protective gloves before testing each new patient.

For more information, refer to the following references:

1. "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
2. Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmb15/>. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition," Clinical and Laboratory Standards Institute (CLSI) M29-A3.

3. "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication." (2010). <http://www.fda.gov/Medicaldevices/Safety/AlertsandNotices/ucm224025.html>.
4. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens." (2010). <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

3.2 Running a Patient Sample

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

NOTE: 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.

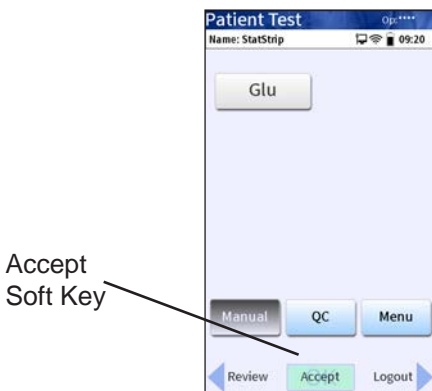


Figure 3.1 Patient Test Screen

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

- Once the Lot Number has been added, press the Accept soft key.

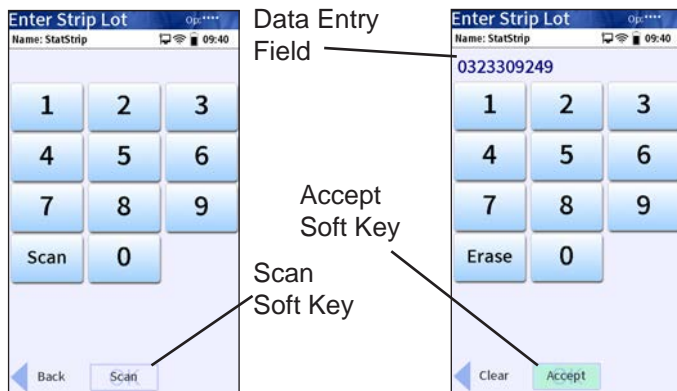


Figure 3.2 Enter Strip Lot Screens

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

StatStrip Glucose Hospital Meter

- 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. Then scan the patient's barcode with the bottom of the meter.

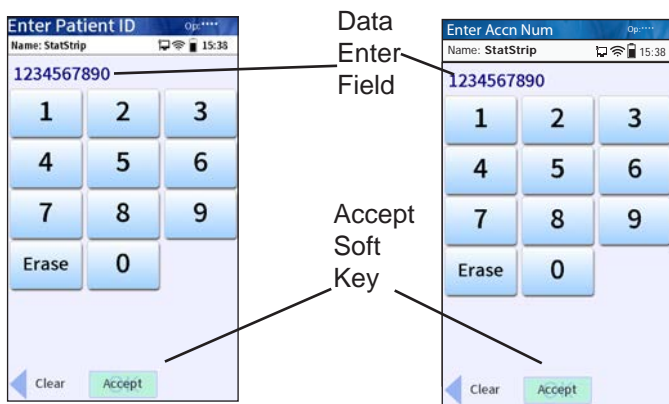


Figure 3.3 Enter Patient ID or Enter Accn Num Screens

- Once the Patient's ID/Accession Number has been entered, press the Accept soft key.
- The Insert Strip screen displays. Insert a test strip as shown on the meter screen.



Figure 3.4 Insert Strip Screen

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

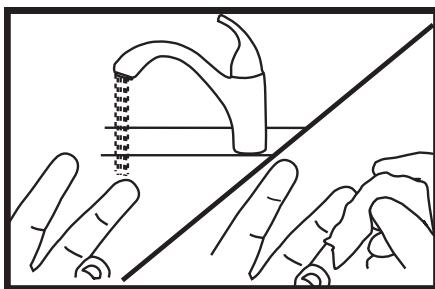


Figure 3.5 Wash the Patient's Finger

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

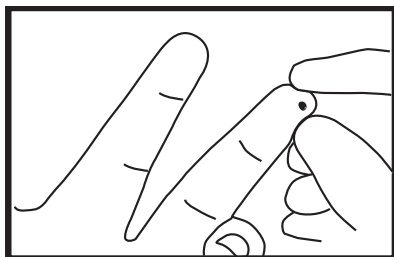


Figure 3.6 Squeeze the Finger to Form a Drop of Blood

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.*

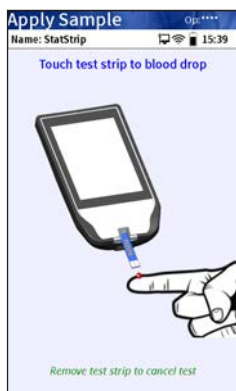


Figure 3.7 Touch Test Strip to Blood Drop Screen

17. The test results will appear in 6 seconds.

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

18. 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.)
All data are stored into memory.

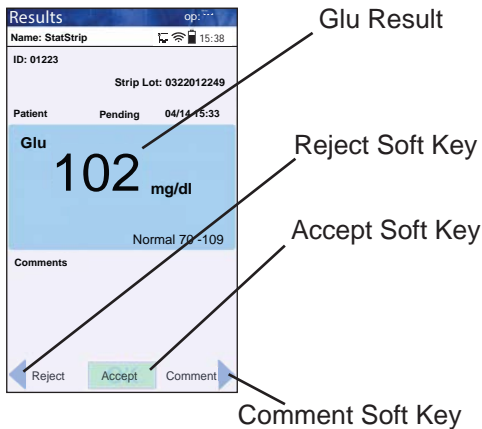


Figure 3.8 Glucose Results Screen

- NOTE:** A single up arrow displays for abnormal high result and 2 up arrows for critical high value.
- NOTE:** A single down arrow displays for abnormal low result and 2 down arrows for critical low value.
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 5.2.

3.3 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.

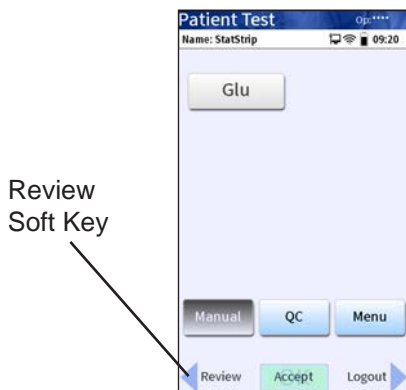


Figure 3.9 Patient Test Screen: Review Soft Key

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, and end.

5. 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.

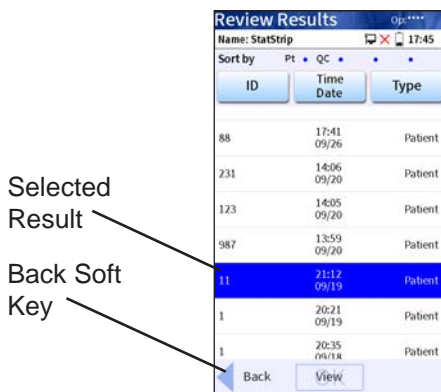


Figure 3.10 Review Results Screen: Result Selected

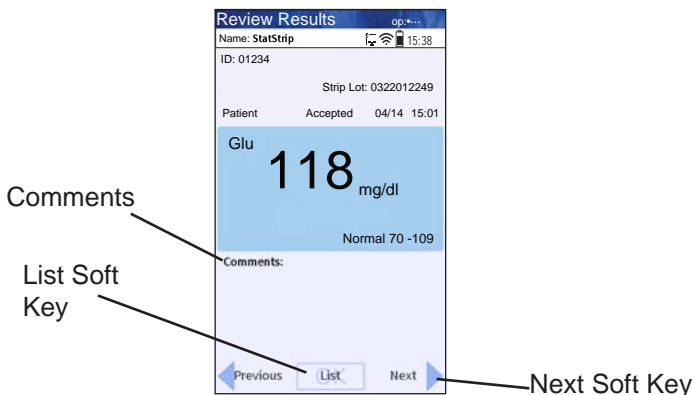


Figure 3.11 Review Result Screen: Selected

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 into a wall outlet.
3. Place the meter into the Charging Station.
4. Connect the Docking/Charging Station to the network through the Ethernet connection at the back of the station.
 - There is one LED light on the docking station. The green blinking light indicates that the meter is charging.



Figure 4.1 The Meter in the Docking/Charging Station

5 Maintenance

The meter is very low maintenance. The meter needs to have the battery (non-replaceable) charged in the Charging Station, and its surface cleaned/disinfected.

5.1 Charging the Meter

When the Battery LOW symbol displays on the screen, place the meter into the Charging Station. The battery is non-replaceable (sealed in the meter).



Figure 5.1 Battery Low: Charge the Battery Screen Alert



Figure 5.2 Meter placed into Charging Station

5. Maint.

5.2 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.

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 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.

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 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.

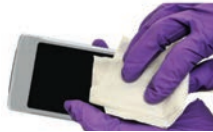


Figure 5.3 Wiping the Surface of the Meter

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**.



Figure 5.4 Ensure Surface Stays Wet for a Minimum of 1 Minute

4. Dispose of wipe and gloves.

- Dispose of used wipe and gloves in a standard biohazard container.



Figure 5.6 Dispose of Wipe and Gloves

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.



Figure 5.7 Wash and Sanitize Hands

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.*

6 Troubleshooting

6.1 Meter Screen Alerts

The meter displays a number of alerts:

1. **Battery Low** - Place the meter onto the Charging/Docking Station.

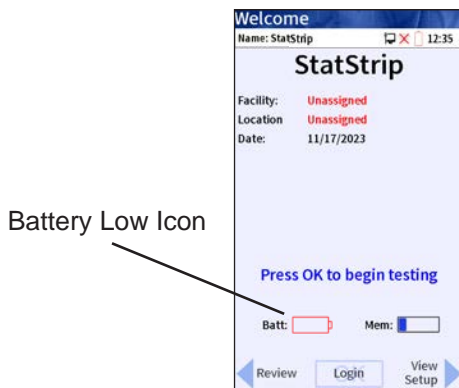


Figure 6.1 Battery Low: Charge Battery Screen Alert

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.



Figure 6.2 Analysis Cancelled screen alert

- 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 6.3 Analysis Error - Temperature Error Screen Alert

- 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.



Figure 6.4 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 an alternate method.



Figure 6.5 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 a test using an alternate method.



Figure 6.6 Analysis Error - Flow Error Screen Alert

- Transfer Failed** - Server refuses to allow dialog with the meter, or Connection to server was broken. Please check the network settings, the status of your network, or contact your administrator for assistance, or contact Nova Biomedical or customer support if an administrator is not available.

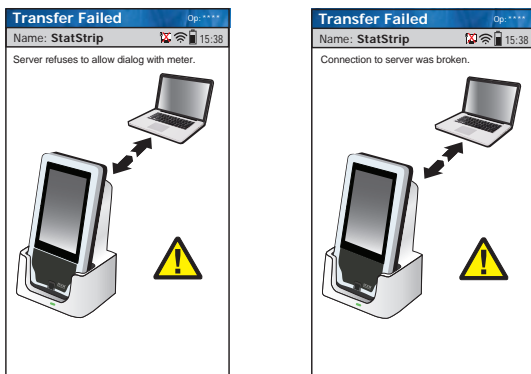


Figure 6.7 *Transfer Failed - Connection Not Allowed or Connection Broken*

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





Figure 6.8 *Transfer Failed - Transfer Incomplete*

A Appendix

Appendix A includes analyzer specifications, solutions and reagents, consumable lists, and reference information 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:	Capillary whole blood (finger stick), Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings, including critical care settings Sample size: 1.2 μ L
Measuring Technology:	Enzyme, Amperometric Glucose Enzyme (Aspergillus sp. >1.0 IU)
Analysis Time:	6 seconds
Meter Memory:	1500 Patient Tests 3000 Patient Records 200 QC Tests 8000 Operator Records
Docking/Charging Station:	Desk mount Input 100-240 VAC  , 50-60 Hz, 0.5 A - 1.0 A Single Output + 12 VDC  , 2 - 2.5 A Single
Data Output Port:	RJ-45 Ethernet (10Mbit)
Connectivity:	Protocol TCP/IP Ethernet Standard POCT1-A Compliant
Battery:	Rechargeable Li-polymer 3.6 V 2200 mAh
Electrical Compliance:	Conforms to the electrical and safety requirements of IEC 61010-1 and 61010-2 standards.

StatStrip Glucose Hospital Meter

Dimensions:	158 mm (6.23 in) x 77 mm (3.04 in) x 28 mm (1.11 in)
Weight:	215 grams (0.47 lbs.)
Power:	3.6V Li Polymer battery (rechargeable)
Environmental:	
Temperature Range:	59°F – 104°F (15°C – 40°C)
Altitude:	Up to 15,000 feet (4,572 meters)
Relative Humidity:	Up to 90% (noncondensing)

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 2-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
 - f. PDF417
 - g. Maxicode
 - h. Data Matrix
 - i. AZTEC
 - j. QR CODE
-

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.3.1 Barcode Readability, Risks, and Safety

If a barcode data/symbol is read incorrectly, it may lead to patient mistaken identity (or) inaccurate patient management decisions.

For additional information, consult the ISO/IEC 15415 and ISO/IEC 15416 standards for the following information:

- Evaluating and grading an overall assessment of symbol quality and adequacy
- Measurement of specific attributes of barcode symbols (e.g. dimensions)
- Information on possible causes of deviation from optimum grades to assist users in taking appropriate corrective action.

A.4 Normal Glucose Adult Values Non-diabetic

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	Less than 100 mg/dL (5.55 mmol/L) Normal Fasting
	Less than 140 mg/dL (7.77 mmol/L) 1-2 hours after meals

References:

1. American Diabetes Association. Diagnosis and Classification of Diabetes: Standards of Medical care in Diabetes. Diabetes Care, Volume 41, Supplement 1, January 2018.

A.5 Ordering Information

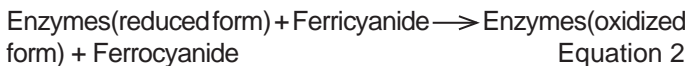
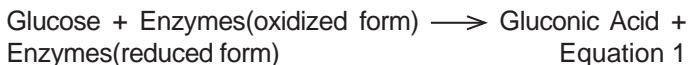
Supplies and parts for the StatStrip Glucose Hospital Meter are available from Nova Biomedical.

DESCRIPTION	Part #
Carrying Case for Meter & Supplies	53425
Docking Station (Single) with AC Adapter	65736
Instructions for use manual, printed	65965
Quick Reference Guide.....	65966
Safety Lancets, 28-Gauge, 100 per box	41224
StatStrip Glucose Control Solution, Level 1, 1 vial ..	41741
StatStrip Glucose Control Solution, Level 2, 1 vial ..	41742
StatStrip Glucose Control Solution, Level 3, 1 vial ..	41743
StatStrip Glucose Linearity Kit, 5 Levels, 1 vial of each level.....	42173
StatStrip Glucose Test Strips, 1800 test strips, 36 vials, 50 per vial	42214

A.6 Theory

A.6.1 Glucose

The glucose measurement is based on the following methodology:



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

B Appendix: Administrative Instructions (for Non CLIA-Waived Users)

Appendix B includes information for non CLIA-Waived users and administrators of the StatStrip Glucose Hospital Meter.

B.1 Administration (Admin) Screen

This screen has soft keys to perform many 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.

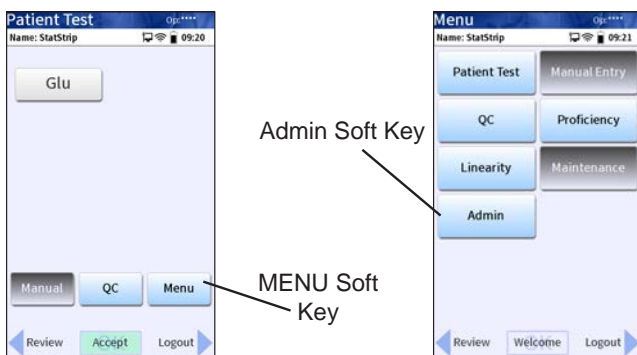


Figure B.1 Patient Test Screen and MENU Screen



Figure B.2 The Admin Screen

B.1.1 Naming the Meter

The meter can be given a name with respect to where it will be used: i.e., Your Location.

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.

B.1.2 View Setup

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

B.1.3 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.

B.1.4 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.

B.1.5 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.

B.2 Interfering Substances

Glucose Interferences:

The StatStrip Glucose Hospital Meter System exhibits **no** interference from the following list of drugs or physiological conditions commonly found in patients in intensive care settings with complex medical conditions and drug regimens up to the following concentration levels:

StatStrip Glucose Hospital Meter

Tested Interfering Substances	Tested Concentration Level	
Acetaminophen	20.0 mg/dL	1.323 mmol/L
Acetoacetate	51.0 mg/dL	5 mmol/L
Acetone	69.7 mg/dL	12 mmol/L
Acyclovir	0.6 mg/dL	0.027 mmol/L
Albuterol	0.06 mg/dL	0.0025 mmol/L
Amitriptyline	0.06 mg/dL	0.0022 mmol/L
Amoxicillin	5 mg/dL	0.137 mmol/L
Ampicillin	0.8 mg/dL	0.0229 mmol/L
Ascorbic Acid	22.5 mg/dL	1.278 mmol/L
Atropine	0.01 mg/dL	0.000346 mmol/L
Beta-hydroxybutyrate	166.6 mg/dL	16 mmol/L
Bilirubin	29.3 mg/dL	0.5 mmol/L
Captopril	0.6 mg/dL	0.0276 mmol/L
Carbamazepine	1 mg/dL	0.0423 mmol/L
Cefaclor	35 mg/dL	0.952 mmol/L
Cholesterol	1000 mg/dL	25.86 mmol/L
Cimetidine	5 mg/dL	0.198 mmol/L
Citric Acid	384.3 mg/dL	20 mmol/L
Creatinine	6 mg/dL	0.53 mmol/L
Digoxin	0.3 mg/dL	0.0038 mmol/L
Diltiazem	0.1 mg/dL	0.0024 mmol/L
Dopamine	20 mg/dL	1.306 mmol/L
Enalapril	0.5 mg/dL	0.0133 mmol/L
Ephedrine	1 mg/dL	0.0605 mmol/L
Ethanol	399.9 mg/dL	86.8 mmol/L
Famotidine	0.042 mg/dL	0.0012 mmol/L
Fluconazole	2 mg/dL	0.0653 mmol/L
Fluoxetine Hydrochloride	2 mg/dL	0.0647 mmol/L
Fructose	500 mg/dL	27.75 mmol/L
Furosemide	3 mg/dL	0.0907 mmol/L
Galactose D(+)	500 mg/dL	27.75 mmol/L
Galactose-1-Phosphate	500 mg/dL	19.22 mmol/L
Gentamicin sulfate	12 mg/dL	0.2513 mmol/L
Glycerol	500 mg/dL	54.30 mmol/L
Heparin	1.2 mg/dL	N/A
Hydrochlorothiazide	2 mg/dL	0.0672 mmol/L

Tested Interfering Substances	Tested Concentration Level	
Hydrocortisone	20 mg/dL	0.552 mmol/L
Ibuprofen	48.0 mg/dL	2.33 mmol/L
Ketoprofen	6 mg/dL	0.236 mmol/L
Lactose	500 mg/dL	14.61 mmol/L
Lansoprazole	20 mg/dL	0.542 mmol/L
L-dopa	5 mg/dL	0.25 mmol/L
Levofloxacin	1.8 mg/dL	0.0498 mmol/L
Lidocaine	0.7 mg/dL	0.0299 mmol/L
Lisinopril	0.5 mg/dL	0.0123 mmol/L
Maltose D(+)	500 mg/dL	14.61 mmol/L
Maltotetraose D(+)	240 mg/dL	3.6 mmol/L
Maltotriose D(+)	240 mg/dL	4.76 mmol/L
Mannitol	6000 mg/dL	329.4 mmol/L
Mannose	500 mg/dL	27.75 mmol/L
Methyldopa	0.9 mg/dL	0.042 mmol/L
Metoprolol Tartrate Salt	1.8 mg/dL	0.0673 mmol/L
N-acetylcysteine	81.6 mg/dL	5 mmol/L
Naproxen	40 mg/dL	1.74 mmol/L
Nifedipine	0.02 mg/dL	0.00058 mmol/L
Norepinephrine	10 mg/dL	0.591 mmol/L
Nortriptyline Hydrochloride	0.02 mg/dL	0.00076 mmol/L
Olanzapine	0.02 mg/dL	0.00064 mmol/L
Pancuronium bromide	0.4 mg/dL	0.0070 mmol/L
Penicillin	72 mg/dL	2.02 mmol/L
Phenytoin	2.5 mg/dL	0.099 mmol/L
Prednisone	1 mg/dL	0.0279 mmol/L
Propofol	3.2 mg/dL	0.18 mmol/L
Propranolol Hydrochloride	0.3 mg/dL	0.012 mmol/L
Ranitidine hydrochloride	1 mg/dL	0.032 mmol/L
Salicylate	120.0 mg/dL	7.50 mmol/L
Sodium Chloride Deviation from a normal sodium or chloride level	234 mg/dL	40 mmol/L
Sodium Nitroprusside dihydrate	0.05 mg/dL	0.0019 mmol/L
Sorbitol	500 mg/dL	27.45 mmol/L
Sucrose	500 mg/dL	14.61 mmol/L

Tested Interfering Substances	Tested Concentration Level	
Sulfamethoxazole	1.5 mg/dL	0.059 mmol/L
Tetracycline	30 mg/dL	0.675 mmol/L
Theophylline	2 mg/dL	0.111 mmol/L
Tolazamide	45 mg/dL	1.45 mmol/L
Tolbutamide	50 mg/dL	1.85 mmol/L
Triglyceride	1500 mg/dL	16.9 mmol/L
Uric Acid	23.5 mg/dL	1.4 mmol/L
Vancomycin hydrochloride hydrate	3 mg/dL	0.021 mmol/L
Verapamil Hydrochloride	0.1 mg/dL	0.0022 mmol/L
Warfarin	1.2 mg/dL	0.039 mmol/L
Xylose	500 mg/dL	33.3 mmol/L
Hematocrit	5% to 75%	
Oxygen	All concentrations	
pH	6.6 and 8.0	

B.3 Linearity Test

This section describes how to perform Linearity tests with the StatStrip Glucose Hospital Meter. There are 5 levels in the StatStrip Glucose Linearity kit.



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

B.3.1 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.

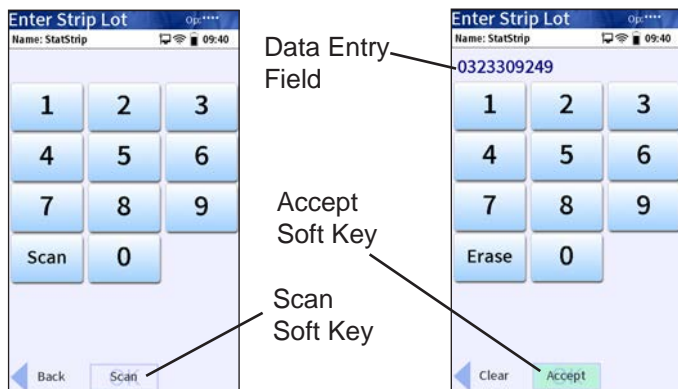


Figure B.3 Enter Strip Lot Screens

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.

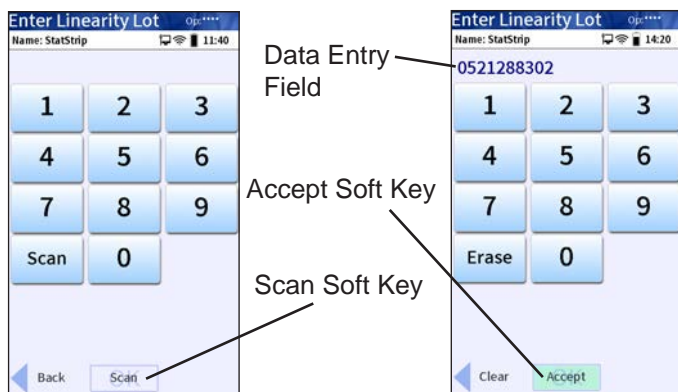


Figure B.4 Enter Linearity Lot Screens

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



Figure B.5 Insert Strip Screen

- With the test strip correctly inserted, the Apply Sample screen displays.
- Gently mix the StatStrip Linearity Solution before each use.
- Discard the first drop of linearity solution from the bottle to avoid contamination.
- 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 B.6 Apply Sample (Linearity Solution) to Test Strip Screen

- Recap the linearity solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.
- When the meter completes the test, the Linearity Result screen displays with the results in mg/dL or mmol/L.

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

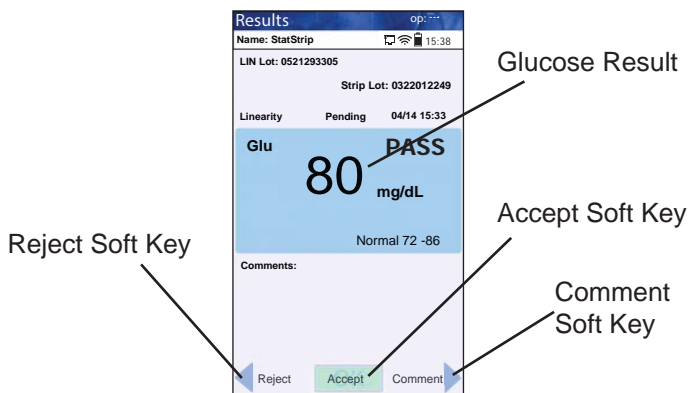


Figure B.7 Linearity Result Screen

- Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.
- To add a comment, press the Comment soft key. (See Section 2.4 Add Comment to Result.)
- To accept the result, press the Accept soft key.

B.4 Results of Multi-Center Clinical Study: Patients Requiring Intensive Medical Intervention/Therapy

Introduction

Nova Biomedical conducted a large multi-center study of the StatStrip Glucose Hospital Meter System at five (5) leading medical centers to demonstrate clinical performance within all hospital and all professional healthcare settings on 1,698 different patients requiring intensive medical intervention. A description of the clinical study sites is found below.

Clinical study **Site #1** and **Site #2** are part of the largest tertiary hospital system in the Netherlands with 994 beds and more than 550,000 outpatient visits, 47,000 inpatient admissions and 51,000 outpatient care patients. The clinical study was conducted by Point-of-Care (POC) personnel within the health care settings. The clinical study data from both sites encompasses 1,245 arterial and venous blood glucose results (927 arterial and 318 venous) from 1,245 different patients. The peripheral arterial and peripheral venous specimens were obtained from patients in medical and surgical units with a mix of critical heart, lung, diabetes, trauma, neurology and gynecological conditions. Patient specimens obtained from the emergency departments include patients with a mix of heart, lung, diabetes, trauma, neurology and gynecological conditions. Specimens obtained from the operating rooms include patients undergoing surgery for heart and lung conditions as well as severe trauma and neurological conditions.

Clinical study **Site #3** is a 619 bed acute-care teaching hospital located in the state of California. The hospital is a leading referral center for some of the most seriously injured or ill patients in the region. The clinical study was conducted by POC staff in the burn center intensive care/trauma unit. The inclusion criteria included adult burn patients with 20% or more total body surface area partial/full-thickness burns. The condition of these burn center patients was considered to be extremely critical and complex. The 123 central arterial specimens included in this clinical study (123) are

from six (6) burn patients treated with drugs, therapeutics and treatment programs (high dose Ascorbic Acid) over an extended period of treatment.

Clinical study **Site #4**, located in Brussels, Belgium, is one of the leading healthcare providers in Europe. It has top-ranked services in Cardiology, Children's Health, Digestive Diseases, Gynecology and Obstetrics, Infectious Diseases and Ophthalmological Surgery. The clinical study was conducted by POC staff in the surgical and cardiovascular intensive care units. The 374 peripheral arterial samples included in this study are from the types of patients that one would see in surgical and cardiovascular intensive care units within a leading university hospital.

Clinical study **Site #5** is one the world's preeminent health care institutions located in Maryland. It is a 560 bed university hospital that includes 33 operating rooms, acute care and intensive care facilities, oncology, obstetrics, pediatric, and neonatal facilities. The clinical study focused on oncology and renal disease patients and was conducted by POC staff. The 73 peripheral arterial and peripheral venous specimens were collected from 73 different patients and are from the types of patients that one would see in oncology and renal healthcare settings.

StatStrip performance versus the laboratory methods was evaluated by paired specimen analyses (arterial and venous whole blood versus plasma) from patients within various clinical settings. The clinical studies included patients throughout all hospital settings involving 19 primary medical condition categories with 257 different medical condition sub-categories. The clinical study patients received approximately 8,000 medications representing 33 parent drug classes and 144 medication sub-classes. The patient populations investigated represent a highly diverse spectrum of severity of illness (acuity). The effect of confounding factors such as PO_2 (ventilation), pH, hematocrit, medications, endogenous substances, acuity of illness, and specimen types were given special consideration within these clinical settings and were analyzed along with study results.

In addition to the medical condition for each clinical study patient, when available, the following information was obtained:

- Specimen type: (Arterial or Venous only)
- Collection site: (Central or Peripheral draw site)
- Patient Demographic Information: (Male or Female, Date of Birth)
- Measured Whole Blood Glucose: StatStrip Glucose Hospital Meter System
- Measured Plasma Glucose: Central laboratory method
- Hospital Wards/Divisions: ICU, ED, OR, etc.
- Diagnosis or Medical Condition: Reason for Hospital stay
- Drugs and Other Substances: Listing of all drugs and other endogenous substances for patient on day of clinical study testing
- Measured Hematocrit: Central laboratory method
- Measured Chemistries: Central laboratory method
- Oxygenation Status: Arterial blood gas results for patient, if available on day of testing

The StatStrip system performed consistently independent of the institution, without significant clinical interference from drugs, ventilation (O₂), endogenous substances, hematocrit, medical condition, medical unit, or patient condition.

All arterial and venous patient specimens were analyzed first on the StatStrip system and then spun down within 15 minutes to obtain a fresh plasma specimen and measured on the central laboratory method.

Evaluation and Analysis

Nova Biomedical applied a number of clinical assessment methods to demonstrate the performance of the StatStrip versus central laboratory reference glucose methods. Each of the assessment methods demonstrated that StatStrip demonstrates acceptable clinical performance with both

Health Care Professionals (HCP's) and POC operators within the intended use population. A listing of the clinical assessment methods used to evaluate the clinical data is found below.

A detailed Medical Condition analysis (based upon World Health Organization medical condition categories) was performed on the clinical data set from all five (5) clinical study sites to identify any potential safety issues with the use of the StatStrip system within each medical condition subpopulation. Based upon clinical chart review, paired glucose results for each study participant within a medical condition category were reviewed. Frequency distribution tables for each Medical Condition are presented in Section B.4.1.

A detailed Parent Drug Class (based upon U.S. Pharmacopeia) analysis was performed on the clinical dataset from all 5 clinical study sites to identify any potential safety issues with the use of the StatStrip system within the intended use population. Based upon clinical chart review, paired glucose results for each study participant on one or more drugs within a parent drug class were reviewed. Frequency distribution tables for each Parent Drug class are presented in section B.4.2.

A separate analysis was performed on all patient glucose results <70mg/dL to identify any potential safety issues with the use of the StatStrip system in the hypoglycemic range within the intended use population.

An analysis was performed to determine whether the specimen collection site (central or peripheral) or specimen type (arterial or venous) has an impact on the performance of the StatStrip system with the intended use population.

B.4.1 Clinical Study Performance

Below is the analytical and system accuracy comparison data for glucose at different concentrations using arterial and venous whole blood specimens.

Table B-1 Arterial Specimens

Analytical and System Accuracy Comparison: Glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
Site #1	64/82 (78.0%)	75/82 (91.5%)	78/82 (95.1%)	79/82 (96.3%)	3/82 (3.7%)
Site #2	79/93 (84.9%)	89/93 (95.7%)	91/93 (97.9%)	92/93 (98.9%)	1/93 (1.1%)
Site #3	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0.0%)
Site #4	19/25 (76.0%)	24/25 (96.0%)	25/25 (100%)	25/25 (100%)	0/25 (0.0%)
Site #5	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)
Combined All Sites	163/201 (81.1%)	189/201 (94.0%)	195/201 (97.0%)	197/201 (98.0%)	4/201 (2.0%)

Table B-2 Arterial Specimens

Analytical and System Accuracy Comparison: Glucose concentrations ≥ 75 mg/dL

Site	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 12.5\%$	Within $\pm 15\%$	Within $\pm 20\%$	Exceeds $\pm 20\%$
Site #1	362/538 (67.3%)	497/538 (92.4%)	515/538 (95.7%)	523/538 (97.2%)	532/538 (98.9%)	6/538 (1.1%)
Site #2	120/214 (56.1%)	195/214 (91.1%)	208/214 (97.2%)	214/214 (100%)	214/214 (100%)	0/214 (0.0%)
Site #3	83/122 (68.0%)	112/122 (91.8%)	115/122 (94.3%)	117/122 (95.9%)	120/122 (98.4%)	2/122 (1.6%)
Site #4	257/349 (73.6%)	330/349 (94.6%)	340/349 (97.4%)	346/349 (99.1%)	348/349 (99.7%)	1/349 (0.3%)
Site #5	22/44 (50.0%)	41/44 (93.2%)	42/44 (95.5%)	44/44 (100%)	44/44 (100%)	0/44 (0.0%)
Combined All Sites	844/1,267 (66.6%)	1,175/1,267 (92.7%)	1,220/1,267 (96.3%)	1,244/1,267 (98.2%)	1,258/1,267 (99.3%)	9/1,267 (0.7%)

Table B-3 Venous Specimens

Analytical and System Accuracy Comparison: Glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
Site #1	17/20 (85.0%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	0/20 (0.0%)
Site #2	51/59 (86.4%)	57/59 (96.6%)	58/59 (98.3%)	59/59 (100%)	0/59 (0.0%)
Site #5	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)	0/0 (N/A)
Combined All Sites	68/79 (86.1%)	77/79 (97.5%)	78/79 (98.7%)	79/79 (100%)	0/79 (0.0%)

Table B-4 Venous Specimens

Analytical and System Accuracy Comparison: Glucose concentrations ≥ 75 mg/dL

Site	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 12.5\%$	Within $\pm 15\%$	Within $\pm 20\%$	Exceeds $\pm 20\%$
Site #1	77/112 (68.8%)	108/112 (96.4%)	111/112 (99.1%)	111/112 (99.1%)	112/112 (100%)	0/112 (0.0%)
Site #2	84/127 (66.1%)	116/127 (91.3%)	123/127 (96.9%)	127/127 (100%)	127/127 (100%)	0/127 (0.0%)
Site #5	10/29 (34.5%)	22/29 (75.9%)	26/29 (89.7%)	29/29 (100%)	29/29 (100%)	0/29 (0.0%)
Combined	171/268 (63.8%)	246/268 (91.8%)	260/268 (97.0%)	267/268 (99.6%)	268/268 (100%)	0/268 (0.0%)
All Sites						

B.4.2 Medical Condition Analysis Summary Tables

The following is a frequency distribution breakdown of the medical conditions based upon World Health Organization medical condition categories included in the clinical study sites:

Table B-5 Medical Condition Analysis: Top Level Summary

Medical Condition Category	Frequency
Burn Trauma	124
Cardiac Surgical, Pre & Post	151
Cardiac Medical	134
Cardiac Surgical	385
Endocrinology	30
Gastroenterological	61
Miscellaneous	24
Neuro-Trauma	96
Neurological	25
Obstetrics / Gynecological	105
Oncology	101
Oncology, Surgical	27

Medical Condition Category	Frequency
Pulmonary	161
Renal	27
Sepsis and Infection	90
Suicide	7
Surgical General	71
Trauma	62
Unknown at time of Patient Test	133
Total*	1,814

* One patient in the clinical database did not include a medical condition

Table B-6 Medical Condition Analysis: Burn Trauma

Burn Patient Reason For Hospitalization	
Condition	Frequency
22% TBSA burns	35
27% TBSA burns	6
28% TBSA burns	6
55% TBSA burns	42
56% TBSA electrical and flame burns	24
62% TBSA self-inflicted burns	10
Burn Patient	1
Total	124

Table B-7 Medical Condition Analysis: Cardiac Disease

Cardiac Patient Reason For Hospitalization		
Sub Category	Condition	Frequency
Pre and Post Surgical	Observation: Thoracic Surgery	3
	Post thoracic surgery	141
	Pre-Op Coronary Arterial Angiography	7

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Cardiac Patient Reason For Hospitalization			
Sub Category	Condition	Frequency	
<i>Cardiac - Medical</i>			
		Acute coronary syndrome	1
		Heart failure	14
		Acute Myocardial Infarction	46
		Ventricular Rhythm Disorders	9
		Arterial Vascular Disease	3
		Artery Disease	3
		Bradycardia	2
		Cardiac arrest	5
		Cardiogenic shock	2
		Cardiomyopathy	1
		Chronic heart failure	1
		Coronary Angiography	4
		Endocarditis	6
		Cardiac Gangrene	1
		Hypertension	2
		Myocardial Infarction/ Ventricular-Fib	1
		Resuscitation	21
		Stable Angina	11
	Transient Ischemic Attack	1	
<i>Cardiac - Surgical</i>			
		Angiography	1
		Endarterectomy	12
		Cardio Thoracic (Aortic Bypass Surgery)	12
		Cardio Thoracic (Aortic Rupture)	4
	Femoral Aneurism Rupture	2	

Cardiac Patient Reason For Hospitalization		
Sub Category	Condition	Frequency
	Fibrosing Mediastinitis	1
	Obstructive Arteriopathy	1
	Pacemaker Surgical Implant	47
	Percutaneous Transluminal Ablation (PCTA Stent)	3
	Pericardial Surgery (Pericardial Patch)	1
	Aortic Aneurism	12
	Thoracic Surgery (Robotic Assisted)	1
	Ventricular Septal Rupture	7
<i>AVR/MVR</i>		
	Aortic Stenosis	4
	Aortic Valve Replacement	17
	Cardio Thoracic (Arterial Valve Replacement (↑ Aorta))	11
	Cardio Thoracic (Atrial Fibrillation (Maze + MVP))	8
	Cardio Thoracic (AVR + MVR)	7
	Mitral Valve Replacement	34
	Cardio Thoracic (AVR + MPL)	3
<i>CABG</i>		
	CABG surgery	29
	Cardio Thoracic (CABG (1 art) + AVR)	9
	Cardio Thoracic (CABG (2 art) + AVR)	16
	Cardio Thoracic (CABG + AVR + Maze)	4
	Cardio Thoracic (CABG + mpl + Maze)	9
	Cardio Thoracic (CABG > = 3 art. grafts (incl ven graft)	46

Cardiac Patient Reason For Hospitalization		
Sub Category	Condition	Frequency
	Cardio Thoracic (CABG banned venous grafts)	7
	Cardio Thoracic (CABG robot ven 3art. > = graft)	4
	Cardio Thoracic (CABG robot ven 1 art. graft)	2
	Cardio Thoracic (CABG ven gr or max. 1 art. graft)	7
	Cardio Thoracic (Re-CABG)	14
	Coronary Artery Disease	6
	Total CABG	190
<i>Maze</i>		
	Cardio Thoracic (Maze Procedure)	5
	Total All Categories	670

Table B-8 Medical Condition Analysis: Endocrinology Disease

Endocrinology Patient Reason For Hospitalization	
Condition	Frequency
Acute Kidney Injury	2
Addison's Disease	6
Anemia	3
Diabetes	1
Diabetes mellitus	3
Diabetes Mellitus (Uncontrolled)	10
Diabetic ketoacidosis	1
Hyperkalemia	1
Hypocalcemic crisis	1
Hypoxemia	1
Inaugural Diabetes	1
Total	30

Table B-9 Medical Condition Analysis: Gastroenterological Disease

Gastroenterological Patient Reason For Hospitalization	
Condition	Frequency
Acute Chronic Liver Failure	2
Adhesive Bowel Obstruction	2
Bleeding Bulbar Ulcer	4
Bleeding Esophagus	1
Constipation	8
Diaphragmatic Hernia	1
Diarrhea	17
Digestive Obstruction	1
Diverticular Peritonitis	1
Gastric Ulcer, Perforated	1
Hepatitis	1
Observation: Abdominal Discomfort	3
Pancreatitis	10
Peritonitis	7
Small Bowel Obstruction	1
Umbilical Hernia	1
Total	61

Table B-10 Medical Condition Analysis: Miscellaneous Disease

Miscellaneous Patient Reason For Hospitalization	
Condition	Frequency
Blood Transfusion	1
Hospitalization by Intensivist (Disease Status Not Given)	4
Hospitalization for Internal Medicine (other reasons)	15
Hospitalization for Internal Medicine (other surgical reasons)	1
Nausea/Vomiting	2
Observation: Pediatrics	1
Total	24

Table B-11 Medical Condition Analysis: Neuro-Trauma Disease

Neuro –Trauma Patient Reason For Hospitalization	
Condition	Frequency
Acute Brain Injury (Aneurysm)	6
Acute Brain Injury (Hematoma-Drilling)	1
Brain Hemorrhage	36
Brain Trauma	3
Chronic Subdural Hematoma	1
Fractured Vertebrae	1
Neuro-trauma	33
Seizure	3
Stroke	10
Subarachnoidal Hemorrhage	1
Subdural Hematoma	1
Total	96

Table B-12 Medical Condition Analysis: Neurological Disease

Neurological Patient Reason For Hospitalization	
Condition	Frequency
Altered consciousness	1
Confusion	1
Hypercapnic encephalopathy	2
Muscular dystrophy (Pompe disease)	1
Myopathy (Pompe disease)	1
Observation: Neurological	16
Observation: Psychiatric	1
Sacral meningocele dural fistula	1
Tetraplegia ankylosing spondylitis	1
Total	25

Table B-13 Medical Condition Analysis: Obstetrics / Gynecological

OBGYN Patient Reason For Hospitalization	
Condition	Frequency
Cesarean Section	26
Dilatation & Curettage	1
Gemellary Pregnancy	1
Gemellary Pregnancy Delivery	1
Observation: Primary Cesarean Section	3
Obstetric Hemorrhage Atonic Uterus	1
Obstetrics (pre-term labor)	17
Ovarian Hyperstimulation syndrome	1
Postpartum Hemorrhage Placental Retention	2
Pre Eclampsia	2
Pregnancy Associated Vomiting	4
Refractory Vomiting, Pregnancy	1
Stall Wife After Parturition	44
Fistula Revision	1
Total	105

Table B-14 Medical Condition Analysis: Oncology Disease

Oncology Patient Reason For Hospitalization	
Condition	Frequency
Acute Lymphocytic Leukemia w/ Tumor Lysis Syndrome	2
Acute Myeloid Leukemia	16
AIDS Cerebral Lymphoma	1
Ampullary Adenocarcinoma	1
Ampullary Tubular Pancreatic Adenoma	1
Bile Duct and Gallbladder Adenocarcinoma	1
Bladder Cancer	3
Brain Metastasis	1
Brain Metastasis from Mammary Cancer	1
Carcinoma of the mouth	1

Oncology Patient Reason For Hospitalization	
Condition	Frequency
Carcinomatous Peritonitis from Ovarian Sarcoma Resection	1
Central Nervous System Lymphoma	1
Chemotherapy	22
Cholangiocarcinoma	3
Chronic Lymphocytic Leukemia	1
Chronic Lymphoid Leukemia	1
CMML Type 2	1
Colorectal Cncr	1
Distal Esophageal Adenocarcinoma	3
Laryngeal Cancer	2
Lung Cancer w/pleural	1
Lung Carcinoma	4
Mantle Cell Lymphoma	2
Meningioma	1
Metastatic NSCLC	3
Mucinous Adenocarcinoma	2
Multiple Myeloma	3
Neuroendocrine (Pancreas)	2
Obstructive Laryngeal Cancer	1
Esophageal Leiomyoma	1
Ovarian Cancer	1
Pancreatic Cancer	1
Pancreatic Ductal Adenocarcinoma	1
Peritoneal Carcinomatosis	2
Thyroid Cancer	1
Prostate Stromal Sarcoma	1
Pulmonary Cancer	2
Pulmonary Metastasis from Colic Adenocarcinoma	1
Rectal Cancer	3

Oncology Patient Reason For Hospitalization	
Condition	Frequency
Relapsed T-Cell Prolymphocytic Leukemia	1
Small Cell Lung Carcinoma	1
T Cell Lymphoma	1
Brain Tumor Resection	1
Total	101

Table B-15 Medical Condition Analysis: Oncology Surgical Disease

Oncology – Surgical Patient Reason For Hospitalization	
Condition	Frequency
Cerebral Metastasis Resection	1
Colon Cancer Surgery	11
Gastrectomy for Gastric Cancer	1
Glossectomy for Cancer	1
Lipoma Surgical Removal	1
Neoplastic Colonic Obstruction	1
Pulmonary Bilobectomy for Lung Cancer	1
Lung Lobectomy	6
Pneumonectomy for Cancer	2
Supra Cellar Meningioma Surgery	1
Temporal Meningioma Removal Surgery	1
Total	27

Table B-16 Medical Condition Analysis: Pulmonary Disease

Pulmonary Patient Reason For Hospitalization	
Condition	Frequency
Acute Lung Edema	4
ARDS	1
Asthmatic Crisis	2
Hemoptysis	1
COPD Exacerbation	28

Pulmonary Patient Reason For Hospitalization	
Condition	Frequency
Dyspnea (Respiratory Distress)	32
Hyperventilation	1
Idiopathic Pulmonary Fibrosis	3
Observation: Pulmonologist	2
Pneumocystis Jiroveci Pneumonia	3
Pneumonia	62
Pneumothorax	4
Pseudomonas Aeruginosa Bilateral Pneumonia	1
Pulmonary Embolism	11
Pulmonary Hypertension	2
Respiratory Failure	4
Total	161

Table B-17 Medical Condition Analysis: Renal Disease

Renal Patient Reason For Hospitalization	
Condition	Frequency
Acute Chronic Renal Failure	2
Chronic Kidney Disease	6
End Stage Renal Disease	3
Hematuria	10
Renal Failure	1
Renal Insufficiency	5
Total	27

Table B-18 Medical Condition Analysis: Sepsis and Infection

Sepsis And Infection Patient Reason For Hospitalization	
Condition	Frequency
AIDS	10
Cirrhosis	6
Erysipelas (Acute Infection)	7
Fever E.C.I.	1
General Malaise	3
Hemorrhagic shock	2
Liver Cirrhosis	1
Meningitis	3
Meningoencephalitis	1
Osteitis	1
Sepsis	17
Sepsis (Urological Origin)	6
Septicemia	2
Severe Malaria (falciparum)	1
Toxic Coma	1
Tuberculous Meningitis	2
Tuberculous Pneumonia	1
Urinary Tract Infection	5
Urological Catheter and AWES	1
Urosepsis	2
Variceal Bleeding Cirrhosis	2
Wound Infection	4
Total	90

Table B-19 Medical Condition Analysis: Suicide

Patient Reason For Hospitalization	
Condition	Frequency
Suicide	7

Table B-20 Medical Condition Analysis: Surgical General

Surgical - Patient Reason For Hospitalization	
Condition	Frequency
Acoustic Schwannoma Resection	1
Bariatric Surgery BMI	3
Cervical Schwannoma	2
Decortication Surgery	7
Hip Dislocation	1
Hip Replacement	1
Morbid Obesity	1
Nephrectomy Transabdominal	1
Observation: Surgery	12
Percutaneous Endoscopic Gastronomy Catheter Placement	1
Abdominal Surgery	15
Craniotomy	7
Pharyngolaryngectomy	1
Lung Surgery	6
Pulmonary Nodule Resection	1
Meningeal Leak Closure	1
Pontocerebellar Arachnoidal Cyst Removal	1
Subdural Hematoma	1
Surgical Removal of Schwannoma of the VIII	1
Postoperative Gastric By-Pass for Obesity Peritonitis	2
Multinodular Thyroid Goiter	1
Kidney Transplant	2
Total	71

Table B-21 Medical Condition Analysis: Trauma

Trauma - Patient Reason For Hospitalization	
Condition	Frequency
Abdominal Stab Wound	1
Carbamazepine Overdose	1
Coma	1
Drug Overdose	1
Drug Overdose Coma	1
Femoral Fracture	1
Head Trauma	13
Leg Trauma	1
Methadone Alcohol Overdose	2
Multiple Trauma	13
Observation (Emergency)	1
Pelvic Fracture	1
Polytrauma	5
Thoracic Trauma	1
Trauma	18
Traumatic Coma	1
Total	62

B.4.3 Parent Drug Class Summary Tables

The following is a frequency distribution breakdown of the parent drug classes based upon the U.S. Pharmacopia included in the clinical study sites:

Table B-22 Parent Drug Class Analysis: Alcohol

Alcohol Parent Drug Class Subclass Analysis	Frequency
Alcohol	1

Table B-23 Parent Drug Class Analysis: Anti-Infectives

Anti-Infective Parent Drug Class Subclass Analysis	Frequency
Quinolones	6
Anthelmintics	5
Antibiotic	970
Anti-fungal	515
Anti-malarial	10
Anti-tuberculosis	2
Anti-Viral	99
Anti-Viral Protease Inhibitors	78

Table B-24 Parent Drug Class Analysis: Antidotes

Antidote Parent Drug Class Subclass Analysis	Frequency
Antidote	32

Table B-25 Parent Drug Class Analysis: Anti-Neoplastics

Anti-Neoplastic Parent Drug Class Subclass Analysis	Frequency
Alkylating Agent	2
Anti-Metabolites	5
Monoclonal Antibodies	8
VEGF Inhibitors	1

Table B-26 Parent Drug Class Analysis: Anti-Psoriatics

Anti-Psoriatics Parent Drug Class Subclass Analysis	Frequency
Vitamin A Retinoid	3

Table B-27 Parent Drug Class Analysis: Anti-Rheumatics

Disease Modifying Anti-Rheumatic Parent Drug Class Subclass Analysis	Frequency
Anti-Rheumatic	1

Table B-28 Parent Drug Class Analysis: Anti-Vertigo

Anti-Vertigo Parent Drug Class Subclass Analysis	Frequency
Anti-Vertigo	3

Table B-29 Parent Drug Class Analysis: Biologicals

Biologicals Parent Drug Class Subclass Analysis	Frequency
Recombinant Human Erythropoietins	27

Table B-30 Parent Drug Class Analysis: Blood Products

Blood Products Parent Drug Class Subclass Analysis	Frequency
Plasma	11
Platelets	6
RBCs	29

Table B-31 Parent Drug Class Analysis: Calcimimetic

Calcimimetic Parent Drug Class Subclass Analysis	Frequency
Calcium Receptor	11

Table B-32 Parent Drug Class Analysis: Cardiovascular Agents

Cardiovascular Agents Parent Drug Class Subclass Analysis	Frequency
ACE Inhibitor / Diuretic	1
ACE Inhibitors	364

Cardiovascular Agents Parent Drug Class Subclass Analysis	Frequency
Alpha-adrenergic Blockers	21
Angiotensin II Inhibitors	93
Antiadrenergic	197
Antidysrhythmic	380
Antihypertensive	22
Beta Blocker	556
Calcium Channel Blocker	328
Diuretic	741
Inotropes	300
Vasodilator	376
Vasopressors	68
Vasopressors or Inotropics	367

Table B-33 Parent Drug Class Analysis: Central Nervous System

Cholinergic Muscle Stimulant Parent Drug Class Subclass Analysis	Frequency
Choline Thick Stimulant	1

Table B-34 Parent Drug Class Analysis: Central Nervous System

Central Nervous System Agent Parent Drug Class Subclass Analysis	Frequency
5HT3 Antagonist Antiemetic	185
Anaesthetic	465
Analgesic - NSAID	947
Analgesics - narcotic	840
Anticholinergic	40
Anticonvulsant	140
Antiemetic	71
Anti-Parkinson	10

Central Nervous System Agent Parent Drug Class Subclass Analysis	Frequency
Benzodiazepines	719
Muscle Relaxer	138
Sedative	7
Stimulants	2

Table B-35 Parent Drug Class Analysis: Coagulation Modifiers

Coagulation Modifiers Parent Drug Class Subclass Analysis	Frequency
Anticoagulants	957
Anti-Platelet	30
Thrombolytics	142

Table B-36 Parent Drug Class Analysis: Contrast Agents

Radiologic Agent Parent Drug Class Subclass Analysis	Frequency
Contrast Agents	4

Table B-37 Parent Drug Class Analysis: Gastrointestinal

Gastrointestinal agent Parent Drug Class Subclass Analysis	Frequency
Antacid	91
Antacid and Electrolyte	2
Antidiarrheals	13
Antispasmodic	4
Digestive enzymes	11
Gallstone Solubilizing Agents	12
Gastrointestinal Deamination	400
GI Stimulant (also used as antiemetic)	376
H-2 Antagonist	229

Gastrointestinal agent Parent Drug Class Subclass Analysis	Frequency
Laxative	611
Laxative / Antacid	61
Protectant	8
Proton-pump Inhibitor	754

Table B-38 Parent Drug Class Analysis: Genitourinary

Genitourinary Tract Agent Parent Drug Class Subclass Analysis	Frequency
Antispasmodic	15
PDE5 Inhibitor	10

Table B-39 Parent Drug Class Analysis: Hemodialysis

Hemodialysis Parent Drug Class Subclass Analysis	Frequency
Hemodialysis	6

Table B-40 Parent Drug Class Analysis: Hormonal Agents

Hormonal Agents Parent Drug Class Subclass Analysis	Frequency
Glucocorticoids	467
Hormone - Sex	175
Hormone	3
Hormone - Growth	6
Hormone - Peptide	99
Hormone - Pituitary	1
Hormone - Polypeptide	3
Hormone - Thyroid	60
Hormone- Antidiuretic	71
Insulin – Injectable and Oral	705
Somatostatine Analog	15

Table B-41 Parent Drug Class Analysis: Hyperkalemia

Hyperkalemia Agent Parent Drug Class Subclass Analysis	Frequency
Uncategorized Agent to treat Hyperkalemia	40

Table B-42 Parent Drug Class Analysis: Immunologic Agent

Immunologic Agent Parent Drug Class Subclass Analysis	Frequency
Immunoglobulins	3
Immunostimulants	4
Immunostimulants - Vaccine	3
Immunosuppressant	32

Table B-43 Parent Drug Class Analysis: Metabolic / Nutritional

Metabolic / Nutritional Parent Drug Class Subclass Analysis	Frequency
Glucose Elevating / Electrolyte	58

Table B-44 Parent Drug Class Analysis: Metabolic

Metabolic agent Parent Drug Class Subclass Analysis	Frequency
Anti-diabetic	100
Anti-hyperlipidemic	16
Anti-hyperuricemic	19
Bisphosphonates	55
Glucose Elevating Agent	177
Statin	433

Table B-45 Parent Drug Class Analysis: Nutritional

Nutritional Product Parent Drug Class Subclass Analysis	Frequency
Amino Acid	100
Electrolyte	81
Herbal Supplement	7
Iron	52
Mineral / Electrolyte	685
Multivitamin	94
Vitamin	15
Vitamin / Mineral	351
Vitamin B	54
Vitamin B-12	20
Vitamin B-6	2
Vitamin C	113
Vitamin D	38

Table B-46 Parent Drug Class Analysis: Phosphate Binder

Phosphate Binder Parent Drug Class Subclass Analysis	Frequency
Phosphate Binder	41

Table B-47 Parent Drug Class Analysis: Plasma Expanders

Plasma Expander Parent Drug Class Subclass Analysis	Frequency
Blood Products	36
Gelatin	1
Globular proteins	104
Plasma Replacement	3
Starch	46

Table B-48 Parent Drug Class Analysis: Psychotherapeutic Agent

Psychotherapeutic Agent Parent Drug Class Subclass Analysis	Frequency
Antidelirium	12
Antidepressants	79
Antipsychotic - Atypical	68
Antipsychotic - Non-phenothiazine	221
Antipsychotic - Phenothiazines	5
Bipolar Agent	40

Table B-49 Parent Drug Class Analysis: Respiratory Agent

Respiratory Agent Parent Drug Class Subclass Analysis	Frequency
Antihistamine	175
Bronchodilator	636
Decongestant	22
Expectorant	12
Leukotriene modifier	1
PDE4 Inhibitors	1

Table B-50 Parent Drug Class Analysis: Smoking Cessation

Smoking Cessation Agent Parent Drug Class Subclass Analysis	Frequency
Smoking Cessation Agent	45

Table B-51 Parent Drug Class Analysis: Topical Agent

Topical Agent Parent Drug Class Subclass Analysis	Frequency
Anti-hemorrhagic	54
Antimicrobial Irrigation	66
Dental and Oral Agents	118
Dermatological Cr�em	10

Topical Agent Parent Drug Class Subclass Analysis	Frequency
Dermatological Powder	78
Emollients	95
Hydrating Eye Ointment	179
Medicated Ointment	248
Medicated Ophthalmic Drops	40
Medicated Ophthalmic Drops and Steroid	11
Nasal Antibiotic	116
Nasal Decongestant	2
Nasal Steroid	10
Ophthalmic Diagnostic Agent	1
Ophthalmic Glaucoma Agent	20
Ophthalmic Medicated Steroid	6
Ophthalmic Preparation	5
Topical Photochemotherapeutics	4

Table B-52 Parent Drug Class Analysis: Topical Anti-Infective

Topical Anti-Infective Parent Drug Class Subclass Analysis	Frequency
Antibiotic Crème	3
Dermatological Antibacterial	90

B.5 Results of Multi-Center Capillary Critical Care Study: Patients Requiring Intensive Medical Intervention/Therapy

Introduction

Nova Biomedical conducted a large multi-center study of the StatStrip Glucose Hospital Meter at 3 leading medical centers to demonstrate the clinical performance of capillary whole blood specimens obtained by finger stick within critical care hospital settings on patients receiving intensive medical intervention/therapy. Clinical Study Site #1 was a CLIA-

Waived prospective study and the other 2 studies conducted in Site #2 and Site #3 were CLIA Waived retrospective studies designed to assess real world clinical performance. Study Site #1 and #3 is one of the top ranked hospitals in Diabetes & Endocrinology located in Rochester, MN and Study Site #2 is one of the world's preeminent healthcare institutions located in Maryland. A description of the clinical study is found below.

B.5.1 Prospective Clinical Study

The prospective critical care clinical study (Site #1) included 568 enrolled critical care patients undergoing treatment within 3 critical care departments (CVICU, MICU and OR). The critical care patients from the CVICU and MICU included 80 unique patient conditions receiving a total of 3,785 medications representing 17 parent drug classes. Medical conditions and medications were unavailable for critical care patients in the OR.

Table B-53: Study Site #1 Breakdown

Departments	Patients Enrolled
CVICU	150
MICU	50
OR	368
Total Patient Enrollment	568

The capillary whole blood glucose results were compared to plasma glucose results obtained from arterial or venous specimens measured on an IDMS traceable Roche Cobas Modular P800 hexokinase method (Roche Diagnostics, Indianapolis, IN).

B.5.2 Real World Evidence Studies

Retrospective studies using real world evidence obtained from critically ill patients were designed to evaluate the differences between specimen types from critically ill patients with a broad range of complex medical conditions and treatment regimens to determine if capillary whole blood testing is acceptable for use in these settings using the StatStrip system.

Table B-54: Real World Study Site Breakdown

Study Sites	Patients Enrolled
Mayo Clinic, MN	2,133
Johns Hopkins Bayview, MD	14,645
Total Patient Enrollment	16,778

Clinical Study #2 was a real world clinical review of 2,133 critical care patients throughout all critical care settings that had a glucose test performed using a capillary whole blood specimen obtained by finger stick and a plasma glucose test performed in the central laboratory within 15 minutes of the capillary test. Medical conditions and medications were unavailable for critical care patients in this study.

Clinical Study #3 was a real world clinical review of 14,645 critical care patients throughout all critical care settings that had a glucose test performed using a capillary whole blood specimen obtained by finger stick and a plasma glucose test performed in the central laboratory within 15 minutes of the capillary test. Medical conditions and medications were unavailable for critical care patients in this study.

The capillary whole blood glucose results were compared to plasma glucose results obtained from arterial or venous specimens measured on an IDMS traceable Roche Cobas Modular P800 hexokinase method (Roche Diagnostics, Indianapolis, IN).

B.5.3 Clinical Study Performance

Table B-55 Study #1 (Prospective Study)

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within +5 mg/dL	Within +10 mg/dL	Within +12 mg/dL	Within +15 mg/dL	Exceeds +15 mg/dL
1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0%)

Fingertip capillary samples with glucose concentrations >75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 12\%$	Within $\pm 15\%$	Within $\pm 20\%$	Exceeds $\pm 20\%$
277/567 (48.9%)	450/567 (79.4%)	484/567 (85.4%)	516/567 (91.0%)	549/567 (96.8%)	18/567 (3.2%)

Table B-56 Study #2 and #3 (Retrospective Combined)

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
907/1894 (47.9%)	1470/1894 (77.6%)	1614/1894 (85.2%)	1737/1894 (91.7%)	157/1894 (8.3%)

Fingertip capillary samples with glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 12\%$	Within $\pm 15\%$	Within $\pm 20\%$	Exceeds $\pm 20\%$
7473/ 14884 (50.2%)	11807/ 14884 (79.3%)	12799/ 14884 (86.0%)	13712/ 14884 (92.1%)	14350/ 14884 (96.4%)	534/ 14884 (3.6%)

B.6 Wireless Meter Use

The StatStrip Glucose Hospital Meter is configured/factory installed with WiFi functionality.

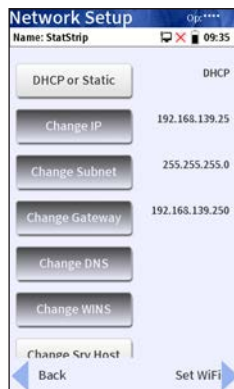
B.6.1 Enabling/Disabling the WiFi Radio

If the meter is equipped with the wireless radio option, an authorized operator may enable or disable its functionality as required.

To enable the WiFi Radio, proceed as follows:

1. Log on to the meter with an appropriate Operator ID.
2. Press the Menu, then the Admin, then the Network buttons.
3. Press the Set Srv, then the Set WiFi buttons in the bottom right corner of each screen.
4. Press the Install Cert. button to load and activate the security and encryption certificates (if applicable for the radio setup).
5. Press the WiFi ON/OFF button to toggle the radio ON.
6. Press the Factory/Custom button to toggle to Custom.
7. The meter now displays the name of the attached SSID, CA, and User certificate names and expiration date.

The WiFi Radio is now “ON” and will start the WAP association. If the WiFi Radio connection is successful, the WiFi icons on the Screen Title Bar will change to indicate the signal strength and network communication with the device manager.



NOTE: When placed in a wired docking station, the meter will connect in the following manner:

- a. Radio ON and associated with a WAP – Meter connects and communicates via WLAN.
- b. Radio ON and NOT associated with a WAP – Meter connects and communicates via LAN.
- c. Radio OFF – Meter connects and communicates via LAN.

NOTE: When the radio is enabled, the StatStrip Glucose Hospital Meter with wireless option monitors the Quality of Service (QoS) of the WLAN communication connection. Should the last attempt to communicate fail, the Radio is OFF or no connection to WAP™ icon will be displayed on the Screen Title Bar.

A degraded QoS will not impact the testing functionality of the meter but may delay the communication of results to the device manager. Users should be aware that real-time communication of blood glucose readings cannot be guaranteed by the StatStrip Glucose Hospital Meter with the wireless option.

B.6.2 Wired & Wireless Network Unauthorized Access Protection

When the StatStrip Meter is connected to a local area wireless 802.11a/b/g/n/ac network, these networks must be properly secured. It is the responsibility of the System Administrator and Local Network Support to:

- Take all reasonable measures, both physically and electronically to protect the local area network and wireless networks on which the meters are connected.
- Provide adequate protection for the network against malicious software and attacks.
- Include measures, such as a firewall, to separate the device from uncontrolled networks.
- Ensure that the connected network is free of malicious code.

B.6.3 Wireless Network Connections (802.11 a/b/g/n/ac WiFi)

The integrated WiFi Radio option for a wireless network connection:

- Eliminates the need to return the meter to the docking station for communication with the device manager.
- Allows the meter to send result data and patient and operator ID queries to the device manager.
- When docked, allows full communication with the device manager.
- Is configurable only by:
 - a. A Trained Nova Biomedical Service Representative, or
 - b. An authorized and trained system administrator.
- Enabled on the meter by an authorized operator.

Follow your facility guidelines for using wireless local area network connections. For information about how to enable or disable this function, **See B.6.1** of this IFU. For a description of the StatStrip Glucose Hospital Meter's (with wireless option) ability to connect to Wireless Local Area Networks (WLAN, WiFi), **See B.6.6**.

B.6.4 Radio Frequency and Radiation Exposure

The Industrial, Scientific and Medical (ISM) frequencies (the 802.11 a/b/g/n/ac bands use the 2.4 and/or 5 GHz) may contain emissions from microwave ovens, heaters, and other non-communication type devices. These types of devices are low powered and usually present no threat of interference. But the possibility exists that some industrial and/or medical device high power systems may wipe out any attempted communication use of a WLAN. The recommendation of Nova Biomedical is to perform a site survey and interference analysis by qualified personnel, with the appropriate testing equipment. Search for signals that might not only be within the frequency range of the intended WLAN but also could be near or at the same frequency and cause interference.

Nova Biomedical

- Supports industry wireless standards.
- Recommends using products that have Wi-Fi certification.
- Wi-Fi certification tests products to the 802.11a/b/g/n/ac industry standards for basic connectivity, security, authentication, Quality of Service (QoS), interoperability and reliability.
- Uses a Wi-Fi CERTIFIED™ RF module that assures that the Wi-Fi Alliance® has tested a product in numerous configurations and with a diverse sampling of other devices to ensure compatibility with other Wi-Fi CERTIFIED equipment that operates in the same frequency band.

The Nova Biomedical StatStrip Glucose Hospital Meter complies with FCC radiation exposure limits set forth for an uncontrolled environment.

- Do not operate or locate this meter near any other antenna or transmitter.
- This equipment should be installed and operated with minimum distance of 8 inches (20 cm) between the radiator and your body.
- Changes or modifications made to this equipment not expressly approved by Nova Biomedical may void the FCC authorization to operate this equipment.

The StatStrip Glucose Hospital Meter with wireless option complies with Part 15 of the FCC Rules and with RSS-247 of Industry Canada under these 2 conditions.

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

WARNING: *Changes and Modifications not expressly approved by Nova Biomedical Corporation can void your authority to operate this equipment under Federal Communications Commissions rules.*

StatStrip Glucose Hospital Meter

The StatStrip Glucose Hospital Meter complies with the emission and immunity requirements described in IEC 60601-1-2.

- Designed and tested to CISPR 11 Class A.
- In a domestic environment, it may cause radio interference.
 - If it does, take measures to mitigate the interference.
- The electromagnetic environment in which the StatStrip Glucose Wireless Meter will be operated should be thoroughly evaluated before operation of the device.
- The StatStrip Glucose Hospital Meter LCD is monitored during immunity testing for display problems, device resets or software freezes.
- The Essential Performance in terms of immunity was defined as follows: On multiple ESD events during testing, the StatStrip Glucose Hospital Meter may run continuously or, after showing a splash screen, return to an operational screen without needing operator intervention. Upon the conclusion of immunity testing the meter shall generate acceptable test results.

NOTE: *Under extreme conditions, the StatStrip Glucose Hospital Meter's LCD screen may be subjected to significant electrostatic discharge (ESD) events. In such cases, the meter software may reboot and return to an operational state within 10-20 seconds, allowing for continued patient testing.*

This meter has been tested and found;

- To comply with the limits for a Class A digital device, according to Part 15 of the FCC Rules
- These limits are designed to provide reasonable protection against harmful interference in a residential installation.

The StatStrip Glucose Hospital Meter generates, uses, and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. But, there is no guarantee that interference will not occur in a particular installation. If the meter does cause harmful interference to radio or television reception, which can be determined by turning the meter off and on, the operator can try to correct the interference by one or more of the following measures:

- Reorient or relocate the meter.
- Increase the separation between the equipment and the meter.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The StatStrip Glucose Hospital Meter complies with Canadian ICES-003.

B.6.5 WiFi Radio Option Operation

Prior to enabling the WiFi radio, an appropriate radio setup packet, as a component of the StatStrip Glucose Hospital Meter with wireless option configuration, must be downloaded to the meter via the device manager. **See Section B.1** of this manual for meter assignment and configuration. The configuration of the StatStrip Glucose Hospital Meter with wireless option can only be accomplished through the device manager by a Trained Nova Biomedical Service Representative, or an authorized and trained system administrator.

WARNING: *If you suspect that the meter's wireless radio may be interfering with other nearby devices, or if other devices may be interfering with the meter, discontinue the use of the meter and remove it from the patient care area. Nova Biomedical recommends you contact your local Information Technology Support for assistance in determining the problem and the appropriate resolution.*

StatStrip Glucose Hospital Meter

Radio and Network Connection status on meters equipped with the wireless option is displayed via icons on the Screen Title Bar.

Radio status is displayed as follows:



Radio is ON and connected to the WAP with the WiFi signal.



Radio is OFF or no connection to WAP or WiFi signal.

Network Connection status is displayed as follows:



Meter has established a connection and is communicating with the device manager.



Meter has not established communication with the device manager.



B.6.6 WiFi Usage Considerations

The StatStrip Glucose Hospital Meter with wireless option is certified for use on Wireless Local Area Networks (WLANs) using electromagnetic waves in the 2.4 GHz and/or 5 GHz frequency ranges to wirelessly transmit data. The three of the currently recognized IEEE standards for WLANs utilized by the StatStrip Glucose Hospital Meter with wireless option are 802.11 a/b/g/n/ac.

During wireless communication to a Wireless Access Point (WAP), the StatStrip Glucose Hospital Meter with wireless option recognizes the local WAP WLAN protocol configuration (802.11 a/b/g/n/ac) and automatically transmits

data using the appropriate communication protocol. The signal quality and strength or access to the bandwidth of one particular WAP client may vary depending on one or more of the following situations:

- Type and number of other clients or devices connected
- Performance of the Wireless Access Point
- In the presence of electromagnetic disturbances
- Or other potential interference factors, e.g., concrete walls

When undocked and communicating via WiFi, the StatStrip Glucose Hospital Meter with wireless option uses a burst-like communication protocol that will only consume bandwidth when results are to be sent or when a Patient or Operator ID query is initiated. Compared to other wireless applications, the meter's bandwidth consumption is minimal. If the WLAN connection to the meter is degraded, the meter is designed to eliminate any impact on testing functionality.

The WiFi Radio may only be set up by a device management system, which configures the meter's wireless communication functions capabilities. Wireless connectivity can help to ensure that data is sent immediately from all networked meters.

NOTE: *The meter must be returned to the docking station for battery recharging and full data exchange with the device manager.*

To change any of the meter configurations wirelessly, including the radio settings and/or meter setup, the StatStrip Glucose Hospital Meter with wireless option must be placed in the docking station with the radio turned on and properly configured.

B.6.7 WiFi Technical Considerations

Before connecting any StatStrip Glucose Hospital Meter with the wireless option to a wireless network, Nova Biomedical recommends that a WLAN site survey be performed.

The WLAN site survey

- To ensure that Wireless Access Points will provide enough coverage
- The performance is enough to support the StatStrip Glucose Hospital Meter with a wireless option.
- Detail RF signals, including all existing WLANs along with any competing RF signals
- Interferences (building structure related and other wireless equipment/devices).

Recommendation of a Wireless Meter implementation:

- A minimum of one wired docking station be connected via an RJ-45 network jack per usage area.
- A networked docking station provides redundancy if a wireless network malfunctions, loses service, or if the meter radio fails to operate correctly.
- If used in an area with low signal or interferences, it is recommended to install a connected wired docking station for redundancy.
- The connected docking station allows immediate bidirectional transmission of data when the radio is turned off and the meter is docked.

See B.6.9 for the complete StatStrip Glucose Hospital Meter with wireless option radio specifications, available configuration parameters, and security and encryption options.

B.6.8 WiFi Function and Performance

As described above, the StatStrip Glucose Hospital Meter with wireless option supports the 802.11 a/b/g/n/ac standards. In a typical WLAN environment (correct WLAN administration, “good” signal quality, the typical population of other clients present, any of the supported security models enabled, etc), this translates into the following WiFi-specific performance:

- All communication between the StatStrip Glucose Hospital Meter with a wireless option and a suitable device manager is in the POCT1-A communication standard.
- The StatStrip Glucose Hospital Meter with wireless option is capable of downloading from a suitable device manager, via WLAN, a complete configuration set, including up to 3000 Patient records, 8000 Operator records, and 30 reagent lot numbers, when operated in a typical WLAN environment.
- The StatStrip Glucose Hospital Meter with wireless option, with WiFi enabled and connected, will immediately transfers Patient and QC Results to a suitable device manager at the completion of the test and result entry into the meter database. Upon receipt of the result, the device manager replies to the meter with an “ACK” indicating the result was properly received. The meter then marks the result as “Transmitted” in its database. If the device manager does not reply with the appropriate “ACK,” the meter will not mark the result in the database, and attempt to resend the result the next time the meter communicates with the device manager. Complete result download and acknowledgement cycle in a typical WLAN environment is less than 1 second.

- The StatStrip Glucose Hospital Meter with wireless option, with WiFi enabled and connected, will immediately query the device manager if an unknown Operator or Patient ID is entered on the meter during a test procedure. If either the Operator or Patient ID is not valid for that meter at the time of the query, the device manager will reply to the meter with corresponding information for the subject. If the ID is valid, the meter will add the data to its operator or patient list in its database. Latency time of up to 10 seconds for query reply is a definable component of the meter configuration set.

An average range for direct connection between the StatStrip Glucose Hospital Meter with wireless option (WiFi on) and the WAP:

- 49 to 66 feet (15 to 20 meters) with air, direct view, and low disturbances
- The actual range depends on the positioning of the WAP's antennas and other topological properties of the space between StatStrip Glucose Hospital Meter with a wireless option with WiFi enabled and WAP.
- Also, dynamic control of the transmitting power of the access point may reduce the maximum distance between StatStrip Glucose Hospital Meter with a wireless option and WAP where communication can be guaranteed.

The StatStrip Glucose Hospital Meter with wireless option with WiFi enabled:

- Designed to coexist in environments with other wirelessly communicating devices
- Does NOT provide any real-time wireless functionality for the transmission, receipt, or monitoring of data
- Communication is described as exclusive, single, digital data fields, and does NOT communicate in a continuous waveform.

B.6.9 Meter Wi-Fi Settings, Range, Options

Setting	Description	Range	Options
On Meter			
WiFi On/Off	Turns the wireless radio on or off	N/A	a. On b. Off
Factory/Custom	Chooses the radio configuration set.	N/A	a. Factory - Installs the factory radio default setup. b. Custom - Installs the defined custom setup.
SSID	Defines the Service Set Identification (SSID) of the network to join.	N/A	Displays the SSID information from the defined custom setup. No user entry.
Install Cert.	Installs the most recently downloaded security certificate into the meter certificate store.	N/A	a. Push button to install certificate.
Ca Cer Installed	Displays the name of last CA certificate installed.	N/A	Displayed information only. No user entry.
Cers Expire	Displays the expiration date of the installed certificates.	N/A	Displayed information only. No user entry.
User Cer Installed	Displays the name of last user certificate installed.	N/A	Displayed information only. No user entry.
From Device Manager			
SSID	Defines the Service Set Identification (SSID) of the network to join.	0-32 Characters	a. Enter the name of the SSID of the network to join.

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PASSWORD	If required, defines the user credential password to be used for authorization on secure networks.	open	a. Enter the password
User Name	If required, defines the user credential name to be used for authorization on secure networks.	open	a. Enter the user name
Certificate Location	Defines where in the certificate(s) are to stored on the meter OS.	N/A	a. None b. File c. Full Store d. In Store
Pass Phrase	Defines the WPA/WPA2 Pass Phrase.	open	a. Enter the pass phrase.
WEP Key 0 - 3	Defines up to four unique WEP keys	N/A	a. Enter the appropriate key for each as required.
WEP Length 0 - 3	Defines the key length for up to four keys.	N/A	a. Not Set b. 40 Bit c. 128 Bit
WEP Key Tx Number	Defines which WEP key is used for transmission.	N/A	a. wepKey0 b. wepKey1 c. wepKey2 d. wepKey3
Pac File Name			
Pac PASSWORD			
Tx Power	Sets the max transmit output power	1 - 63 mW	a. 1 mW b. 5 mW c. 10 mW d. 20 mW e. 30 mW f. 50 mW g. 63 mW(Max)

Authentication Type	Defines the type of security authentication to be used.	N/A	a. Open b. Shared c. NetworkEAP
Power Save			a. Off b. Max c. Fast
Bit Rate		Auto - 54 mb/sec	
Radio Mode	Defines the operational band and bit rates of the radio.	N/A	Mode B Only Mode BG Mode G Only Mode B/G LRS Mode A Only Mode ABG (A preferred) Mode BGA (B and G preferred) AdHoc (A rates optimized) For n band: All G and N rates All A and N rates All A, B, G and N rates with A rates preferred All B, G, A and N rates with B/G rates preferred All B, G, and N rates For ac band: All A, N, AC rates
Encryption Types	Sets the encryption type to be used.	N/A	Manual WEP Auto WEP WPA PSK WPA TKIP WPA2 PSK WPA2 AES CCKM EKIP CKIP Manual CKIP Auto WPA AES WPA2 TKIP

EAP Types	Sets the authentication to be used.		None LEAP FAST PEAPMSCHAP PEAPGTC EAPTLS EAPTTLS PEAPTLS
DFS (Dynamic Frequency Sources) Channels	Enables 16 additional channels that are in the 5.25 GHz and 5.73 GHz frequency range	N/A	Off/On

NOTE: *Not all EAP types are applicable to all Encryption types. Please consult your device manager instructions for details of which EAP and Encryption are used.*

B.7 Cybersecurity Information

Interface and Communication Protocol

StatStrip Glucose Hospital Meters connect and communicate with a data/device manager over a healthcare system's TCP/IP network using the POCT1-A interface protocol. Telnet, FTP ports, and all other communication protocols and features are disabled as part of the OS image installed on the device. An optional 802.11a/b/g/n/ac Wi-Fi communication is also available for the meters utilizing the same POCT1-A interface protocol. Once a meter is connected with the known data/device manager, attempts to connect and communicate with the meter by any third-party system or device are ignored.

Software/Firmware Updates

The StatStrip Glucose Hospital Meter's software/firmware updates are managed by local healthcare system IT administrators with assistance from Nova Biomedical Technical Support. All software/firmware updates are

published by Nova Biomedical, and customer notification is forwarded to designated contacts within a healthcare facility using a Customer Information Bulletin via email announcement. Nova Biomedical Technical Support is responsible for downloading all new software/firmware to the local data/device manager. The local data/device manager then downloads the updated software/firmware to each meter within the healthcare facility when the meter is returned to the docking station. No end-user actions are required on the meter to perform the update, and the meter will return to the Home screen when the update is complete.

Anti-Malware Updates

The StatStrip Glucose Hospital Meter uses a Linux-based Operating System (OS). The meter system is a closed system without the ability to access the OS layer to install any other applications. The meter application software/firmware is loaded as a proprietary, turnkey application onto the meter OS. There is no end user access to the OS on the meter either directly or via remote connection. No other third-party applications or software are allowed to reside or run on the meter.

Recommended Cybersecurity Safeguards

When installing and using the StatStrip Glucose Hospital Meter System in healthcare systems, Nova recommends that the following security safeguards be applied consistent with HIPAA Security Rule, 45 CFR Part 160 and Subparts A and C of Part 164.

1. Appropriate administrative safeguards including but not limited to:
 - a. Ensuring all users and administrators are trained in the operation of the meter and appropriate local security policies and procedures.

2. Appropriate physical safeguards are in place including but not limited to:
 - a. Secure the meters by limiting physical access to only appropriate healthcare staff who require use, or support of the meters.
 - b. Ensure the meters require the scanning of an Operator ID badge or other customer issued identification device.
 - c. Ensure all meters are accounted for at the beginning and end of each departmental shift.
3. Appropriate technical safeguards are employed including but not limited to:
 - a. Ensure the meters verify that only trained and certified healthcare staff are allowed access to, and use of the meters.
 - b. Ensure the meters are configured to operate only on the healthcare system's secured network.

Networking/Connection Dependency Instructions

The StatStrip Glucose Hospital Meter's application is designed to initiate the TCP/IP connection and communication with the healthcare facility data/device manager. Any transmission received that is not identified as a valid POCT1-A protocol from the defined data/device manager is ignored. If communication with the data/device manager is unavailable, or network service is interrupted, the meter remains operational and patient testing may continue. All results collected during any "network downtime" are stored in the meter's encrypted database. Once meter communication is re-established, all test results gathered during the downtime are automatically sent to the data/device manager. Healthcare users and administrators should follow local policies and procedures for network outage events regarding utilization of the meters and subsequent result management.

Cybersecurity Event Management

StatStrip Glucose Hospital Meters are hardened against cybersecurity attacks and do not allow access to any meter software, settings, or data. Once the meter has connected with the known data/device manager and initiates encrypted communication, all other attempts to connect and communicate with the meter by any third-party system or device are ignored. The meters do not audit or log these attempted cybersecurity events.

In the U.S., healthcare facilities are instructed to contact Nova Biomedical Technical Support at 1-800-545-6682 if a cybersecurity event is detected or suspected. Outside of the U.S., contact your local Nova Biomedical distributor.

B.8 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants to 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 6 months 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.

