REF 66232 IVD

Instructions for Use Manual

Stat Strip®

Glucose and β-Ketone Hospital Meter For Export Only

nova® biomedical

Revision History

Revision	Date of Release	Description of Revisions
A	08-2023	Initial Release

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD	*In vitro* diagnostic medical device
	Caution, consult accompanying documents
	Consult instructions for use
	Biological risk
REF	Catalog number
	Manufacturer
	Date of Manufacture
CONTROL	Control
LEVEL	Level
	Do not reuse
Glu	Glucose
Ket	Ketone
7.5V ⎓ 1.7A	Power supply connection

LOT	Batch code
SN	Serial Number
	Temperature limitation
	Upper Limit of Temperature
	Number of Tests
	Use by
	This device complies with Part 15 of the FCC Rules and with RSS-247 of industry Canada
	The system complies with the electrical and safety requirements.

Ordering Information

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

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U.S.A.

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1-978-439-3763
(USA and International)
1-781-891-9718
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EC REP Authorized Representative

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Technical Assistance

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

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

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

Nova Biomedical recommends users report any **serious incidents/ adverse events** back to Nova Biomedical or Nova Biomedical's Authorized Representative as well as to their local Competent Authority as required.

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1 Introduction

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

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

WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products and strips with care. Gloves and protective clothing are recommended. When performing maintenance and troubleshooting procedures, also use protective eyewear.

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

The StatStrip Glucose and β-Ketone Hospital Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose or β-Ketone electrochemical test strips to measure glucose or β-Ketone in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. In addition to measuring glucose and β-Ketone, 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.

Always ensure the proper units of measure are selected to ensure the proper therapy is provided to the patient.

1.1 About This Manual

This manual is for the Nova Biomedical StatStrip Glucose and β-Ketone Hospital Meter.

Throughout this manual, *NOTE:* indicates especially important information, *CAUTION:* indicates information that is critical to avoid instrument damage or incorrect results, and *WARNING:* indicates possible hazard to the operator.

1.2 Safety Instructions

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

Blood-Borne Pathogens Safety

1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the StatStrip Glucose and β-Ketone Hospital Meter.
2. Healthcare professionals should be aware that all parts of the StatStrip Glucose and β-Ketone Hospital Meter are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
3. The StatStrip Glucose and β-Ketone Hospital Meter may only be used 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/2007isolationprecautons.html.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at https://www.cdc.gov/labs/BMBL.html.

"*Protection of Laboratory Workers From Occupationally Acquired Infection; Approved Guideline - Fourth Edition*," Clinical and Laboratory Standards Institute (CLSI) M29-A4.

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Tranmitting Bloodborne Pathogens: Initial Communication." (2010) http://www.fda.gov/Medicaldevices/Safety/AlertsandNotices/ucm224025.html.

"CDC Clinical Reminder: Use of Fingerstick Devices." https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html.

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

General Safety

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

8. The meter should be serviced by qualified service personnel.

Electrical Safety

1. Battery powered: 3.6 V Li Ion battery (rechargeable/replaceable)
2. Desk-mount Wireless Charging Station with Power Adapter
3. An LED indicator light to show the battery is charging: green blinking light indicates that the meter is charging.

Battery Issues

- In case of any issues with the battery, the users are requested to return the Meter to Nova Biomedical for repairs and replacements. This can be done by contacting Nova's Technical Support team to resolve the issues.
- In the USA, please contact Nova Biomedical Technical Support at 1-800-545-6682. Outside the USA, contact your local dealer.

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.
- 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. Do not use test strips, control solutions, or linearity solutions after the expiration date.
3. Test strips are single use only.
4. Operate the Meter in the appropriate environment.
5. Dispose of all waste solutions according to standard procedures.

Environmental

- The operating temperature range for Meter operation: 34˚F to 104˚F (1˚C to 40˚C)
- The relative humidity range for Meter operation: up to 90% non-condensing
- The maximum altitude for Meter operation: Up to 15,000 feet (4572 meters)

Dimensions:

Height:	158 mm (6.23 in)
Width:	77 mm (3.04 in)
Depth:	28 mm (1.1` in)

Weight:

215 g (0.47 lb)

1.3 Intended Use and Tests Performed

Intended Use

The Nova StatStrip Glucose and β-Ketone Hospital Meter System is intended for point-of-care (near-patient testing), *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. It is also intended for the quantitative determination of β-Ketone in capillary finger stick, venous whole blood, and neonate whole blood specimens.

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 and ketonemia.

Clinical Utility

Glucose:
The measurement of glucose[1] is used in the monitoring of carbohydrate metabolism disturbances including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

β-Ketone:
There are 2 major causes of ketoacidosis:

- Most commonly, ketoacidosis is diabetic ketoacidosis (DKA), resulting from increased fat metabolism due to a shortage of insulin. It is associated primarily with type I diabetes, and may result in a diabetic coma if left untreated.[2]
- Alcoholic ketoacidosis (AKA) presents infrequently, but can occur with acute alcohol intoxication, most often following a binge in alcoholics with acute or chronic liver or pancreatic disorders. Alcoholic ketoacidosis occurs more frequently following methanol or ethylene glycol intoxication than following intoxication with uncontaminated ethanol.[3]

A mild acidosis may result from prolonged fasting or when following a ketogenic diet or a very low calorie diet.[4,5]

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

2. Kitabchi AE, Umpierrez GE, Murphy MB, Kreisberg RA (December 2006). "Hyperglycemic crises in adult patients with diabetes: a consensus statement from the American Diabetes Association". Diabetes Care 29 (12): 2739–48. doi:10.2337/dc06-9916.
3. Kraut JA, Kurtz I (January 2008). "Toxic alcohol ingestions: clinical features, diagnosis, and management". Clinical Journal of the American Society of Nephrology : CJASN 3 (1): 208–25. doi:10.2215/CJN.03220807.
4. Hartman AL, Vining EP (January 2007). "Clinical aspects of the ketogenic diet". Epilepsia 48 (1): 31–42. doi:10.1111/j.1528-1167.2007.00914.x.
5. Delbridge E, Proietto J (2006). "State of the science: VLED (Very Low Energy Diet) for obesity". Asia Pac J Clin Nutr 15: 49–54.

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 and β-Ketone Hospital Meter System.
- When performing a capillary heel stick glucose or β-ketone test on a neonate, caution should be exercised to ensure adequate blood flow to

the heel. Healthcare facilities should consider unswaddling the neonate, massaging and/or warming the heel prior to specimen collection.

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.
- Anticoagulants: sodium, lithium, and ammonium heparin
- Fluoride and EDTA blood collection devices should not be used for venous specimens.

1.6 General Precautions

- Prior to 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 test result is higher or lower than expected, run a control solution test to confirm test strip performance.

    1. If control solution result is out of range, remove test strip vial from point of use and repeat control solution test with new test strip

vial.

2. If control solution test is within expected range, repeat patient test.
3. If patient test result is higher or lower than expected, perform the test using an alternate method and consult a healthcare professional.

1.7 The Sample

Glucose

- 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.
- Plasma calibrated patient test results
- Sample size 1.2µL
- Anticoagulants: sodium, lithium, and ammonium heparin

β-Ketone

- Capillary, venous, and neonate whole blood
- Plasma calibrated patient test results
- Sample size 0.8 µL
- Anticoagulants: sodium, lithium, and ammonium heparin

1.8 Interfering Substances

Glucose Interferences:
The StatStrip Glucose and β-Ketone Hospital Meter exhibits **no** interference for Glucose from the following substances up to the following concentration levels:

Tested Interfering Substances	Tested Concentration Level	
Acetaminophen	20.0 mg/dL	1.323 mmol/L
Acetoacetate	51.0 mg/dL	5 mmol/L

Tested Interfering Substances	Tested Concentration Level	
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	15 mg/dL	1.33 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
Hydrocortisone	20 mg/dL	0.552 mmol/L

Tested Interfering Substances	Tested Concentration Level	
Ibuprofen	50 mg/dL	2.43 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
Maltotetriose D(+)	240 mg/dL	4.76 mmol/L
Mannitol	6000 mg/dL	329.4 mmol/L
Mannose	500 mg/dL	27.75 mmol/L
Methy-dopa	1.0 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
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
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

Tested Interfering Substances	Tested Concentration Level	
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	20% and 70%	
Oxygen	All concentrations	
pH	6.6 and 8.0	

β-Ketone Interferences:

The StatStrip Glucose and β-Ketone Hospital Meter exhibits no interference for β-Ketone from the following substances up to the following concentration levels:

Tested Substances	Concentration Level	
Acetaminophen	20mg/dL	1.32 mmol/L
Acetone	10mg/dL	1.72 mmol/L
Acetoacetate	10mg/dL	0.93 mmol/L
Ascorbic Acid	20mg/dL	1.14 mmol/L
Bilirubin	6mg/dL	0.10 mmol/L
Captopril	10mg/dL	0.46 mmol/L
Cholesterol	500mg/dL	12.9 mmol/L
Creatinine	6mg/dL	0.53 mmol/L
Dopamine	10mg/dL	0.53 mmol/L
Ephedrine	0.9mg/dL	0.035 mmol/L
Galactose	500mg/dL	27.75 mmol/L
Glucose	900mg/dL	50.0 mmol/L
Ibuprofen	48mg/dL	2.33 mmol/L
L-Dopa	100mg/dL	0.51 mmol/L
Maltose	500mg/dL	14.61 mmol/L
Methyl-Dopa	1mg/dL	0.042 mmol/L
N-Acetyl-L-Cysteine	10mg/dL	0.61 mmol/L

Tested Substances	Concentration Level	
Tetracycline	30mg/dL	0.62 mmol/L
Tolazamide	15mg/dL	0.48 mmol/L
Tolbutamide	45mg/dL	1.67 mmol/L
Triglycerides	750mg/dL	8.47 mmol/L
Salicylate	30mg/dL	1.87 mmol/L
Uric Acid	20mg/dL	1.05 mmol/L

1.9 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 and β-Ketone 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.

1.9.1 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.

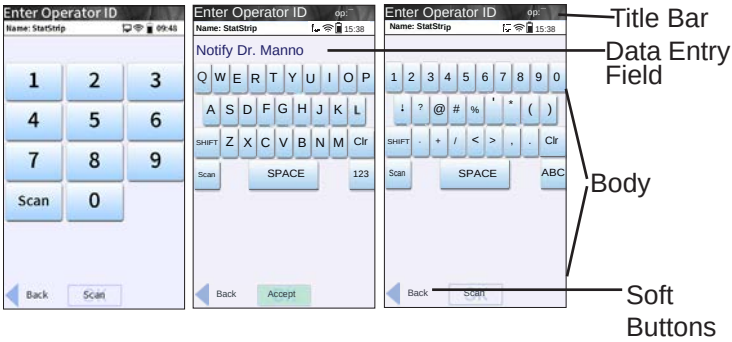

Figure 1.2 The Numerical and the Alphabetic Keypad Screens

NOTE: *The left screen (numeric only) is the default keypad that is displayed, unless the user enables the screens on the right. Once enabled, the user can toggle between the second screen (QWERTY keypad) with alphabetic display and the third screen (numeric keypad with special characters) for ease of use.*

To use the alphabetic and numeric 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) – Colored (Blue for Glucose, Green for β-Ketone, Gray for test not selected), 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 and β-Ketone Hospital Meter has the following operator input mechanisms:

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

1.9.2 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, so as to scroll through the list of characters. Each character is displayed in the data entry field when it has been pressed.

In addition, barcode scan input can be enabled for those menu fields that support it to make data input easier and quicker.

1.9.3 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
- Pressing the ON/Off button

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 test strip
- Pressing the ON/Off button

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.*

1.9.4 Result Alerts

The result is displayed differently depending on whether it is in or out of the normal range for Glucose and β-ketone 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 **glucose result only** 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 **glucose result only** if the value is lower than the lower end of the critical range.
- A β-Ketone result less than 0.1 mmol/L displays as <0.1 mmol/L.

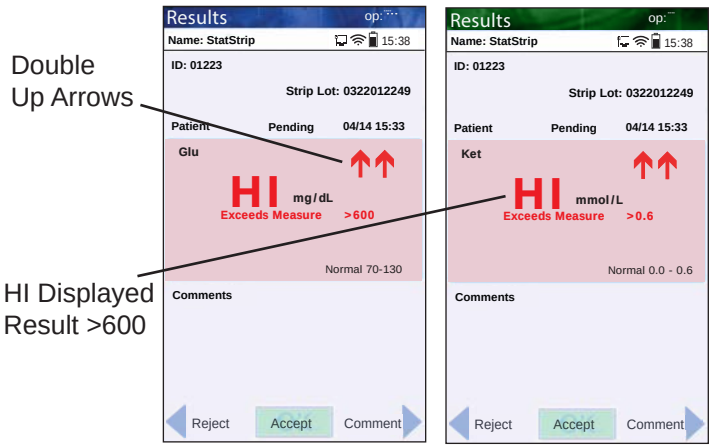

Figure 1.3 Patient Result: Exceeds Measure/HI screen

1.9.5 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/down to navigate through the complete list of screen/menu.

1.10 Installing the StatStrip Glucose and β-Ketone Hospital Meter

The Charging Station must be plugged into an AC wall outlet. The meter displays a green blinking light to indicate that it is charging.

The Charging Station recharges the battery of the meter when the meter is placed into the station. Indicator light 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.

1.10.1 Power Up Procedure

After 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

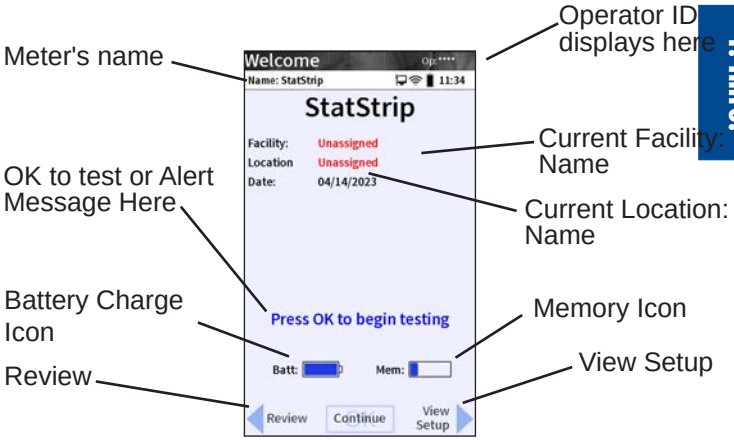

Figure 1.5 Welcome Screen

Messages or Alerts on the Home screen

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

1.11 Operator Login

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

1. From the Home screen, press the Login soft key at the bottom middle of the screen.
2. The Enter Operator ID screen displays.
   a. To enter alphabetic ID's, press the ABC soft key on the touchscreen keypad. An alphabetic keypad will display.
   b. To return to 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 a message "is not a valid ID Try again."*

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

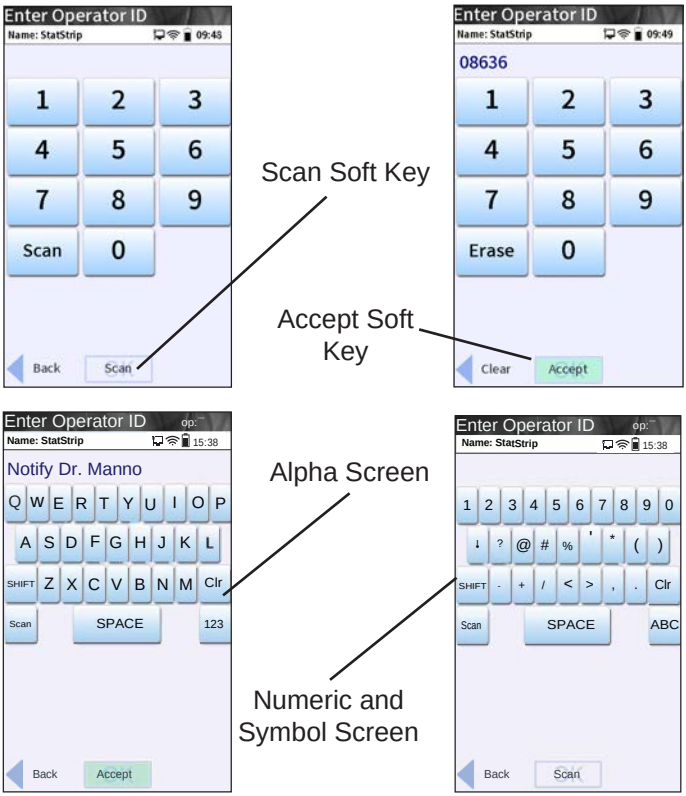

Figure 1.6 Enter Operator ID Screens

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

1.12 Administration (Admin) Screen

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

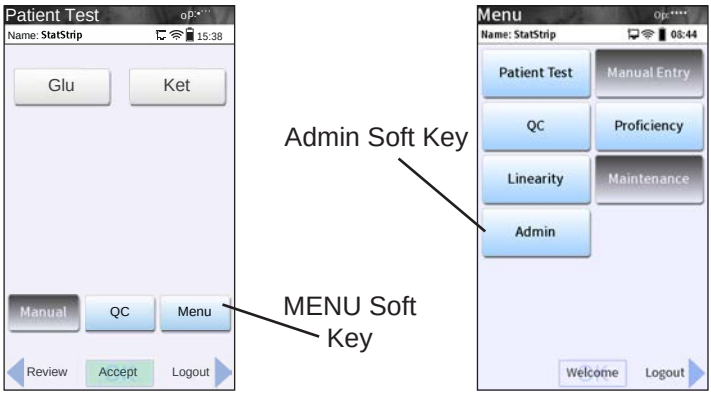

Figure 1.7 Patient Test Screen and MENU Screen

Figure 1.8 The Admin Screen

1.12.1 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, the user can either scroll the numbers up/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.

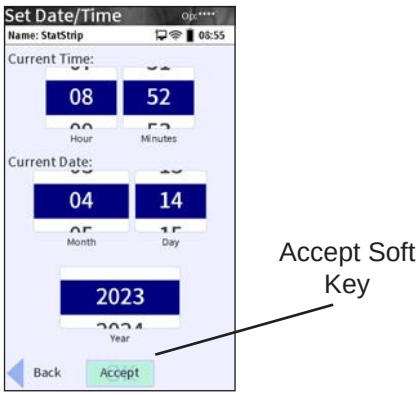

Figure 1.9 The Set Time (and Date) Screen

1.12.2 Naming the Meter

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

1. From the Patient Test screen, press the Menu then the Admin soft button.
2. The Admin screen displays. Press the Meter Name soft key.
3. The Enter Meter Name screen displays. To add or change the name, enter the name onto the soft keypad on the screen.

NOTE: *Maximum number of characters is 10.*

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

1.12.3 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.

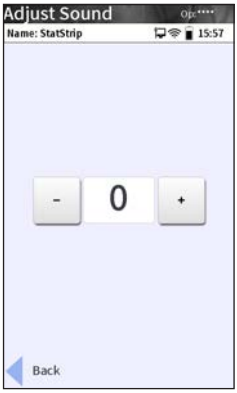

Figure 1.10 The Sound Screen

1.12.4 View Setup

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

1.12.5 Unarchive

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

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

1.12.6 Resetting the Facility

The meter's facility name can be reset.

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

1.13 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. From the Patient Test Screen, press the Menu then the Admin soft button
3. The Admin screen displays. Press the Assign Location soft key and select a location from the displayed list.
4. With the new location selected, press the Accept soft button.
5. Press the Accept soft button again to confirm the location.
6. Dock the meter to upload the new location configuration.

1.14 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:

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

2 Quality Control

2.1 When to Perform a QC Test

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

2.2 StatStrip Glucose and β-Ketone Control Solution

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

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

- With each new operator
- Before using the StatStrip Meter for the first time
- If a patient test has been repeated and the blood results are still lower or higher than expected

- If there are other indications that the system is not working properly
- Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).
- As required by the institution's quality control policy or local regulatory requirements

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

2.3 Quality Control Test

NOTE: *The operation overview provided in this section is for hospital settings. The meter configuration and screens may vary depending on your healthcare setting (e.g. Ambulatory Care Settings).*

The following section explains how to run a Quality Control Test with one of the 3 control solutions.

1. From the Patient Test screen, press the QC soft key.
2. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key.

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

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

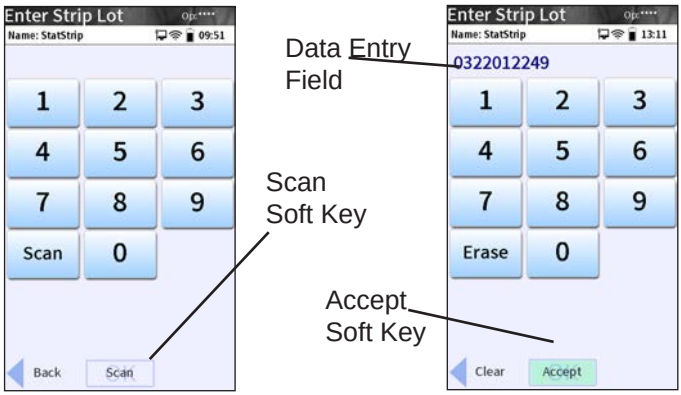

Figure 2.1 Enter Strip Lot Screens

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

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

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

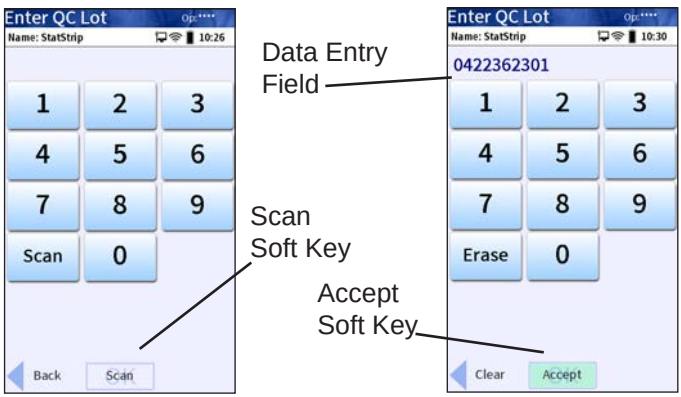

Figure 2.2 Enter QC Lot Screens

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

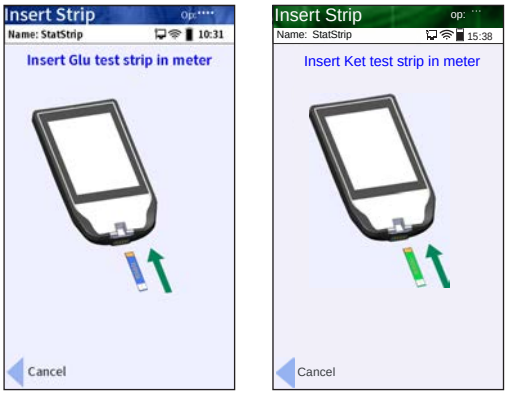

Figure 2.3 Insert Strip Glu or Ket Screen

NOTE: *If the Test Strip is not the selected type, the Analysis Error screen displays: "Replace Wrong Strip."*

7. With the test strip correctly inserted, the Apply Sample screen displays.
8. Gently mix the control solution vial 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.

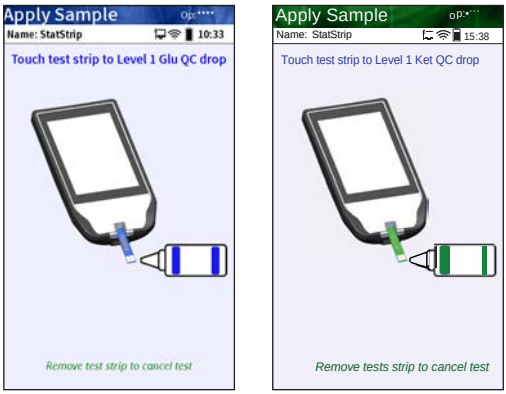

Figure 2.4 Apply QC Solution to Test Strip Screen

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.

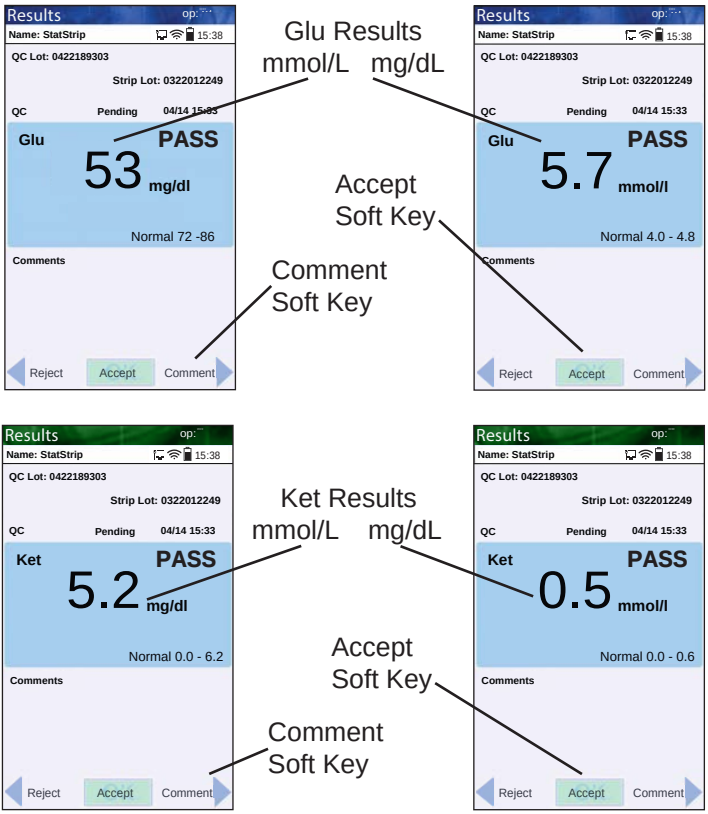

Figure 2.5 QC Result Screens

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 control solutions vial label. If a QC test does not fall within the specified range, verify that the test strips and control solutions are not past their expiration dates. Repeat the test with a new strip. If the second test fails, inspect and clean the meter according to Section 6.3, Cleaning and Disinfecting the Meter. If the third test fails, contact Nova Biomedical Technical Support.*

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.

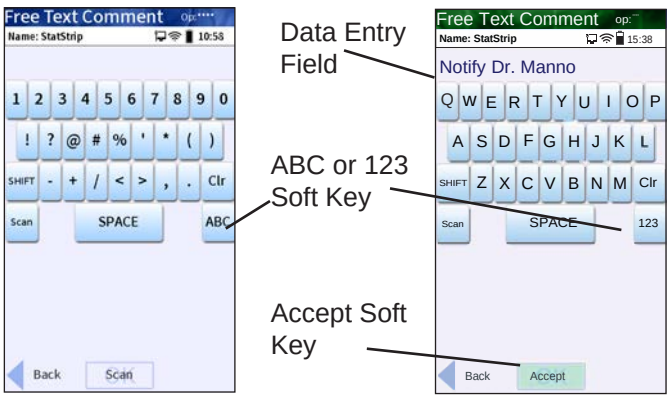

Figure 2.6 Add Comment Screens

3 Patient Samples

This section describes how to perform tests with the StatStrip Glucose and β-Ketone Hospital Meter.

3.1 Important Safety Instructions

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

All parts of the StatStrip Glucose and β-Ketone 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 and β-Ketone 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.

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/bmbl5/. "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

NOTE: *The operation overview provided in this section is for hospital settings. The meter configuration and screens may vary depending on your healthcare setting (e.g. Ambulatory Care Settings).*

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

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

1. From the Patient Test screen, press the Accept soft key. Or, just insert the glucose or β-ketone test strip, and the meter will adjust to that test.

NOTE: *The header will turn from Grey to Blue for Glucose or Green for β-Ketone after you insert the Test Strip of choice.*

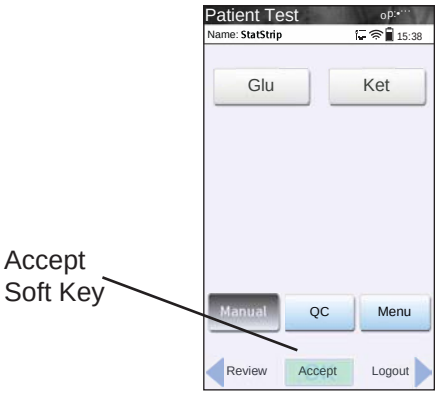

Figure 3.1 Patient Test Screen

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

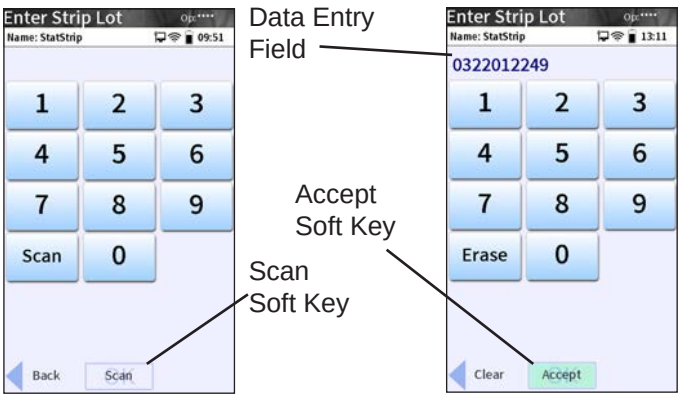

Figure 3.2 Enter Strip Lot Screens

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

5. If the diagnosis code is enabled, the Enter Diagnosis Code screen displays next. Enter the code: from Diagnosis Code List screen (press List soft key), by pressing numeric/alphabetic soft keys (press the ABC... soft key), or by scanning the barcode ID.
6. Depending on what is enabled to the meter, one of three screens will display: Enter Patient ID, Enter Accn Num, or Sample ID Type.
7. If Sample ID Type is enabled, select (soft keys) Enter Accn Num (Accession Number) or Enter Patient ID: either the Enter Accn Num screen or the Enter Patient ID screen will display.
8. From the Enter Patient ID screen, enter the Patient ID: from Patient ID List screen (press List soft key), by pressing numeric/alphabetic soft keys (press the ABC... soft key), or scanning the barcode ID.
9. From the Enter Accn Num screen, enter the Accession Number: by pressing numeric/alphabetic soft keys (press the ABC... soft key), or by scanning the barcode ID.

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

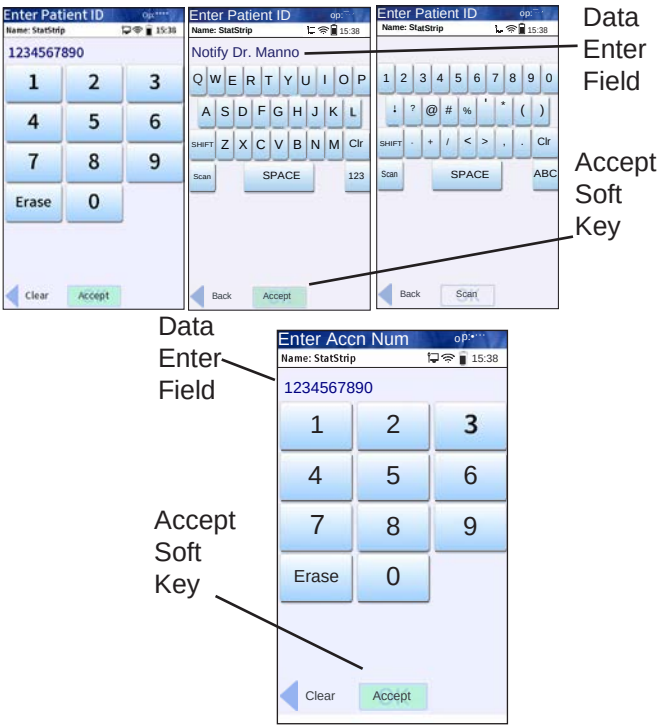

Figure 3.3 Enter Patient ID or Enter Accn Num Screens

10. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.
11. If a strip has not been inserted, the Insert Strip screen displays. Insert a Test Strip as shown on the screen.

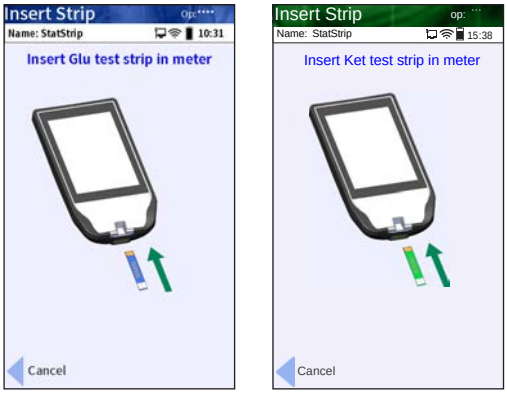

Figure 3.4 Insert Strip Screen

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

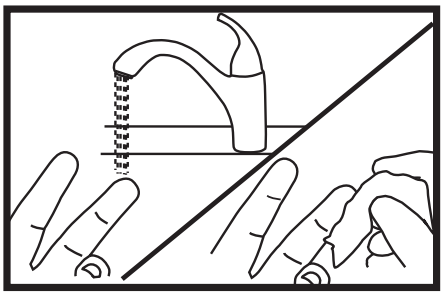

Figure 3.5 Wash the Patient's Hand

13. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
14. Use the Safety Lancet to puncture the finger.
15. Squeeze the finger to form a drop of blood following hospital protocol. Wipe away the first drop of blood then squeeze the finger again to form a second drop of blood.

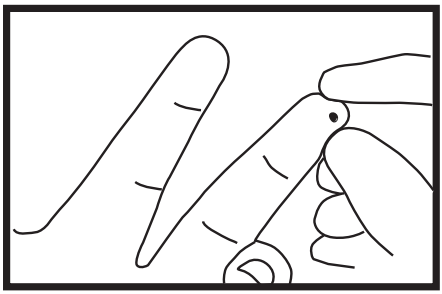

Figure 3.6 Squeeze the Finger to Form a Drop of Blood

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.*

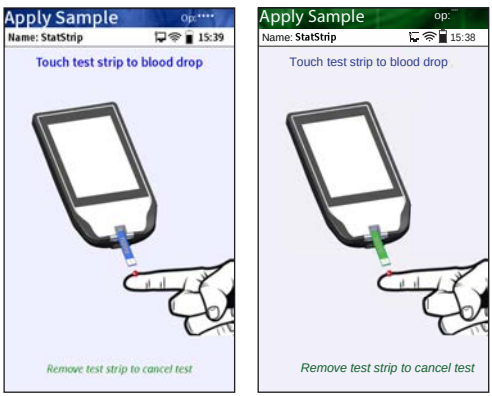

Figure 3.7 Touch Test Strip to Blood Drop Screen

17. The test results will appear in 6 seconds for glucose or 10 seconds for β-Ketone.

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.
20. When patient testing is completed, the StatStrip Glucose and β-Ketone Meter should be cleaned and disinfected after use prior to testing with a new patient. For cleaning and disinfecting instructions, see Section 6.3.

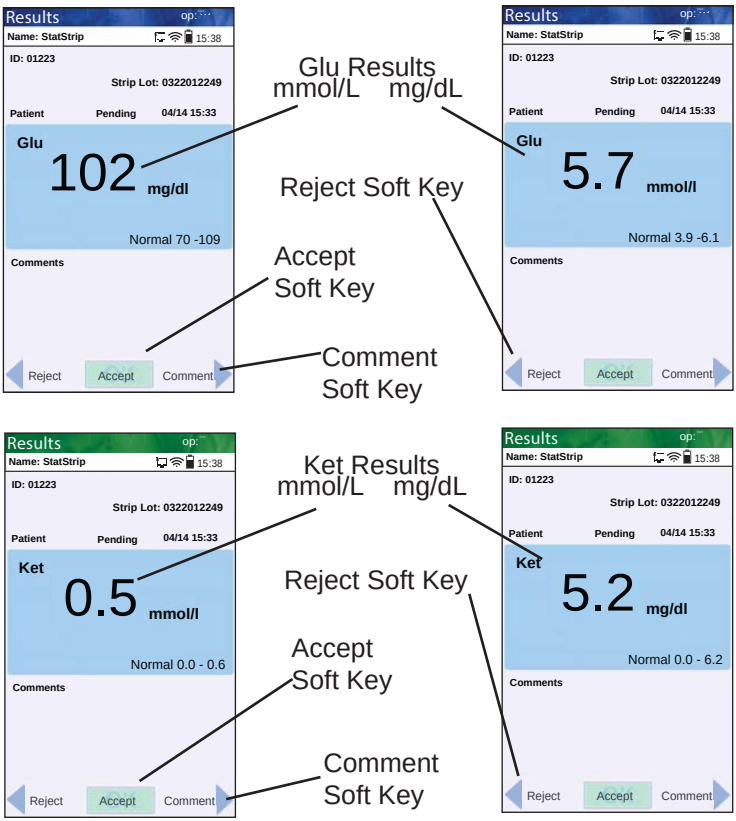

Figure 3.8 Glucose and β-Ketone Results Screens

NOTE: *A single up arrow displays for abnormal high result and 2 up arrows for critical high value for both Glucose and β-Ketone results.*

A single down arrow displays for abnormal low result and 2 down arrows for critical low value for Glucose results only.

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.

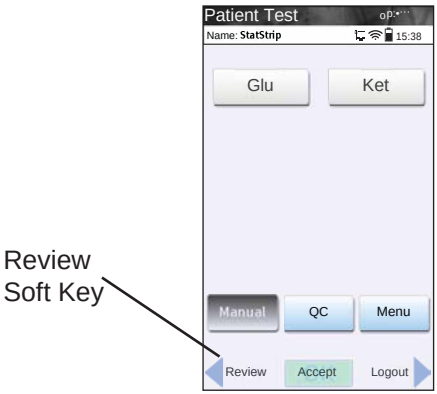

Figure 3.9 Patient Test Screen: Review Soft Key

2. The Review Result screen displays.
3. Select how to sort the results by pressing ID, Time/Date, or Type.

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

4. Scroll through the stored results.
5. Select the result that you want to review.
6. Press the View soft key to view the selected result.
7. Press the Previous soft key to view the previous result.
   Press the Next soft key to view the next result.

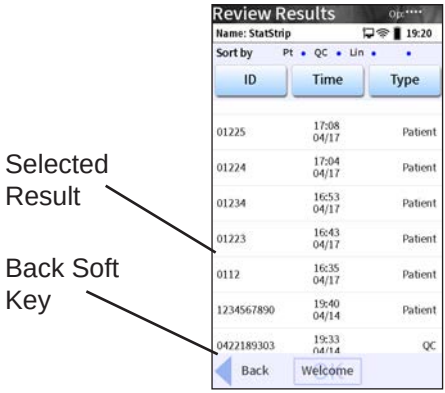

Figure 3.10 Review Results Screen: Result Selected

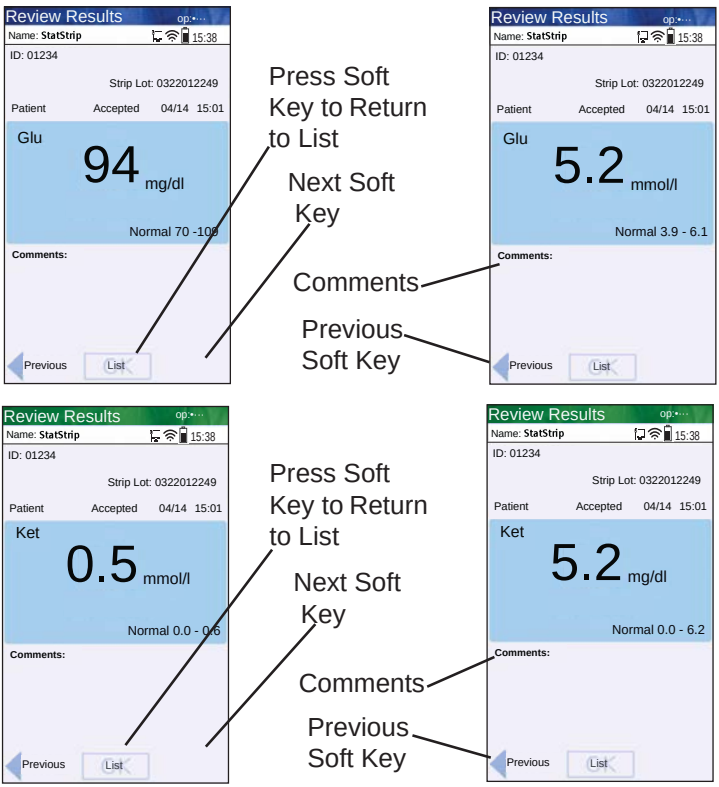

Figure 3.11 Review Result Screen: Selected

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. The connection is marked with the Ethernet <•••> symbol.

    - 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 Linearity Test

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

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

5.1 Running a Linearity Test

1. From the Patient Test screen, press the Menu soft key. If you insert a test strip first, the color bar will turn to either blue for Glucose or green for β-Ketone.
2. From the Menu screen, press the Linearity soft key.
3. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key.

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

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

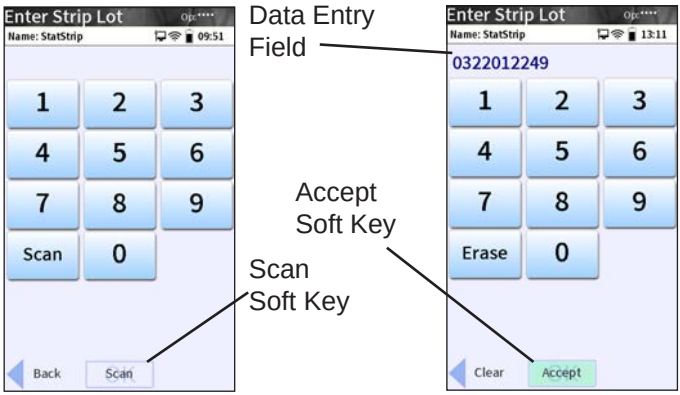

Figure 5.1 Enter Strip Lot Screens

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

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

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

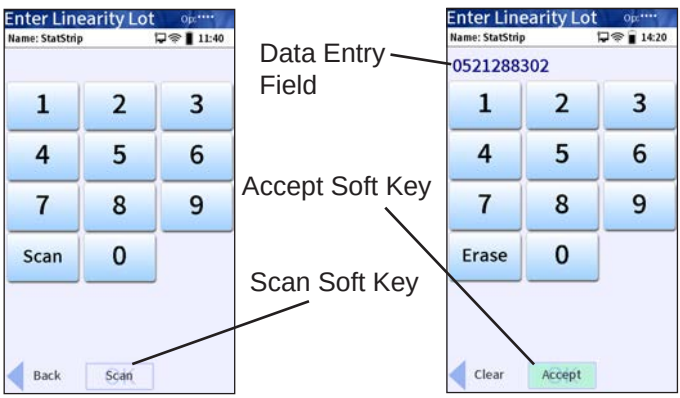

Figure 5.2 Enter Linearity Lot Screens

7. If a strip has not been inserted, the Insert Strip screen displays. Insert a Test Strip as shown on the screen.

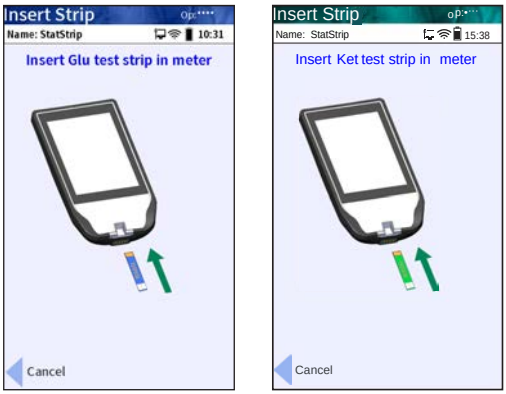

Figure 5.3 Insert Strip Screen

NOTE: *If the Test Strip is not the selected type, the Analysis Error screen displays: "Replace Wrong Strip."*

8. With the test strip correctly inserted, the Apply Sample screen displays.
9. Gently mix the StatStrip Glucose and β-Ketone Linearity Solution before each use.
10. Discard the first drop of linearity solution from the bottle to avoid contamination.
11. Place a drop of linearity solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter.

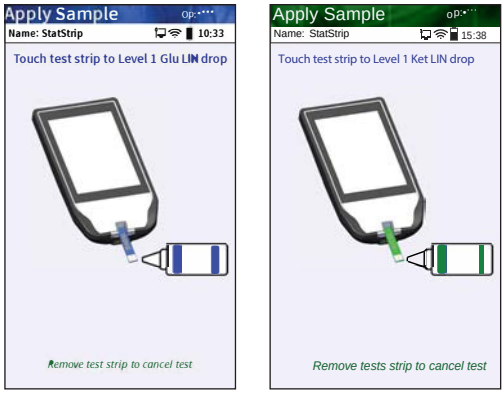

Figure 5.4 Apply Sample (Linearity Solution) to Test Strip Screen

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

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

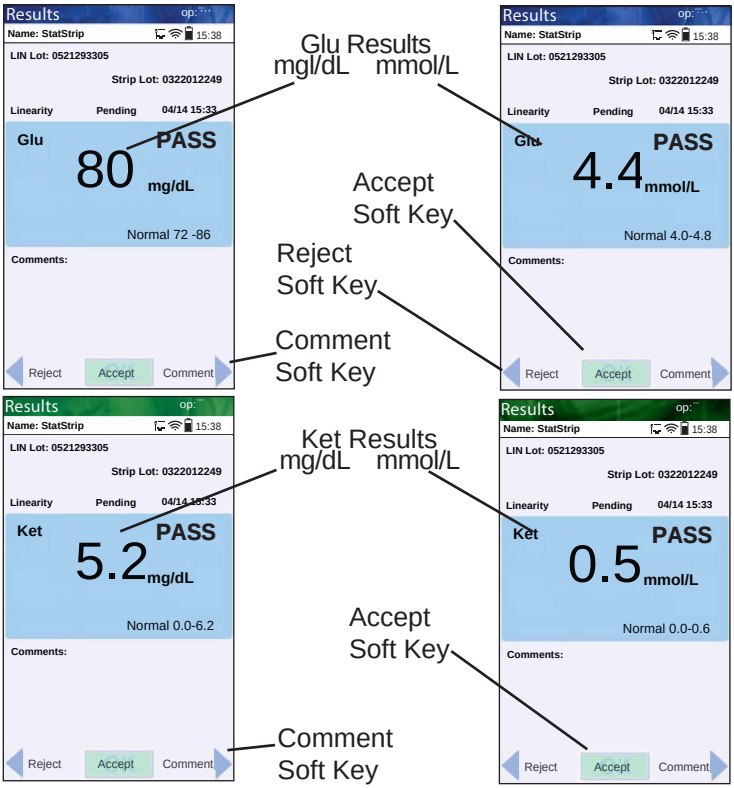

Figure 5.5 Linearity Result Screen

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

6 Maintenance

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

6.1 Charging the Meter

When the Battery LOW symbol displays on the screen, place the meter into the Charging Station.

Figure 6.1 Battery Low: Charge Battery Screen Alert

Figure 6.2 Meter placed into Charging Station

6.2 Cleaning and Disinfecting the Meter

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

- Clorox Germicidal Healthcare® Bleach Wipes, EPA Registration #67619-12, or any disinfectant product with EPA Registration #67619-12
- Super Sani Disposable Wipes (Sani Wipes) EPA Registration #9480-4
- 70% Isopropyl (rubbing) Alcohol may be used.
- Commercial surface decontamination preparations that are approved for use by your facility can be used. Apply to a small test area first to ensure surface finish integrity.
- Avoid harsh solvents such as benzene and strong acids.
- Care should be used to limit exposing test ports to fluids as it may result in damage to the unit.

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

***WARNING: T**he StatStrip Glucose and β-Ketone 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.*

7 Troubleshooting

7.1 Meter Screen Alerts

The meter displays a number of alerts:

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

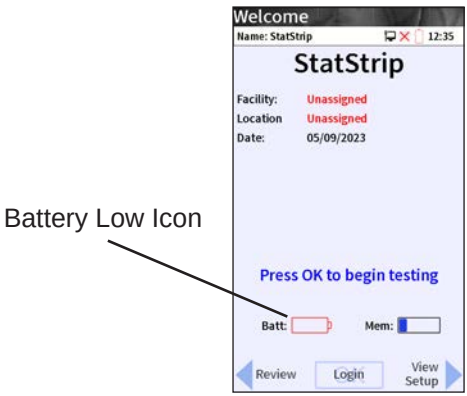

Figure 7.1 Battery Low: Charge Battery Screen Alert

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

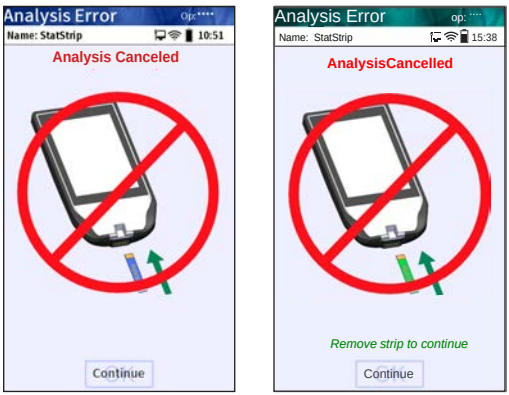

Figure 7.2 Analysis Error: Analysis Cancelled Screen Alert

3. **Temperature** - Meter will only work within the temperature range of 34°F to 104°F (1°C to 40°C). Return the meter to an environment within the specified temperature range of 34°F to 104°F (1°C to 40°C).

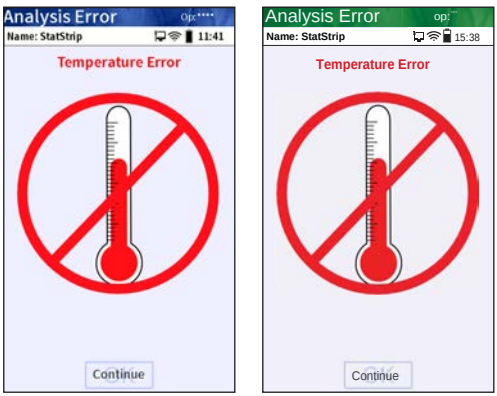

Figure 7.3 Analysis Error - Temperature Error Screen Alert

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

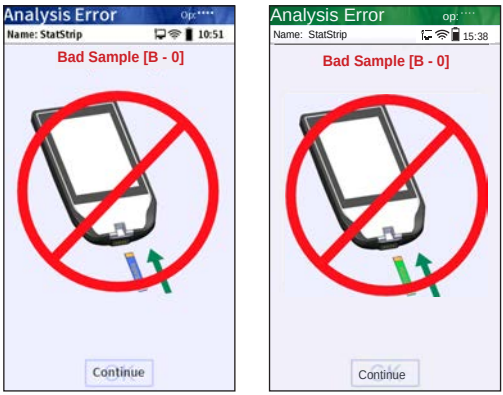

Figure 7.4 Analysis Error - Bad Sample Screen Alert

5. **Replace Strip** - Occurs after insertion of strip or occurs during analysis. Insert another strip and retest. If the error code persists, perform the test using an alternate test strip vial or alternate method.

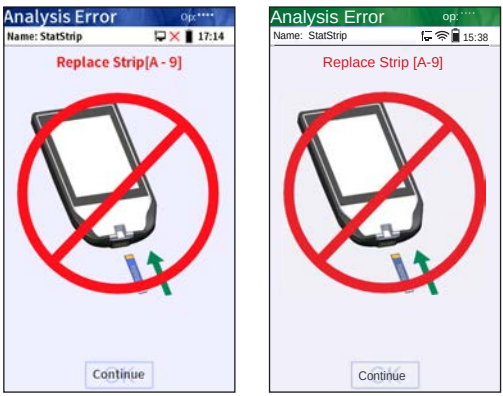

Figure 7.5 Analysis Error - Replace Strip Screen Alert

6. **Flow Error** - The specimen was incorrectly drawn into the test strip due to either insufficient or incorrect sample application. Repeat the test with a new strip. If the error code persists, perform test using an alternate method.

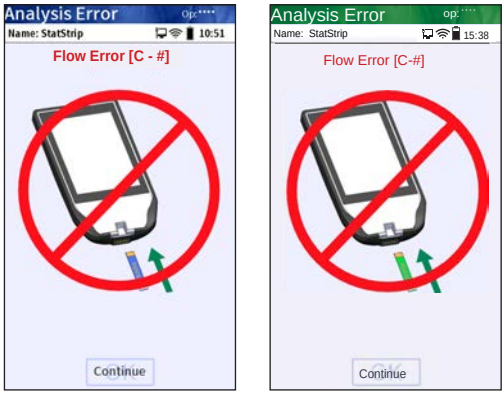

Figure 7.6 Analysis Error - Flow Error Screen Alert

7. **Transfer Failed** - Server refuses to allow dialog with the meter, or Connection to server was broken. Please check the network settings, the status of your network, or contact your administrator for assistance.

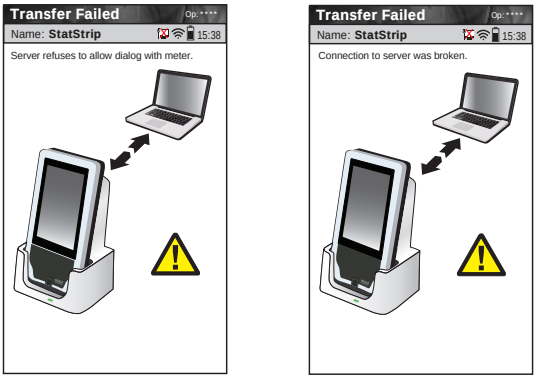

Figure 7.7 Transfer Failed - Connection Not Allowed or Connection Broken

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

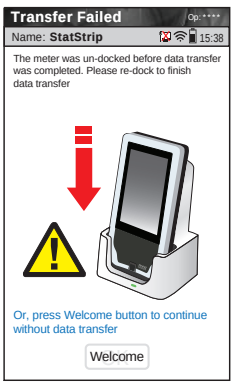

Figure 7.8 Transfer Failed - Transfer Incomplete

A Appendix

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

A.1 StatStrip Glucose and β-Ketone Hospital Meter Specifications

Measurement Range:	Glucose: 10-600 mg/dL or 0.6-33.3 mmol/L β-Ketone: 0.1-7.0 mmol/L
Acceptable Samples:	Glucose: 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 β-Ketone: Capillary, Venous, and Neonate whole blood samples
Measuring Technology:	Enzyme, Amperometric Glucose Enzyme(Aspergillus sp.,>1.0 IU) β-hydroxybutyrate dehydrogenase (Alcaligenes fecalis 0.3 IU)
Analysis Time:	6 seconds (Glu); 10 seconds (β-Ket)
Sample Volume:	1.2 µL (Glu); 0.8 µL (β-Ket)
Meter Memory:	1500 patient tests 3000 patient records 200 QC tests 8000 Operators
Docking/Charging Station:	Desk mount Input 100-240 V ~, 50-60 Hz 0.5 - 1.0 A single Output +12 V ⎓ 2 - 2.5 A single
Data Output Port:	RJ-45 Ethernet (100 Mbit)
Connectivity:	Protocol TCP/IP Ethernet Standard POCT1-A Compliant
Battery:	Rechargeble Li-Ion 3.6 V 2200 mAh

Electrical Compliance:	Conforms to the electrical and safety requirements of EN 61010-1 and 61010-2 standards.
Dimensions:	158 mm (6.23 in) x 77 mm (3.04 in) x 28 mm (1.11 in)
Weight:	215 grams (0.47 lb)
Power:	3.6V Li Ion battery (Rechargeable)

Operating Ranges:

Temperature range	34°F - 104°F (1°C - 40°C)
Altitude	Up to 15,000 feet (4572 meters)
Relative Humidity	Up to 90% (noncondensing)

Chemistry Measurement

Precision of the StatStrip Glucose and β-Ketone Meter System was measured with both whole blood and linearity solutions in the laboratory. Typical Within-Run Precision results for Glucose can be found in the Nova StatStrip Glucose Test Strip Insert Sheets.

Precision of the StatStrip Glucose and β-Ketone Meter System was measured with both whole blood and control solutions in the laboratory. Typical Within-Run Precision results for β-Ketone can be found in the Nova StatStrip β-Ketone Test Strip Insert Sheets.

Limit of Detection (LoD) and Limit of Quantitation (LoQ) Data

Test	LoQ	LoD
Glucose	5.26 mg/dL or 0.29 mmol/L	3.40 mg/dL or 0.19 mmol/L
β-Ketone	0.086 mmol/L	0.086 mmol/L

A.2 Controls/Linearity Solutions

This section covers the solutions required for the StatStrip Glucose and β-Ketone Hospital Meter.

Solutions to be used by the Meter:

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

A.2.1 Traceability

Glucose measurement is traceable to National Institute of Standards and Technology (NIST) Standard SRM-917.

β-Ketone measurement is traceable to the StanBio β-hydroxybutyrate reagent test kits.

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. QRCODE
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 & Safety Information

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

For additional information, consult to 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 Reference Values

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

Reference Values Serum and Plasma

Test	Value
Glucose[6]	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
β-Ketone[7]	0 - 0.6 mmol/L

References:

6. American Diabetes Association. Diagnosis and Classification of Diabetes: Standards of Medical care in Diabetes. Diabetes Care, Volume 41, Supplement 1, January 2018.
7. NHS UK website: https://www.nhs.uk/conditions/diabetic-ketoacidosis

A.5 Ordering Information

Supplies and parts for the StatStrip Glucose and β-Ketone Hospital Meter System are available from Nova Biomedical.

DESCRIPTION	Part #
Carrying Case for Meter & Supplies	53425
Docking Station with AC Adapter	65736
EMS Stat Data Link field carrying/charging station AC adapter	61583
EMS Stat Data Link field carrying/charging station cable	61399
EMS Stat Data Link (AC adapter and Cable)	61901
EMS Stat Data Link Optional Strap	61579
Instructions for use manual, printed	66232
Quick Reference Guide	66233
Safety Lancets, 28-Gauge, 100 per box	41224
StatStrip Glucose and β-Ketone Control Solution, Level 1, One vial	46947
StatStrip Glucose and β-Ketone Control Solution, Level 1, One vial (Germany Only)	64659
StatStrip Glucose and β-Ketone Control Solution, Level 2, One vial	46948
StatStrip Glucose and β-Ketone Control Solution, Level 3, One vial	46949
StatStrip Glucose and β-Ketone Linearity Kit, 5 levels, One vial of each level	46950
StatStrip Glucose Test Strips, 1800 test strips, 36 vials, 50 per vial	42214
StatStrip β-Ketone Test Strips, 50 test strips, 2 vials, 25 per vial	46951
StatStrip Glucose Test Strips,100 test strips, 2 vials, 50 per vial	61500
StatStrip StatSensor Disposable Meter Bags, 100 Count	43394

A.6 Theory

A.6.1 Glucose

The glucose measurement is based on the following methodology:

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

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

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

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

A.6.2 β-Ketone

The β-ketone measurement is based on the following methodology:

$$\beta\text{-3-hydroxybutyrate} + \text{NAD} \xrightarrow{\text{enzyme}} \text{Acetoacetate} + \text{NADH} + \text{H+} \qquad \text{Equation 4}$$

Mediator* (ox) + NADH ———> Mediator (red) + NAD Equation 5

$$\text{Mediator (red)} \xrightarrow[\text{Electrode}]{\text{-e-}} \text{Mediator (ox)} \qquad \text{Equation 6}$$

The current generated at the electrode is proportional to the β-ketone concentration of the sample.

*Mediator = Meldola's Blue > 0.42mg

A.7 Results of Multi-Center Clinical Study: Capillary Finger Stick, Arterial, Venous, Neonatal Heel Stick, and Neonatal Arterial Specimens

Accuracy was assessed on capillary finger stick, arterial, venous, neonatal heel stick and neonatal arterial specimens. Capillary and venous specimens were tested within 3 POC sites within a hospital. Arterial discarded specimens were tested from a 2nd hospital. Neonate arterial and heel stick specimens were tested from a 3rd hospital. Neonate heel stick specimens were compared to the Vitros Chemistry Analyzer (Ortho Diagnostics, NJ) capillary finger stick, venous, arterial, and neonate arterial specimens were compared to the YSI 2300 Stat Plus analyzer (Yellow Springs Instrument Co., Yellow Springs, OH).

Clinical Study Accuracy: Capillary Whole Blood System Accuracy Results for Glucose Concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1/1 (100%)	1/1 (100%)	1/1 (100%)

System Accuracy Results for Glucose Concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
38/88 (43%)	64/88 (73%)	84/88 (95%)	86/88 (98%)

Clinical Accuracy: Venous Whole Blood System Accuracy Results for Glucose Concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7/14 (50%)	10/14 (71%)	13/14 (93%)

System Accuracy Results for Glucose Concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
69/106 (65%)	100/106 (94%)	106/106 (100%)	106/106 (100%)

Clinical Accuracy: Arterial Whole Blood
System Accuracy: Results for Glucose Concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
30/37 (81%)	37/37 (100%)	37/37 (100%)

System Accuracy Results for Glucose Concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
44/92 (48%)	85/92 (92%)	92/92 (100%)	92/92 (100%)

Clinical Neonatal Study Accuracy: Neonatal Arterial Whole Blood System Accuracy Results for Glucose Concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
32/37 (86%)	37/37 (100%)	37/37 (100%)

System Accuracy Results for Glucose Concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
21/63 (33%)	40/63 (63%)	58/63 (92%)	62/63 (98%)

Clinical Accuracy: Neonatal Heel Stick Whole Blood System Accuracy Results for Glucose Concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
51/69 (74%)	68/69 (99%)	68/69 (99%)

System Accuracy Results for Glucose Concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
14/30 (47%)	26/30 (87%)	28/30 (93%)	30/30(100%)

A.8 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 (O_2), 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 A.8.1.

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 A.8.2.

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 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.

A.8.1 Clinical Study Performance

Table A-1 Arterial Specimens

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

Site	Within ± 5 mg/ dL	Within ±10mg/dL	Within ±12mg/ dL	Within ±15mg/ dL	Exceeds ±15mg/ 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 A-2 Arterial Specimens

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

Site	Within ± 5%	Within ± 10%	Within ± 12.5%	Within ± 15%	Within ± 20%	Exceeds ± 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 A-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 A-4 Venous Specimens

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

Site	*Within ± 5%*	*Within ± 10%*	*Within ± 12.5%*	*Within ± 15%*	*Within ± 20%*	*Exceeds ± 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 All Sites	*171/268 (63.8%)*	*246/268 (91.8%)*	*260/268 (97.0%)*	*267/268 (99.6%)*	*268/268 (100%)*	*0/268 (0.0%)*

A.8.2 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 A-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
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 A-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 A-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
Cardiac - Medical		
	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
Cardiac - Surgical		
	Angiography	1
	Endarterectomy	12
	Cardio Thoracic (Aortic Bypass Surgery)	12
	Cardio Thoracic (Aortic Rupture)	4
	Femoral Aneurism Rupture	2
	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
AVR/MVR		
	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

CABG		
	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
	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
Maze		
	Cardio Thoracic (Maze Procedure)	5
	Total All Categories	670

Table A-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 A-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 A-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 A-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 A-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: Psychiatrics	1
Sacral meningocele dural fistula	1

Tetraplegia ankylosing spondylitis	1
Total	25

Table A-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 A-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
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 Cncer	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
Relapsed T-Cell Prolymphocytic Leukemia	1
Small Cell Lung Carcinoma	1
T Cell Lymphoma	1

Brain Tumor Resection	1
Total	101

Table A-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 A-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
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 A-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 A-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 A-19 Medical Condition Analysis: Suicide

Patient Reason For Hospitalization	
Condition	Frequency
Suicide	7

Table A-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
Multinodulary Thyroid Goiter	1
Kidney Transplant	2
Total	71

Table A-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

A.8.3 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 A-22 Parent Drug Class Analysis: Alcohol

Alcohol Parent Drug Class Subclass Analysis	Frequency
Alcohol	1

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

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

Table A-24 Parent Drug Class Analysis: Antidotes

Antidote Parent Drug Class Subclass Analysis	Frequency
Antidote	32

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

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

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

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

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

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

Table A-29 Parent Drug Class Analysis: Biologicals

Biologicals Parent Drug Class Subclass Analysis	Frequency
Recombinant Human Erythropoietins	27

Table A-30 Parent Drug Class Analysis: Blood Products

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

Table A-31 Parent Drug Class Analysis: Calcimimetic

Calcimimetic Parent Drug Class Subclass Analysis	Frequency
Calcium Receptor	11

Table A-32 Parent Drug Class Analysis: Cardiovascular Agents

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

ACE Inhibitors	364
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 A-33 Parent Drug Class Analysis: Central Nervous System

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

Table A-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
Benzodiazepines	719
Muscle Relaxer	138

Sedative	7
Stimulants	2

Table A-35 Parent Drug Class Analysis: Coagulation Modifiers

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

Table A-36 Parent Drug Class Analysis: Contrast Agents

Radiologic Agent Parent Drug Class Subclass Analysis	Frequency
Contrast Agents	4

Table A-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
Laxative	611
Laxative / Antacid	61
Protectant	8
Proton-pump Inhibitor	754

Table A-38 Parent Drug Class Analysis: Genitourinary

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

Table A-39 Parent Drug Class Analysis: Hemodialysis

Hemodialysis Parent Drug Class Subclass Analysis	Frequency
Hemodialysis	6

Table A-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 A-41 Parent Drug Class Analysis: Hyperkalemia

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

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

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

Table A-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 A-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 A-46 Parent Drug Class Analysis: Phosphate Binder

Phosphate Binder Parent Drug Class Subclass Analysis	Frequency
Phosphate Binder	41

Table A-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 A-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 A-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 A-50 Parent Drug Class Analysis: Smoking Cessation

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

Table A-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 Crèam	10
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 A-52 Parent Drug Class Analysis: Topical Anti-Infective

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

A.9 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 the world's preeminent healthcare institutions located in Maryland. A description of the clinical study is found below.

A.9.1 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 A-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).

A.9.2 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 A-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).

A.9.3 Clinical Study Performance

Table A-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 ±5%	Within ±10%	Within ±12%	Within ±15%	Within ±20%	Exceeds ±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 A-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 ±5%	Within ±10%	Within ±12%	Within ±15%	Within ±20%	Exceeds ±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%)

A.10 Results of β-Ketone Clinical Study: Capillary and Venous Specimens

This near-patient testing clinical study conducted in Florida, USA evaluated the performance of the Nova Beta-Hydroxybutyrate (β-Ketone) Test Strip that is used on the Nova StatStrip Glucose and β-Ketone Hospital Meter System, compared to a reference (StanBio Chemistry Liquicolor® Beta-Hydroxybutyrate (β-HB) reagent run on the Siemens Dimension ExL Analyzer).

A.10.1 Protocol Overview

One hundred thirty-seven (137) subjects were consented to participate in the IRB approved clinical study. Each subject was pre-screened to ensure they met all inclusion requirements. Following the detailed instructions in the Instructions for Use labeling, each subject had their fingers cleaned, disinfected, and lanced using a 21-gauge safety lancet to obtain two (2) capillary specimens. After lancing each finger, the first blood droplet from each finger was wiped away and a 2nd droplet was used for testing. The near-patient testing staff performed two (2) successive fingerstick capillary whole blood measurements on each subject using the Nova β-Ketone test strips on two (2) meters. The test results were recorded in the Case Report form.

Each subject then had a heparinized venous whole blood specimen obtained by venipuncture drawn into a blood collection tube by the sites trained healthcare staff. The venous specimen was mixed and then the near-patient testing staff performed two (2) successive venous whole blood measurements on each subject using the Nova

β-Ketone test strips on two (2) meters. The test results were recorded in the Case Report form.

The remaining venous whole blood in the blood collection was then immediately spun down and the plasma was decanted into two (2) cryovials, capped tightly, and refrigerated. The plasma was then measured on the IDMS Traceable Siemens Dimension RxL Analyzer in the central laboratory running the Stanbio Chemistry Liquicolor® β-HB reagent. The results were recorded on the Case Report Form.

Whole Blood specimens were altered with Beta-Hydroxybutyrate as required to ensure the full measurement range of the β-Ketone assay was covered for both capillary and venous specimens.

A.10.2 Results

	(R^2)	Slope (m)	Intercept (b)
Nova StatStrip – Venous Samples (N: 147)	0.9837	0.9617	0.0375
Nova StatStrip – Capillary Samples (N: 244)	0.9872	0.9515	0.0865

A Clinical Accuracy Concordance Assessment was performed for all subjects enrolled in the clinical study in which the Nova Biomedical β-Ketone test strip reported β-Ketone test results below 0.1 mmol/L to ensure the central laboratory comparator method also reported a normal β-Ketone test result. The clinical Accuracy Concordance Assessments for capillary and venous specimens are follows:

Clinical Concordance Assessment- Capillary Whole Blood

Capillary Whole Blood				
Clinical Concordance Assessment - Low β-Ketone				
		RxL Reference Method		
	mmol/L	<0.1	0.1 - 0.2	0.2 - 0.3
Nova β-Ketone	<0.1	45/70 (64.3%)	24/70 (34.3%)	1/70 (1.4%)

Clinical Concordance Assessment - Venous Whole Blood

Venous Whole Blood				
Clinical Concordance Assessment - Low β-Ketone				
		RxL Reference Method		
	mmol/L	<0.1	0.1 - 0.2	0.2 - 0.3
Nova β-Ketone	<0.1	118/168 (70.2%)	47/168 (28.0%)	3/168 (1.8%)

A.11 Results of β-Ketone Clinical Study in Neonates

This study was designed to assess the performance of Nova StatStrip β-Ketone assay in the hands of trained POC staff/technician, relative to an accepted reference standard; β-Hydroxybutyrate Liquicolor® Procedure No. 2440 (STANBIO Laboratory and EKF Diagnostics Company) on discarded neonate whole blood specimens obtained from neonate subjects.

A.11.1 Protocol Overview

One hundred neonate subject whole blood specimens were collected as part of standard of care and forwarded to the laboratory. Once the laboratory completed the standard of care testing, specimens with enough remaining blood volume were used in the next step of the clinical study. The next sequential study Subject ID number was assigned to each discarded whole blood specimen. Each specimen was properly mixed. The β-Ketone test was performed using the STANBIO β-Hydroxybutyrate Method and the results were recorded.

A β-Ketone measurement was performed with each properly mixed whole blood specimen using 2 Nova StatStrip Glucose/β-Ketone Meters and 2 lots of Test Strips.

To ensure the entire StatStrip β-Ketone measurement range of 0.1-8.0 mmol/L was covered, 10 additional neonatal whole blood specimens were manipulated by spiking each specimen with β-Hydroxybutyrate and mixing thoroughly according to standard laboratory protocol. Each manipulated specimen was tested on both meters and analyzed by the STANBIO β-Hydroxybutyrate Method.

Clinical Study Accuracy Assessment Acceptance Criteria: The 220 whole blood β-Ketone results measured on the StatStrip β-Ketone meter system were paired with the results measured by the STANBIO β-Hydroxybutyrate Method and analyzed using linear regression analysis. Clinical Accuracy was assessed using Linear Regression Analysis for all 220 data points from the two lots of test strips (N=110 per lot).

A.11.2 Results

The sample distribution and performance of the StatStrip β-Ketone Monitoring System, in the hands of healthcare professionals compared to the STANBIO β-Hydroxybutyrate in neonatal populations is presented below.

Table A-57 The distribution of neonatal whole blood β-Ketone results across the measuring range of the StatStrip system

Measured β-Ketone Range (mmol/L)	Number of Specimens
0.1 - 0.5 0.6 -1.0 1.2 - 1.9 > 2.0	172 18 10 20

Table A-58 *Linear Regression Statistical Summary*

	1	2	3
StatStrip vs STANBIO β-Hydroxybutyrate Method	Pearson Coefficient (R)	Y-Intercept (mmol/L)	Slope
Neonate Whole Blood	0.9941	0.0683	1.0379

A.12 Wireless Meter Use

The StatStrip Glucose and β-Ketone Hospital Meter is configured/factory installed with WiFi functionality.

A.12.1 Wired & Wireless Network Unauthorized Access Protection

When the StatStrip Meter is connected to a local area wireless 802.11 a/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.

A.12.2 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 A.12.5** of this IFU. For a description of the StatStrip Glucose and β-Ketone Hospital Meter's (with wireless option) ability to connect to Wireless Local Area Networks (WLAN, Wi-Fi), **See A.12.9**.

A.12.3 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 802.11 a/b/g/n/ac industry standards for basic connectivity, security, authentication, Quality of Service (QoS), interoperability and reliability.
- Nova Biomedical 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 and β-Ketone 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 and β-Ketone Hospital Meter 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.

The StatStrip Glucose and β-Ketone 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 and β-Ketone Meter will be operated should be thoroughly evaluated prior to operation of the device.

The StatStrip Glucose and β-Ketone 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 and β-Ketone 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 and β-Ketone 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
- Pursuant 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 and β-Ketone 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.

This StatStrip Glucose and β-Ketone Hospital Meter complies with Canadian 003.

A.12.4 WiFi Radio Option Operation

Prior to enabling the WiFi radio, an appropriate radio setup packet, as a component of the StatStrip Glucose and β-Ketone Hospital Meter with wireless option configuration, must be downloaded to the meter via the device manager. **See Section 1.10** of this manual for meter assignment and configuration. The configuration of the StatStrip Glucose and β-Ketone 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.*

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 manger.

A.12.5 Enabling/Disabling the WiFi Radio

If the meter is equipped with the wireless radio option, an authorized operator may enable or disable it's 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 follow 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 and β-Ketone 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 and β-Ketone Hospital Meter with wireless option.

A.12.6 WiFi Usage Considerations

The StatStrip Glucose and β-Ketone 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 and β-Ketone 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 and β-Ketone 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 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 and β-Ketone 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 setup 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 and β-Ketone Meter with wireless option must be placed in the docking station with the radio turned on and properly configured.

A.12.7 WiFi Technical Considerations

Prior to connecting any StatStrip Glucose and β-Ketone Hospital Meter with 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 and β-Ketone Hospital Meter with 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.

A.12.8 WiFi Function and Performance

This section explains the complete wireless option radio specifications, available configuration parameters, and security and encryption options.

As described above, the StatStrip Glucose and β-Ketone 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, 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 and β-Ketone Hospital Meter with wireless

option and a suitable device manager is in the POCT1-A communication standard.

- The StatStrip Glucose and β-Ketone Hospital Meter with wireless option is capable of downloading from a suitable device manger, 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 and β-Ketone 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 and β-Ketone 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.

Average range for direct connection between the StatStrip Glucose and β-Ketone 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 and β-Ketone Hospital Meter with 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 and β-Ketone Hospital Meter with wireless option and WAP where communication can be guaranteed.

The StatStrip Glucose and β-Ketone 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.

A.12.9 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.

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 the certificate(s) are 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 kength 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 prefered) Mode BGA (B and G prefered) 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
Setting: 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.*

A.12.10 Wireless Radio Charging Connectivity

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Howev¬er, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult Nova Technical Support.

FCC Part 15 Clause 15.21:
"Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment."

FCC Part 15.19(a)
"This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation."

ISED RSS-Gen Notice
"This device contains licence-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:
This device may not cause interference.
This device must accept any interference, including interference that may cause undesired operation of the device."

'L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :
L'appareil ne doit pas produire de brouillage;
L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement."

ISED Canada ICES-003 Compliance Label
"CAN ICES-3 (B)/NMB-3(B)"

FCC only Radiation Exposure Statement:
RADIATION EXPOSURE STATEMENT: The device has been found to be compliant to the requirements set forth in CFR 47 Sections 2.1091 for an uncontrolled environment. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC and ISED Radiation Exposure Statement:
Radiation Exposure Statement
The device has been found to be compliant to the requirements set forth in CFR 47 Sections 2.1091 and Industry Canada RSS-102 for an uncontrolled environment. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Le dispositif a été jugé conforme aux exigences énoncées dans les articles 47 CFR 2.1091 et Industrie Canada RSS-102 pour un environnement non contrôle'. L'antenne(s) utilisée pour ce transmetteur doit etre installé pour fournir une distance de séparation d'au moins 20 cm de toutes les personnes et ne doit pas être co-localisés ou fonctionner en conjunction avec une autre antenne ou transmetteur.

A.13 Cybersecurity Information

Software Updates

The StatStrip Glucose and β-Ketone Hospital Meter's software updates are performed exclusively by factory-trained Field Support Specialists. Nova's Customer Service should be contacted in case of any software errors.

Anti-Malware

The StatStrip Glucose and β-Ketone Hospital Meter uses a Linux based Operating System (OS). This Meter system is a closed system, and there is no way to access the OS layer to install any other applications. Healthcare facilities should ensure that appropriate anti-virus applications and other security safeguards are installed on their devices to which the data from the StatStrip Glucose Hospital Meter will be transferred via network wired/wireless connectivity.

A.14 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 the β-Ketone Test Strips and 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/ Ketone 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.