REF 45304

IVD CE

# *Instructions for Use Manual*


# StatSensor®-i

# *Creatinine Hospital Meter*

## *For Export Only*

nova® biomedical

Revision History

| Revision | Date of Release | Description of Revisions |
|---|---|---|
| G | 04-2022 | Updated to meet IVDR requirements |

# NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

Caution

Consult instructions for use

Biological risk

REF — Catalog number

Device for near-patient testing

Manufactured by

CONTROL — Control

LEVEL — Level

EC REP — Authorized Representative in the European Community

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

LOT — Batch code

SN — Serial Number

Temperature limitation

Use by
YYYY - MM - DD

Electronic Waste

# StatSensor®-i Creatinine Meter Instructions for Use Manual - International

## Ordering Information

The *StatSensor®-i Creatinine Hospital Meter Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Write or call:

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FAX: 1-781-891-9718
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## EC REP Authorized Representative

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## Copyright

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# Contents

# 1 Introduction

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

***WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products, disposable meter bags, 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 StatSensor-i Creatinine Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with creatinine electrochemical test strips to measure creatinine in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. In addition to measuring creatinine, 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 a self-prompting environment via a color LCD. The Charging Station recharges the batteries of the Meter.

## 1.1 About This Manual

This manual is for the StatSensor-i Creatinine 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 and Warnings

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.

**Blood-Borne Pathogens Safety**

1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the StatSensor-i Creatinine Meter System.
2. Healthcare professionals should be aware that all parts of the StatSensor-i Creatinine Meter System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
3. The StatSensor-i Creatinine Meter System 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 the Cleaning and Disinfecting the Meter section. 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/2007isolationprec autons.html. Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/ bmbl5/. “Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition,” Clinical and Laboratory Standards Institute (CLSI) M29-A3. “FDA Public Health Notification: Use of 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. “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens.” (2010).

**Electrical Safety**

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

**WARNING:** All rechargeable Lithium batteries have a finite useful life that will vary depending upon use and handling conditions. A Lithium battery exhibiting any of the following conditions should be immediately removed from use and properly disposed of in accordance with local regulations.

- Has exceeded its expiration date
- Swelling, cracking, or damage to the battery case
- Leakage
- Failure to hold a proper charge

The Lithium battery may present a fire or chemical burn hazard, if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate.

**Disposal of Used, IVD Devices, and Electronic Accessories for Customers in Europe**

This symbol  the product label indicates that the product should not be treated as household waste.

**Batteries:** To ensure the used battery is treated properly, remove the used battery from the product and hand over the used battery to the applicable collection point for the recycling of electrical and electronic equipment.

**Devices/Accessories:** To ensure the product is disposed properly, decontaminate the product according to the instructions provided in chapter 6.3 of this manual and hand over the product to the applicable collection point for the recycling of electrical and electronic equipment.

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

**Dimensions:**

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

**Weight:**

360 g (0.8 lb)

## 1.3 Intended Use, Tests Performed, and Clinical Utility

**Intended Use**
The StatSensor-i Creatinine Meter is intended for in vitro diagnostic use by health care professionals and for Near-Patient (Point-Of-Care) usage for the quantitative measurement of creatinine in capillary, venous, and arterial whole blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis. Not for use in neonates.

**Clinical Utility**
The measurement of Creatinine is used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

## 1.4 The Sample

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

## 1.5 Interfering Substances and Limitations

The StatSensor-i Creatinine Meter exhibits **no** interference from the following substances up to the following concentration levels:

| Tested Interfering Substances | Tested Concentration Level |
|---|---|
| Acetaminophen | 10.0 mg/dL |
| Ascorbic Acid | 3.5 mg/dL |
| Bilirubin | 15.0 mg/dL |
| Cholesterol | 1000.0 mg/dL |
| Creatine | 4.0 mg/dL |
| Dopamine | 10.0 mg/dL |
| Glucose | 500 mg/dL |
| Hematocrit (RBC) | 30% - 60% |
| Heparin | 120 units/dL |
| L-Dopa | 300.0 mg/dL |
| D(+) Maltose Monohydrate | 100.0 mg/dL |
| Triglycerides | 1000.0 mg/dL |
| Uric Acid | 20.0 mg/dL |

**Disclaimer**
Standard algorithms are available to convert the creatinine value into an estimated glomerular filtration rate (eGFR). When using an eGFR derived value, you should not assume that the patient does not have chronic kidney disease (CKD) until a physician confirms it.

## 1.6 Operation Overview

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


*Figure 1.1 StatSensor-i Creatinine Meter*

The Meter provides audible feedback (if activated) 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 Laser light or point it towards anyone's eyes while scanning a barcode.***

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

- The Meter stores patient test data, quality control test data, linearity test data, and other information relating to the patient, patient sample, and operator. The operator can recall and review test data stored in the Meter.

- Meter operation involves entering operator, patient, QC, and strip lot data, as needed. Insert a test strip into the Meter. Touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps. 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.

- 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 is stored in a non-volatile memory to prevent data loss.

### 1.6.1 Using the Display Keypad

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

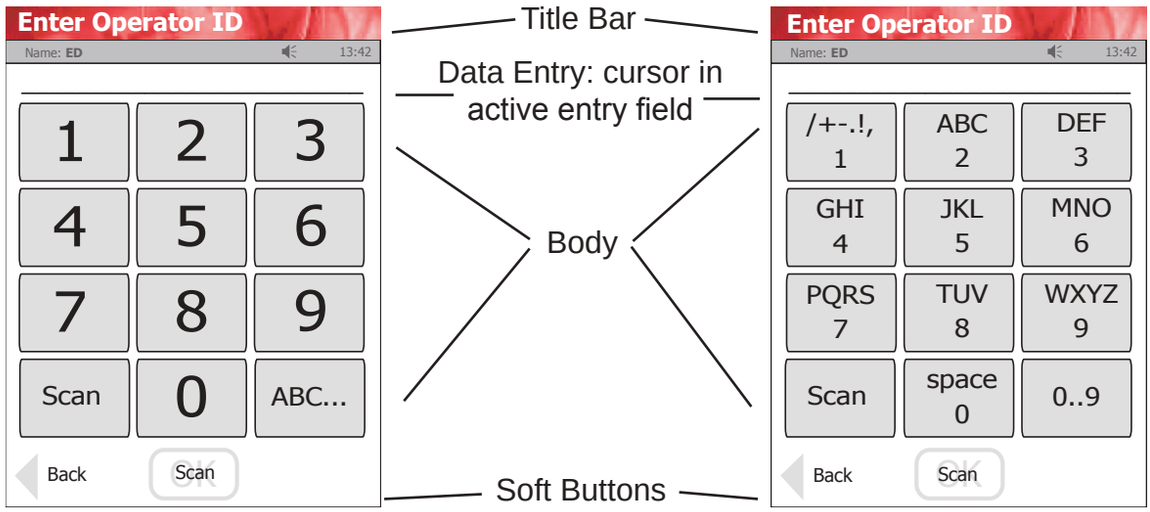


*Figure 1.2 The Numerical and the Alphanumerical Keypad Screens*

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

The screen is composed of 3 sections:

1. A Title Bar (top) – the title of the screen, Time of day, logged-in operator ID, Sound status, Meter name
2. The Body – data entries, selections, and screens
3. The Soft Key Bar – confirmation of data entry and screen navigation
   The Soft Key Bar duplicates and labels the functionality of the Left, OK, and Right hard buttons.

The StatSensor-i Creatinine Meter has the following operator input mechanisms:

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

## 1.6.2 Hard Buttons

The following are the StatSensor-i Creatinine Meter hard buttons:

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

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

**Sleep Button**

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

- If the Meter is currently measuring (analyzing) a sample, the Power button is disabled.

**Scan/Home Buttons**

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

### 1.6.3 Soft Buttons

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

**Soft Keyboard**

The soft keyboard functions in the following manner:

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

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

**Cursor**

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

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

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

### 1.6.4 Meter Sleep/Wakeup

The LCD display is turned off to conserve battery power (sleep mode) after 90 seconds of no activity. Keep-awake activities include:

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

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

- If a 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.

**Wakeup**

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

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

### 1.6.5 Result Alerts

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

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

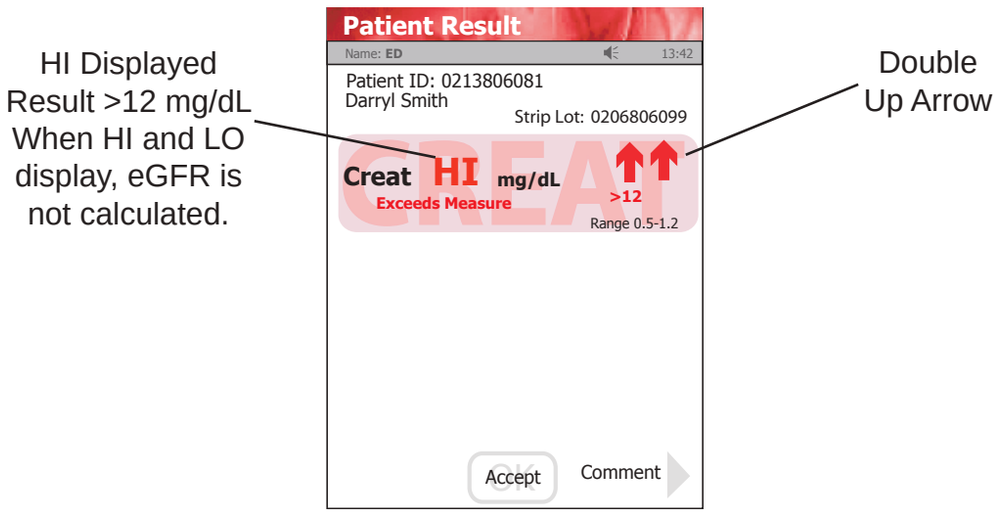


*Figure 1.3 Patient Result: Not in Measured Range Screen*

### 1.6.6 Multi-screen Menus

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

## 1.7 Installing the StatSensor-i Creatinine Meter

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

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

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

### 1.7.1 Power Up Procedure

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

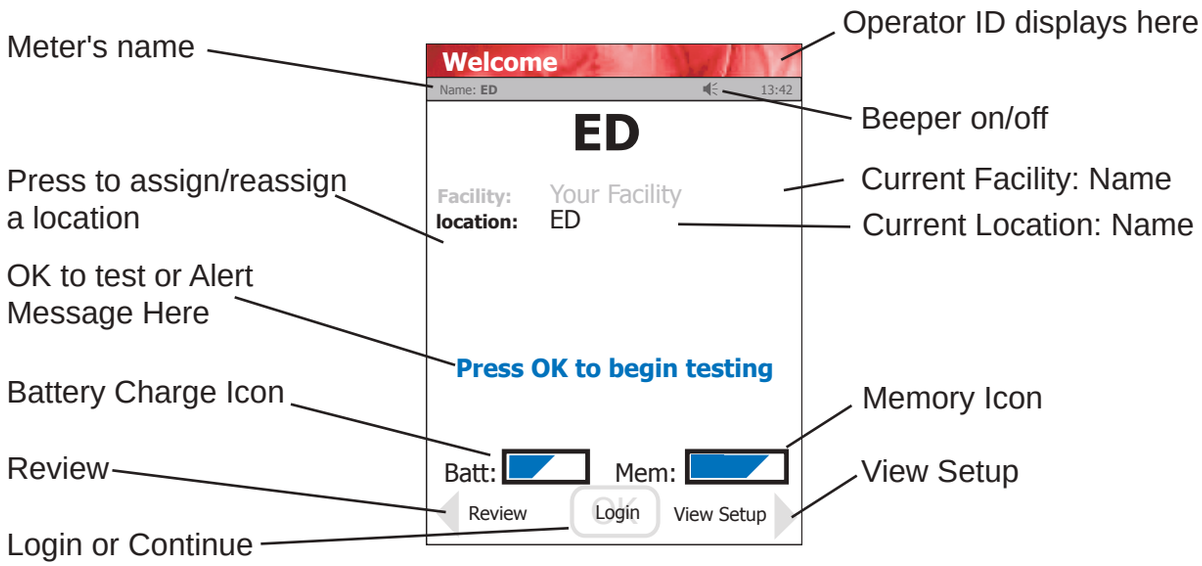


*Figure 1.4 Welcome Screen*

Messages or Alerts on the Welcome screen

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

## 1.8 Operator Login

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

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

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

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

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

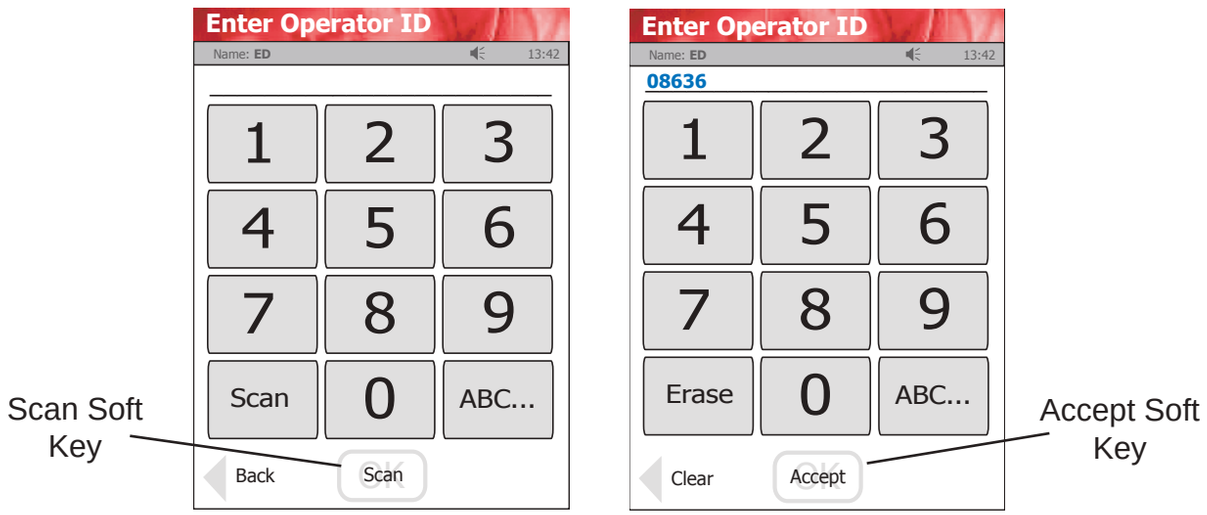


*Figure 1.5  Enter Operator ID Screens*

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

## 1.9 Administration (Admin) Screen

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

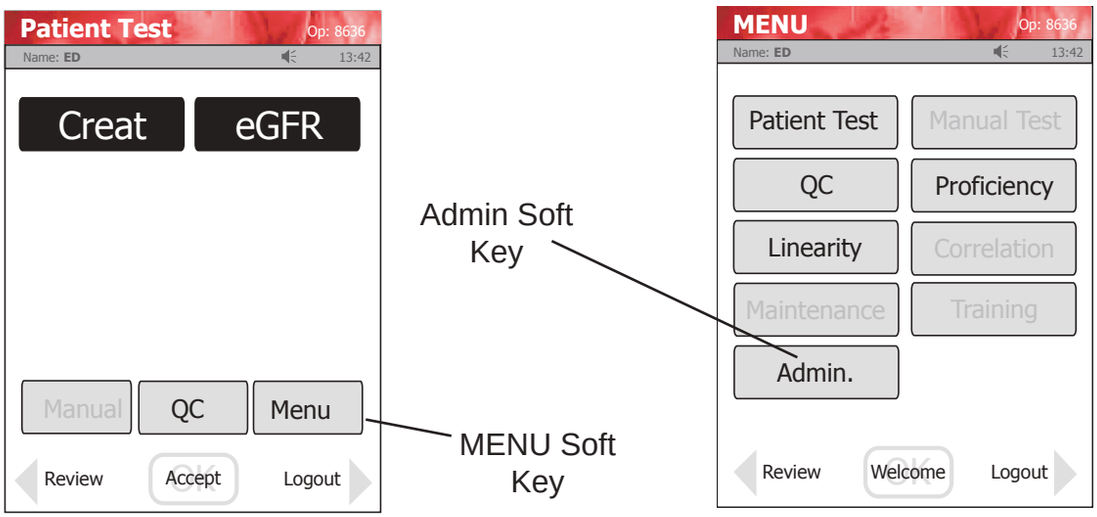


*Figure 1.6 Patient Test Screen and MENU Screen*

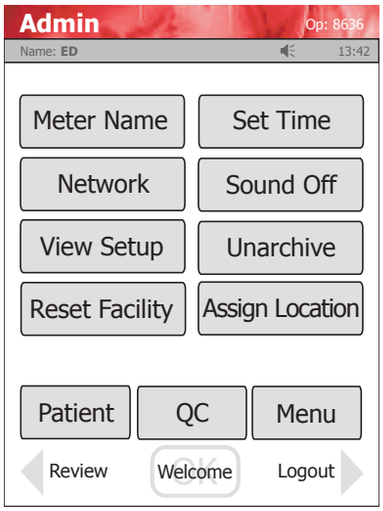


*Figure 1.7 The Admin Screen*

### 1.9.1 Naming the Meter

The Meter can be given a name with respect to where it will be used: i.e., ED.

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

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

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

***NOTE:*** *Maximum number of characters is 10.*

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

### 1.9.2 Setting the Time/Date

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

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

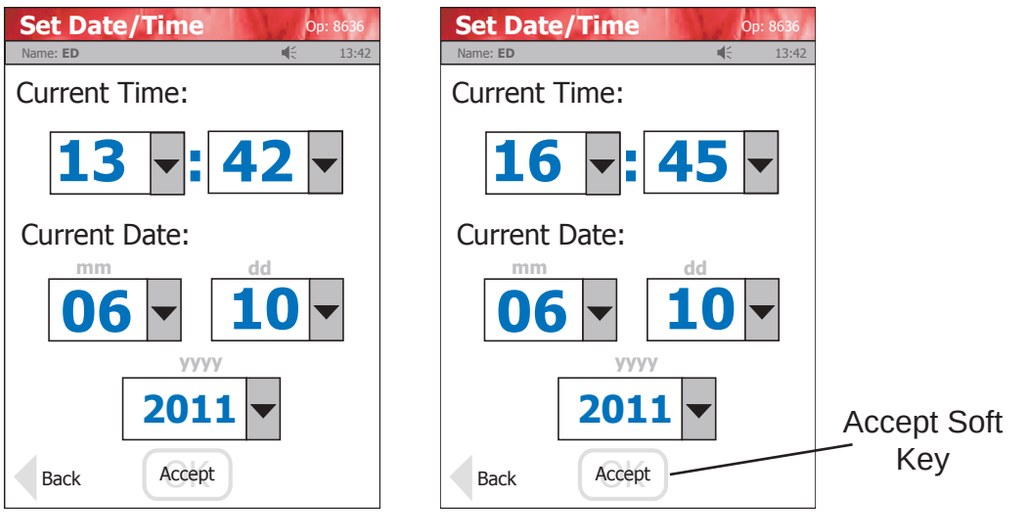


*Figure 1.8 The Set Time (and Date) Screens*

### 1.9.3 Sound On/Off

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

### 1.9.4 View Setup

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

### 1.9.5 Unarchive

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

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

### 1.9.6 Resetting the Facility

The Meter's facility name can be reset.

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

## 1.10 Assign Location

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

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

## 1.11 Meter Transport Case

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

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

# 2 Quality Control

This section describes how to perform Quality Control (QC) tests with the StatSensor-i Creatinine Meter. Quality Control Solutions are used to check that the StatSensor-i Creatinine Meter is functioning properly.



## 2.1 When to Perform a QC Test

Control Solutions are used to confirm that the StatSensor-i Creatinine Meter is working correctly. The control solution test results should fall within the range of results printed on the control solution insert sheets.

Nova recommends that each laboratory performs the following minimum QC procedures on each Meter:

- During each 24 hours of testing, analyze 2 different levels of Control Solution, or follow the quality control policy of your institution.

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

## 2.2 Quality Control Test

The following section explains how to run a Quality Control Test.

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

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

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

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


*Figure 2.1  Enter Strip Lot Screens*

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

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

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

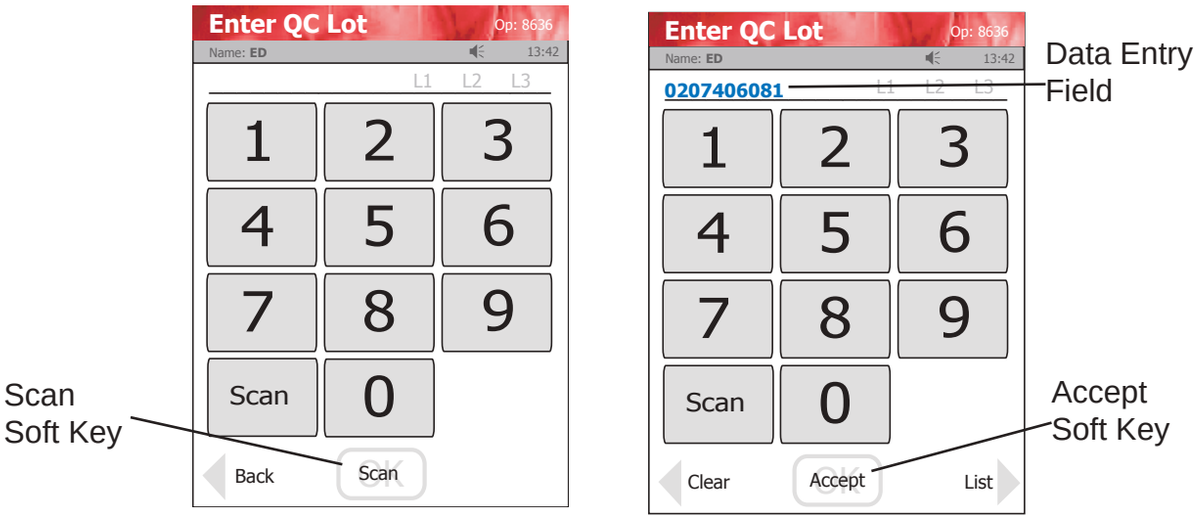


*Figure 2.2 Enter QC Lot Screens*

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

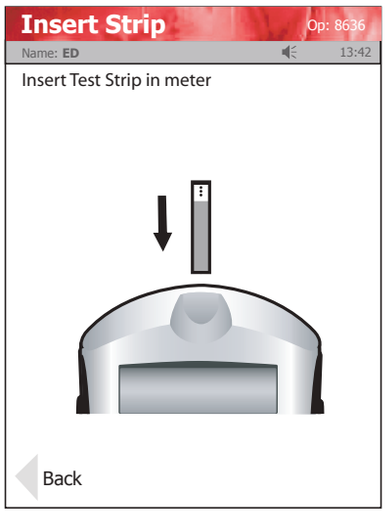


*Figure 2.3 Insert Strip Screen*

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

8. Gently mix the Control Solution before each use.

9. Discard the first drop of Control Solution from the bottle to avoid contamination.

10. Touch the end of the test strip to the control drop until the well of the test strip is full and the meter beeps.


*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 µmol/L.

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

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

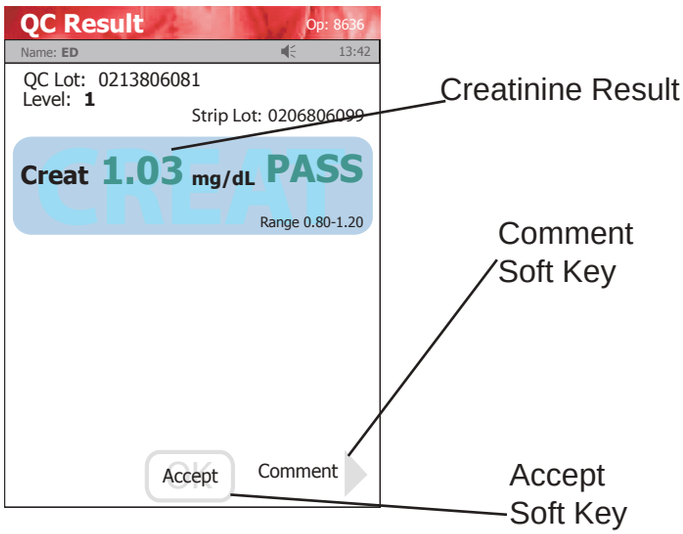


*Figure 2.5 QC Result Screen*

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

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

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

To add a comment to a result, press the Comment soft key on the Result screen. The Add Comment screen displays with preformed comments.

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

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

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

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

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

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

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

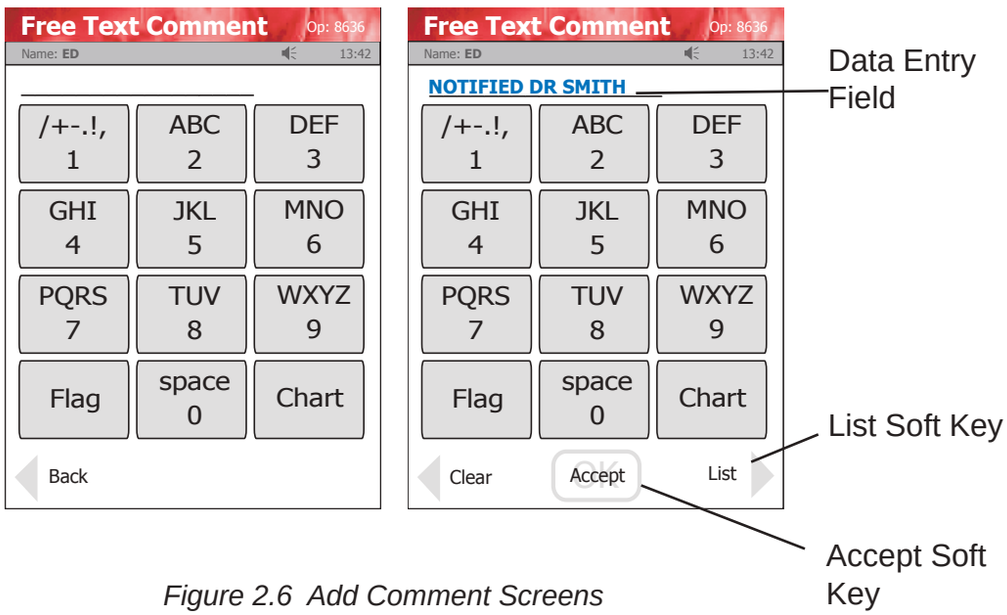


*Figure 2.6 Add Comment Screens*

# 3 Operation

This section describes how to perform tests with the StatSensor-i Creatinine Meter.

## 3.1 Running a Patient Sample

The Meter shows graphically a step-by-step procedure to run a creatinine test.

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



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

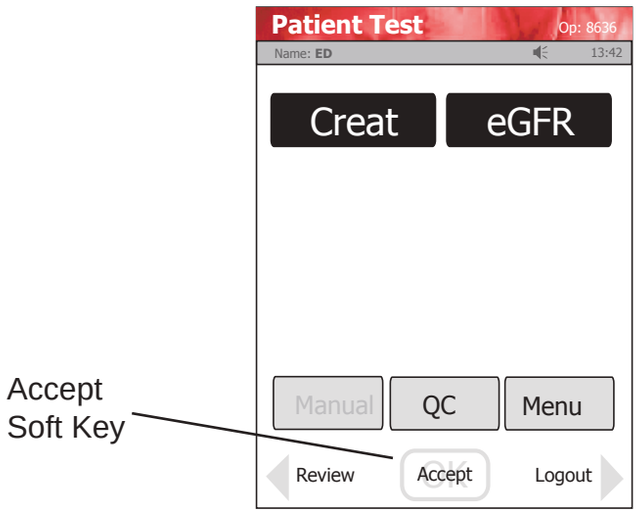


*Figure 3.1 Patient Test Screen*

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

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

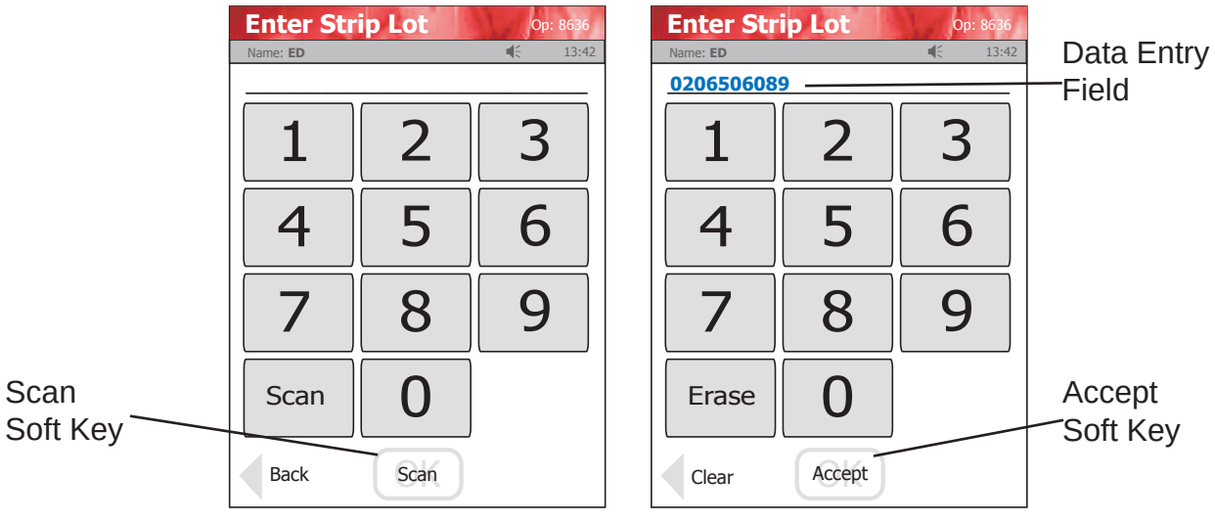


*Figure 3.2 Enter Strip Lot Screens*

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

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

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

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

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

9. From the Enter Accn Num screen, enter the Accession Number: by pressing numeric/alphanumeric soft keys (press the ABC... soft key), or by scanning the barcode ID (optional).

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

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

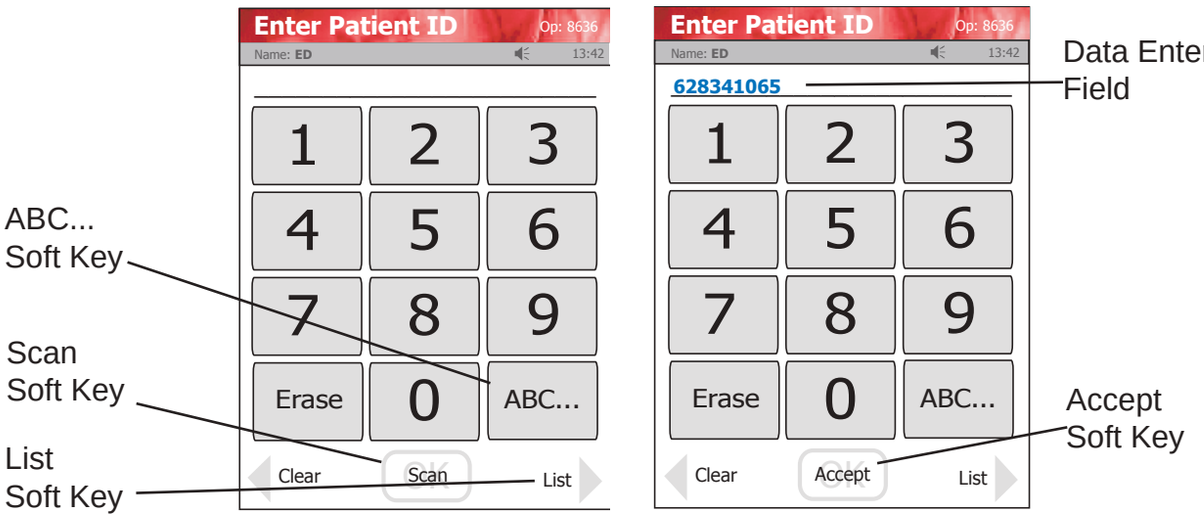


*Figure 3.3 Enter Patient ID or Enter Accn Num Screens*

11. If eGFR is not selected, go to Step 12.
    If eGFR is selected, complete one of the following steps.

**Using the MDRD equation** (modified to include adjustment for race) to calculate an estimated Glomerular Filtration Rate (eGFR), as an indicator of creatinine clearance (CrCl)

a. Enter the patients Age in years (18-130).
b. Select the patient's sex (Male or Female).
v. Select the patient's Race (African American or All Other Races).
   The eGFR values above 90 are reported as >90 mL/min/1.73 $m^2$.

**Using the MDRD-IDMS Traceable Equation for Adults** to calculate an estimated Glomerular Filtration Rate (eGFR) as an indicator of Creatinine Clearance (CrCl):

a. Enter the patient's age.
b. Enter the patient's sex.
c. Enter the patient's race.
   The eGFR values above 90 are reported as >90 mL/ min/1.73 $m^2$.

**Using the MDRD-IDMS Traceable Equation for Japanese Adults**, calculate an estimated Glomerular Filtration Rate (eGFR) as an indicator of Creatinine Clearance (CrCl):

a. Enter the patient's age
b. Enter the patient's sex.
   The eGFR values above 90 are reported as >90 mL/ min/1.73 $m^2$.

**Using the Cockcroft-Gault Equation for Adults** to calculate an estimated Glomerular Filtration Rate (eGFR) as an indicator of Creatinine Clearance (CrCl)

a. Enter the patients age in years (18-130).
b. Select the patients sex (Male or Female).
c. Enter the patients weight in pounds or kilograms.
The eGFR values above 90 are reported as >90 mL/min.

**Using the CKD-EPI Equation for Adults** to calculate an estimated Glomerular FIltration Rate (eGFR) as an indicator of Creatinine Clearance (CrCl):

a. Enter the patients age in years (18-130).
b. Select the patients sex (Male or Female).
c. Enter the patient's race (African American or All Other Races).
The eGFR values above 90 are reported as >90 mL/ min/1.73 $m^2$.

For Children 18 or Under - using the **Schwartz equation**, select the patients Age Group:

Preterm Infant < 1 Yr
Term Infant < 1 Yr
Child 1-12 Yr
Female 13-18 Yr
Male 13-18 Yr

Enter the Patient's Height in Inches or Centimeters.

For Children 18 or Under - using the **Counahan-Barratt equation**, Enter the patients height in inches or centimeters.

12. The Insert Strip screen displays. Insert a test strip as shown on the Meter screen.

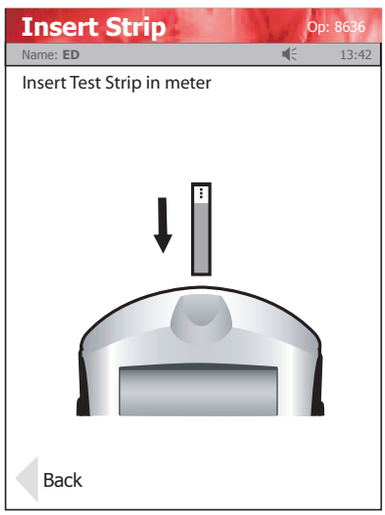


*Figure 3.4 Insert Strip Screen*

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

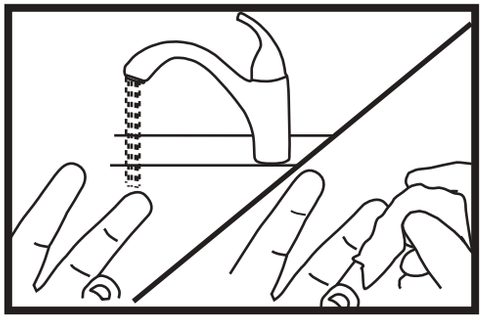

*Figure 3.5 Wash the Patient's Finger*



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

15. Use a single-use, disposable, safety lancet to puncture the finger .To reduce the risk of pre-analytical error facilities should consider using a 21-gauge lancet when collecting capillary samples.

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

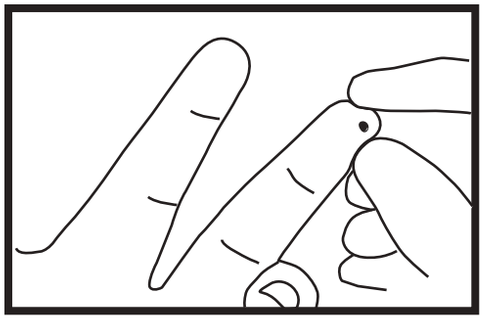

*Figure 3.6 Squeeze the Finger to Form a Drop of Blood*

17. 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.***

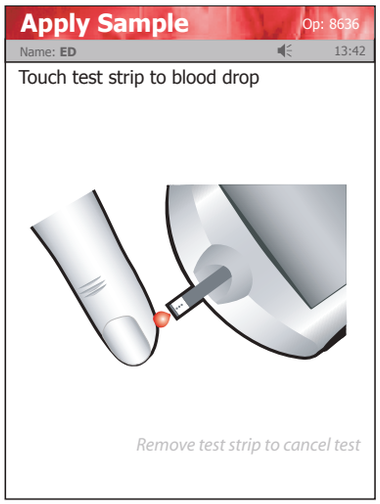


*Figure 3.7 Touch Test Strip to Blood Drop Screen*

18. The test results will appear in 30 seconds.

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

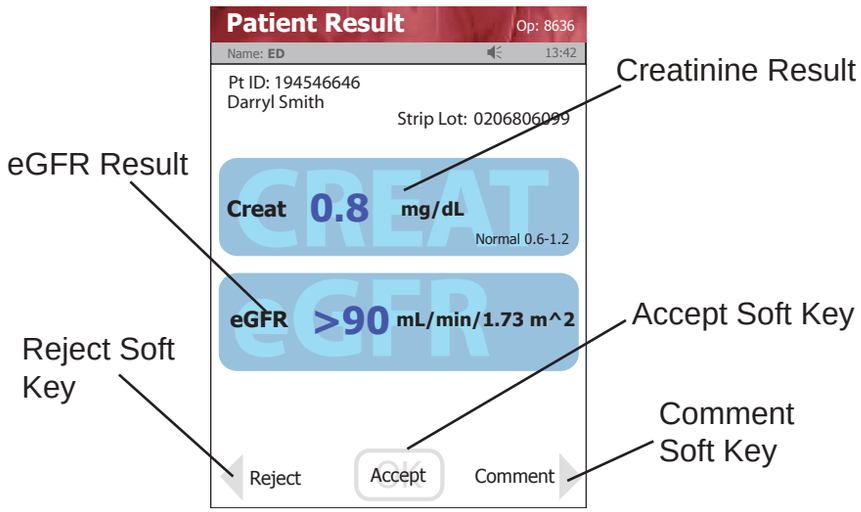


*Figure 3.8 Creatinine Results Screen with MDRD (eGFR) Result*

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

*A single down arrow displays for an abnormal low result and 2 down arrows for critical low result.*

## 3.2 Review Results

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



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

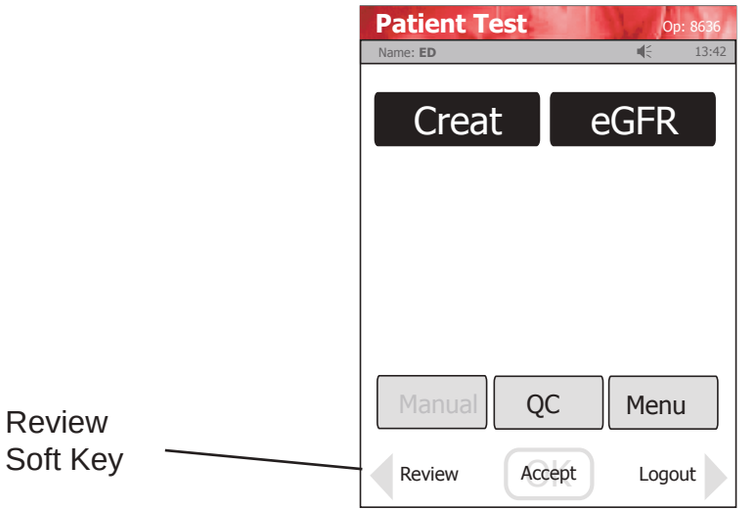


*Figure 3.9 Patient Test Screen: Review Soft Key*

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

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

5. Press the View soft key to view the selected result within the scroll bar.
   Press the Page Down soft key to view the previous page of results.
   Press the Page Up soft key to view the next page of results.
   Press the Previous soft key to view the previous result.
   Press the Next soft key to view the next result.

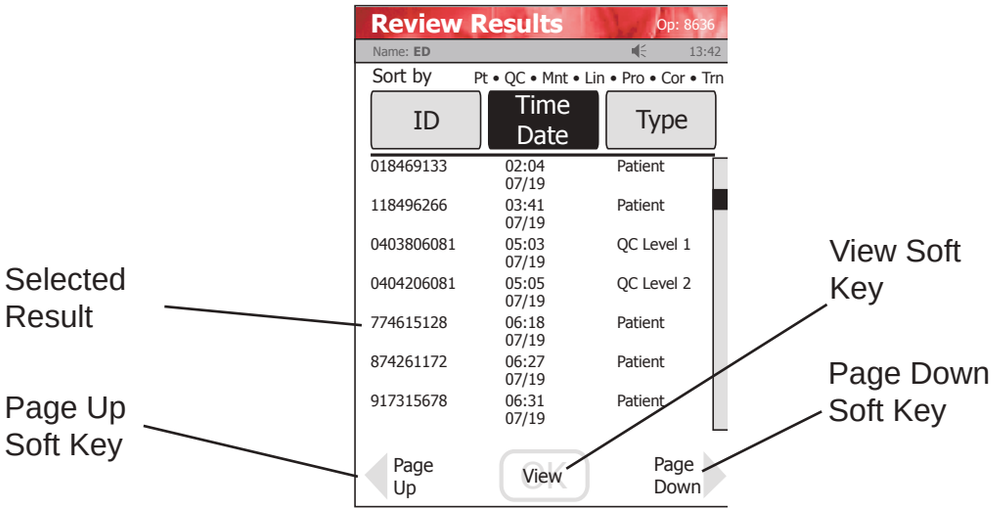


*Figure 3.10 Review Results Screen: Select Result to Review*

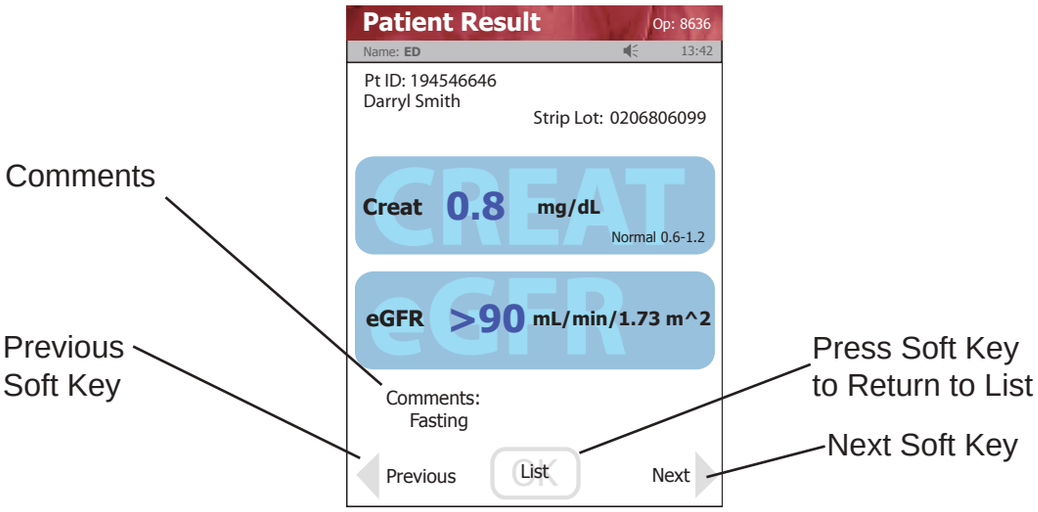


*Figure 3.11 Patient Result Screen*

# 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 wall plug cord into the power supply.

3. Insert the appropriate plug into a wall outlet.

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

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

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



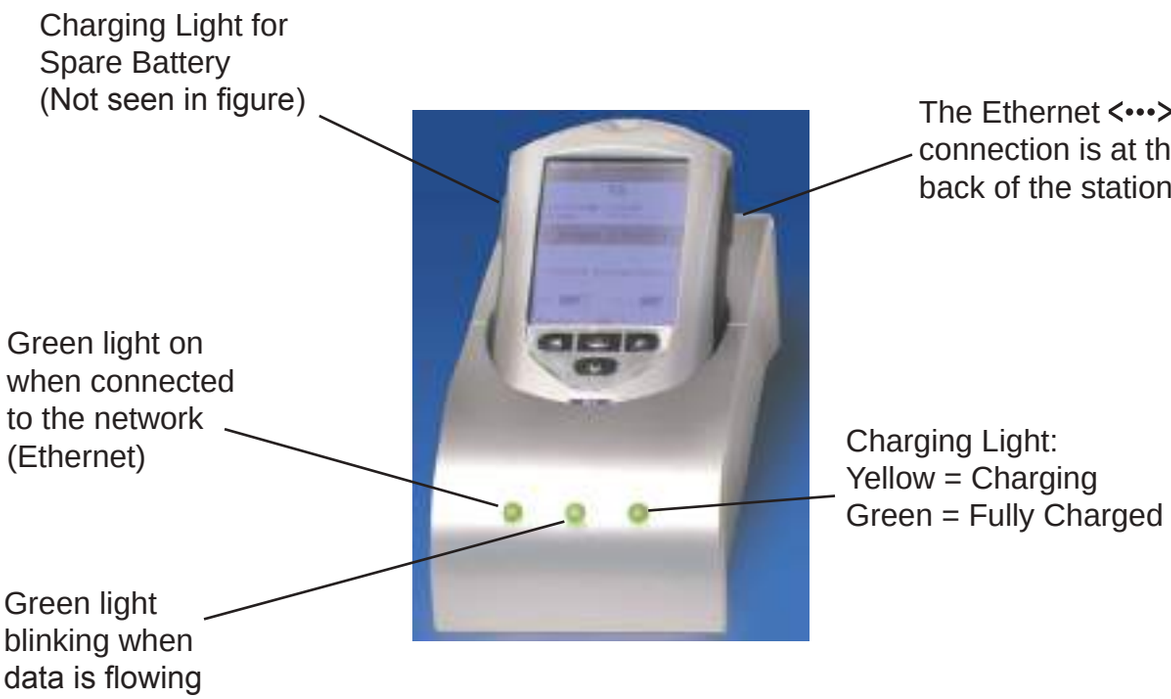


*Figure 4.1 The Meter in the Docking/Charging Station*

# 5 Linearity Test

This section describes how to perform Linearity tests with the StatSensor-i Creatinine Meter.

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

## 5.1 Running a Linearity Test

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

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

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




*Figure 5.1 Enter Strip Lot Screens*

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

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

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

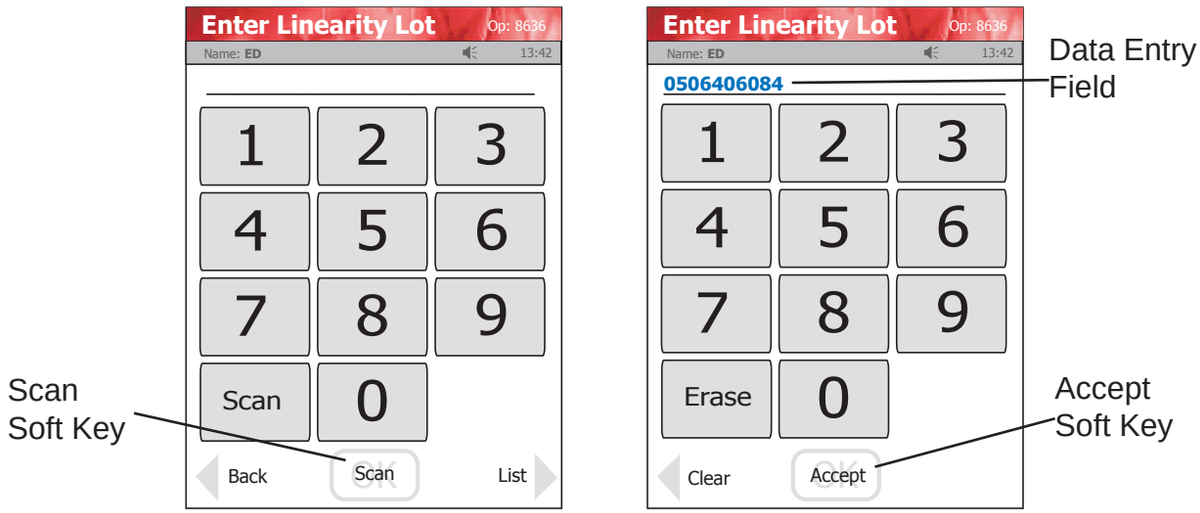


*Figure 5.2 Enter Linearity Lot Screens*

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

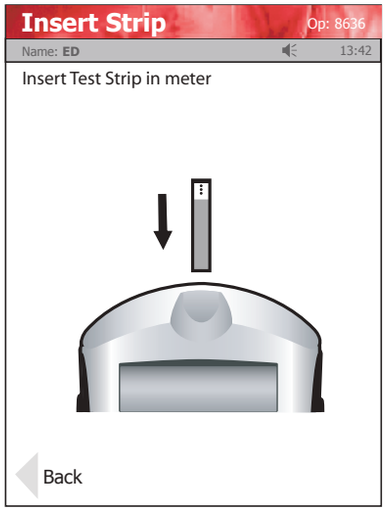


*Figure 5.3 Insert Strip Screen*

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

9. Gently mix the Linearity Solution before each use.

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

11. Touch the end of the test strip to the linearity solution until the well of the strip is full and the meter beeps.

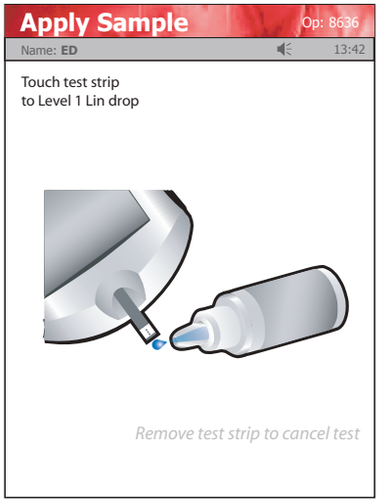


*Figure 5.4 Apply Sample (Linearity Solution) to Test Strip Screen*

12. Recap the linearity solution. The Testing Sample screen displays. The screen

shows a clock with seconds remaining below the clock.

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

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

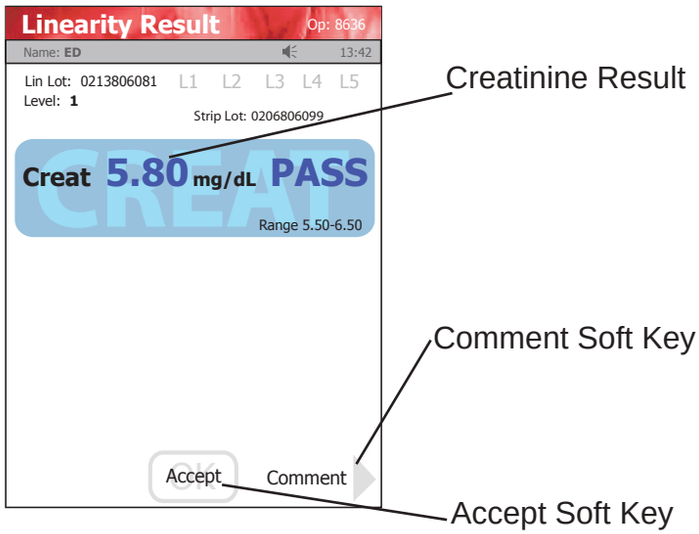


*Figure 5.5 Linearity Result Screen*

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

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

# 6 Maintenance

The Meter requires very little maintenance. Place the Meter into the charging station to recharge the battery or replace the battery with a fully charged one and wipe clean the Meter's surface with disinfectant.

## 6.1 Charging the Meter

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

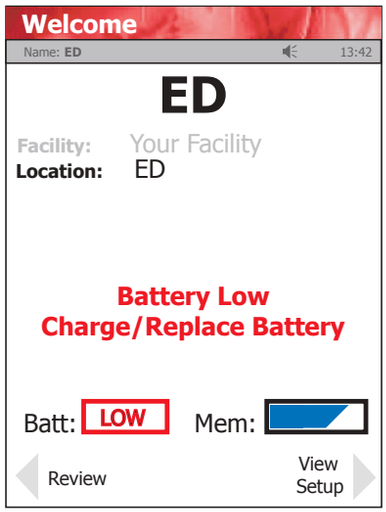


*Figure 6.1 Battery Low: Charge/Replace Battery Screen Alert*

*Figure 6.2 Meter placed into Charging Station*

## 6.2 Changing the Battery

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

***WARNING: Replace the battery with Nova Biomedical Part Numbers 46827, 50436, and 61829 only. Using another battery may present a risk of fire or explosion. If discarding, dispose of the battery promptly as appropriate for lithium polymer batteries. Keep the battery away from children.***

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

***NOTE:*** *If it takes longer than 20 seconds to change the battery, power up the Meter, relogin, and set the date and time: see Section 1.7.1 Power Up Procedure, Section 1.8 Operator Login, and Section 1.9 Setting the Time/Date.*

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

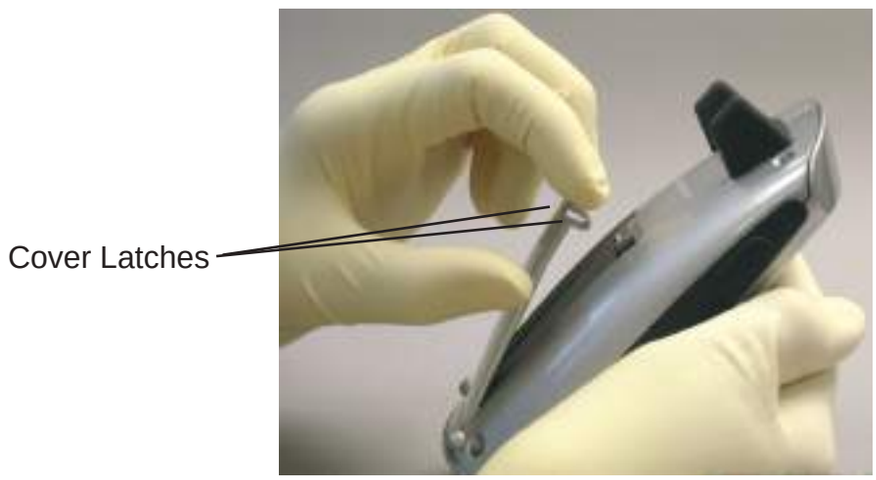


*Figure 6.3 Removing the Battery Cover*

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

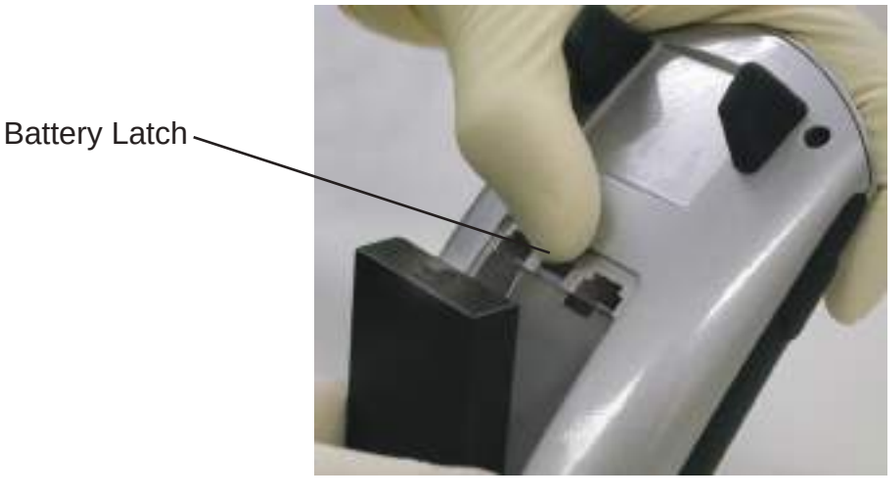


*Figure 6.4 Removing the Battery*

4. Replace with a fully charged battery.

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

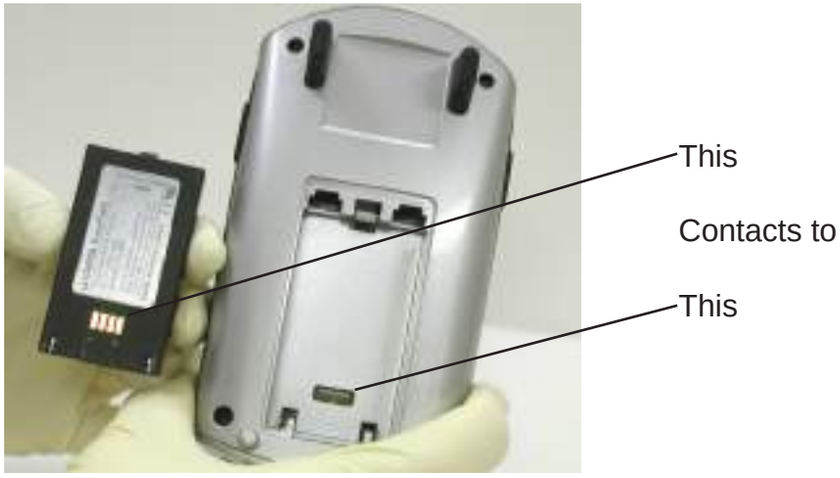


*Figure 6.5 Replacing with a Fully Charged Battery*

5. Replace the battery cover and dock the Meter into the Charging Station prior to use.

6. Place the drained battery into the Charging Station.

## 6.3 Cleaning the Meter

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

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

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

# 7 Troubleshooting

## 7.1 Meter Screen Alerts

The Meter displays a number of alerts:

1. **Battery Low** - Change the battery or place the Meter into the Charging/ Docking Station.

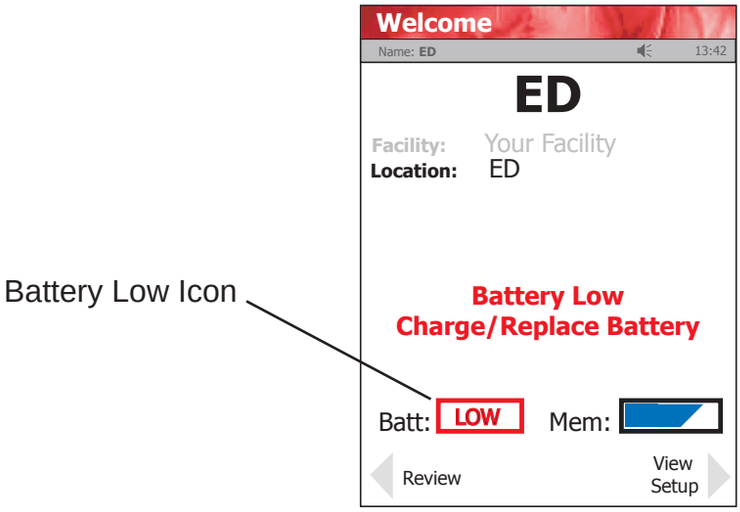


*Figure 7.1 Battery Low: Charge/Replace Battery Screen Alert*

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

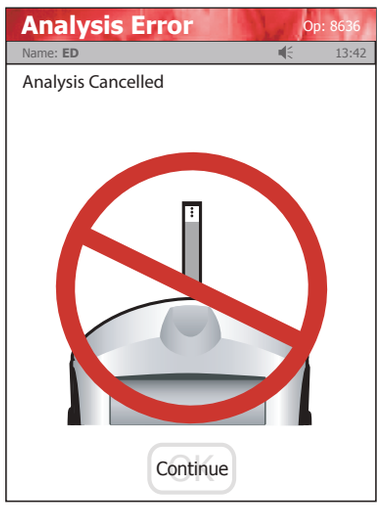


*Figure 7.2 Analysis Error - The Test Strip Was Removed Before Completing the Test*

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

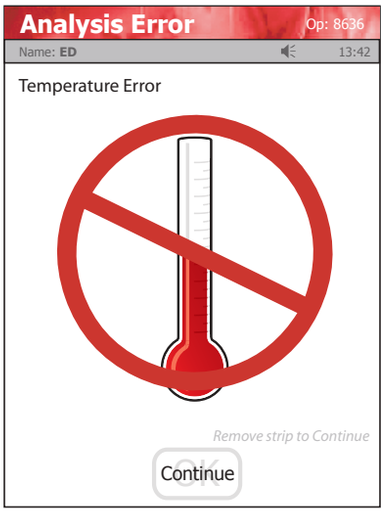


*Figure 7.3 Analysis Error - Temperature Error Screen Alert*

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

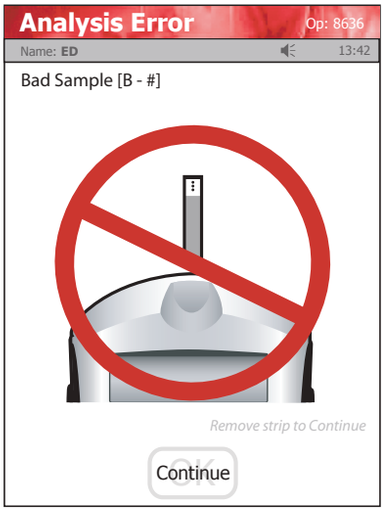


*Figure 7.4 Analysis Error - Bad Sample Screen Alert*

5. **Bad 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 - Bad Strip Screen Alert*

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

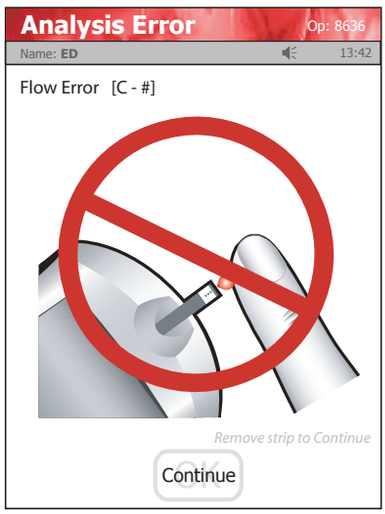


*Figure 7.6 Analysis Error - Flow Error Screen Alert*

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

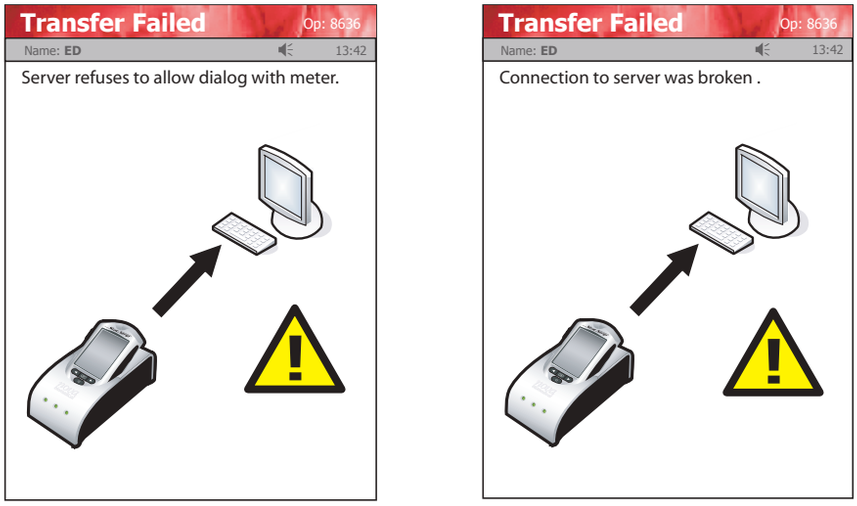


*Figure 7.7 Transfer Failed - Connection Not Allowed or Connection Broken*

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


*Figure 7.8 Transfer Failed - Transfer Incomplete*

# A Appendix

Appendix A includes analyzer specifications, solutions and reagents, consumable lists, reference information, and warranty for the StatSensor-i Creatinine Hospital Meter.

## A.1 Creatinine Meter Specifications

| | |
|---|---|
| Measurement Range: | Creat 0.30 - 12.0 mg/dL or 27 - 1056 µmol/L |
| Acceptable Samples: | Whole Blood: Capillary, Arterial, and Venous |
| Measuring Technology: | Enzyme, Amperometric |
| Analysis Time: | 30 seconds |
| Sample Volume: | 1.2 µL |
| Meter Memory: | 1000 patient tests |
| | 200 QC tests |
| | 8000 Operators |
| Docking/Charging Station: | Desk mount |
| | Input 100-240 V ~, 50-60 Hz, 0.6 A |
| | Output +12 V ⎓, 0.85 A |
| Data Output Port: | RJ-45 Ethernet (10 Mbit) |
| Connectivity: | Protocol TCP/IP Ethernet |
| | Standard POCT1-A Compliant |
| Battery: | Rechargeble Li-polymer 3.7 V 1800 mAh |
| Electrical Compliance: | Meets IEC 61010 standards |
| Dimensions: | 153 mm (6.0 in) x 82.5 mm (3.25 in) x 46 mm (1.8 in) |
| Weight: | 360 grams (0.8 lb) |
| Power: | 3.7V Li Polymer battery (Rechargeable/Replaceable) |
| Environmental: | |
| Temperature range | 59°F - 104°F (15°C - 40°C) |
| Altitude | Up to 15,000 feet (4500 meters) |
| Relative Humidity | up to 90% (noncondensing) |

### Chemistry Measurement

Precision of the StatSensor-i Creatinine Meter System was measured with both whole blood and linearity solutions in the laboratory. Typical Within-Run Precision results for Creatinine can be found in the StatSensor-i Creatinine Test Strip Insert Sheets.

### Clinical Study

Nova Biomedical sponsored a clinical study to evaluate the clinical performance of the StatSensor Creatinine Meter system. The study was performed at five (5) external Point of Care (Near Patient Testing) sites by typical Point of Care (Near Patient Testing) staff untrained in the use of the device.

A method comparison study was performed during which samples of venous, arterial, and capillary fingerstick whole blood collected at the respective sites were compared against spun down plasma from the same specimens/subjects analyzed on each institution's clinical laboratory reference analyzer for creatinine. The clinical study specimens covered the StatSensor Creatinine analytical measurement range.

A matrix comparison was also performed to compare whole blood sample results from various sources (arterial, venous, and capillary) measured on the StatSensor device against serum samples on reference analyzers. The samples were the same as the ones used for the above method comparison study.

### Method Comparison Results:

The below data analysis provides a pooled analysis (capillary, venous and arterial) of the method the comparison between StatSensor and Reference analyzers. Performance on the combined specimens meet the acceptance criteria.

| Sample Type | Number of Subjects | Measurement Range | $R^2$ | Slope | Intercept |
|---|---|---|---|---|---|
| Capillary, Venous and Arterial | 947 | 0.30 - 12.9 mg/dL | 0.9858 | 0.9873 | 0.0241 |

### Matrix Comparison Results:

Below, is the data analysis for the matrix comparison of capillary, venous and arterial blood samples against the different central laboratory reference methods used in the method comparison study.

These samples are the same samples used for method comparison study described above. There was no significant difference in results between specimen types. Performance on each specimen type was determined to be statistically equivalent and meets the acceptance criteria.

| Sample Type | Number of Subjects | Measurement Range | $R^2$ | Slope | Intercept |
|---|---|---|---|---|---|
| Capillary | 149 | 0.40 – 12.9 mg/dL | 0.9829 | 0.9851 | 0.0031 |
| Venous | 722 | 0.30-10.8 mg/dL | 0.9783 | 0.9896 | 0.0244 |
| Arterial | 76 | 0.57-12.0 mg/dL | 0.9946 | 0.9792 | 0.0787 |

## A.2 Controls/Linearity Solutions

This section covers the solutions required for the StatSensor-i Creatinine Hospital Meter.

Reagents to be used by the Meter:

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

The StatSensor Control and Linearity Solutions are traceable to NIST Standard Reference Material.

## A.3 Barcode Scanner

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

## A.4 Reference Values

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

*Table A.1 Reference Values Serum and Plasma*

| Test | Value |
|---|---|
| Creatinine | 0.7 - 1.3 mg/dL (Adult Male)<br>(61.9 - 114.9 µmol/L) |
| | 0.6 - 1.1 mg/dL (Adult Female)<br>(53.0 - 97.2 µmol/L) |

**References:**

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

## A.5 Ordering Information

Supplies and parts for the StatSensor-i Meter are available from Nova Biomedical.

| DESCRIPTION | Catolog # |
|---|---|
| StatStrip StatSensor Replacement Battery, 4 Pack | 46827 |
| StatStrip StatSensor Replacement Battery, 4 Pack | 61829 |
| StatStrip StatSensor Replacement Battery, 5 Pack | 50436 |
| Carrying Case for Meter & Supplies | 45702 |
| Instructions for Use Manual (International), printed | 45304 |
| Quick Reference Guide (International) | 45305 |
| StatSensor-i Creatinine Test Strips, 25 per vial, 2 vials per package | 43272 |
| StatSensor-i Meter Kit | 45328 |
| StatSensor Creatinine Control Solution, Level 1 | 43921 |
| StatSensor Creatinine Control Solution, Level 2 | 43922 |
| StatSensor Creatinine Control Solution, Level 3 | 43923 |
| StatSensor Creatinine Linearity Kit, 5 levels, 1 vial of each level | 44037 |
| StatStrip StatSensor Disposable Meter Bags | 43607 |

## A.6 Theory

### A.6.1 Creatinine

The Creatinine measurement is based on the following methodology:

$$\text{Creatinine} + O_2 \xrightarrow{\text{Enzymes}} H_2O_2 \qquad \text{Equation 1}$$

$$H_2O_2 + \text{Ferrocyanide} \xrightarrow{\text{Enzymes}} \text{Ferricyanide} + H_2O \qquad \text{Equation 2}$$

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

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

## A.7 Calculations for Estimated Glomerular Filtration Rate( eGFR) as an Indicator of Creatinine Clearance (CrCl) for Adults

The StatSensor-i Creatinine Hospital Meter is plasma calibrated.

https://www.niddk.nih.gov/health-information/communication-programs/nkdep/laboratory-evaluation/glomerular-filtration-rate

## A.7.1 Estimated Glomerular Filtration Rate (eGFR) Using the MDRD Equation for Adults

MDRD Conventional

1. The modified MDRD equation (conventional creatinine Units mg/dL)
   $GFR_{MDRD}$ (mL/min/1.73 $m^2$) = 186 x [SCr]$^{-1.154}$ x [age]$^{-0.203}$ x [0.742 if female] x [1.210 if African American]
   The equation requires 4 variables:
   - Serum or plasma, creatinine in mg/dL
   - Age in years (18 years to 130 years)
   - Sex (Male or Female)
   - Race (African American or not)

MDRD SI

2. The modified MDRD equation (SI creatinine Units µmol/L)
   $GFR_{MDRD}$ (mL/min/1.73 $m^2$) = 186 x [SCr/88.4]$^{-1.154}$ x [age]$^{-0.203}$ x [0.742 if female] x [1.210 if African American]
   The equation requires 4 variables:
   - Serum or plasma, creatinine (SCr) in µmol/L
   - Age in years (18 years to 130 years)
   - Sex (Male or Female)
   - Race (African American or not)

## A.7.2 Estimated Glomerular Filtration Rate (eGFR) Using MDRD-IDMS Traceable Equation for Adults

a. eGFR (mL/min/1.73 $m^2$) = 175 x (Creat$^{-1.154}$ in mg/dL) x [Age]$^{-0.203}$ x [0.742 if Female] x [1.210 if African American]

Where:

- SCr is serum or plasma, creatinine in mg/dL
- Age in years (18 years to 99 years)
- Sex (Male or Female)
- Race (African American or not)

b. MDRD-IDMS Traceable Formula for Japanese
   eGFR (ml/min/1.73 $m^2$) = 194 x (Creat$^{-1.094}$ in mg/dL) x [Age]$^{-0.287}$ x [0.739 if Female] *

Where:

- SCr is serum or plasma, creatinine in mg/dL
- Age in years (18 years to 99 years)
- Sex (Male or Female)

## A.7.3 Estimated Glomerular Filtration Rate(eGFR) Using Cockcroft-Gault Equation for Adults

a. Calculations for Conventional Creatinine Units (mg/dL)

**For Males:**

eGFR (mL/min) = [(140 - age) x (weight/0.454)] / SCr (mg/dL) x 72.0 x 1.23

**For Females:**

eGFR (mL/min) = [(140 - age) x (weight/0.454)]/SCr (mg/dL) x 72.0 x 0.85

Where SCr is Serum Creatinine (mg/dL), age is in years (18 years or older), and weight is in pounds.

b. Calculations for SI Creatinine Units (µmol/L)

**For Males:**

eGFR (mL/min) = [(140 - age) x (weight/0.454)]/(SCr (µmol/L) x 88.4) x 1.23

**For Females:**

eGFR (mL/min) = [(140 - age) x (weight/0.454)]/(SCr (µmol/L) x 88.4) x 0.85

Where SCr is Serum Creatinine(µmol/L), age is in years (18 years or older), and weight is in pounds.

***NOTE:*** *The Cockcroft-Gault equation calculates estimated Glomerular Filtration Rate (eGFR) as an indicator of creatinine clearance (CrCl) and is UN-CORRECTED for surface area. Cockcroft DW, Gault MH: Prediction of creatinine clearance from serum creatinine. Nephron 16:31-41, 1976.*

## A.7.4 Estimated Glomerular Filtration Rate (eGFR) Using the CKD-EPI Equation for Adults

The CKD-EPI equation for adults:

a. eGFR (ml/min/1.73 $m^2$) = 141 x $\min(SCr/k,1)^a$ x
$\max(SCr/k,1)^{-1.209}$ x
$0.993^{Age}$ x
1.018 [if female] x
1.159 [if African American]

Where:
- SCr is serum creatinine in mg/dL
- k is 0.7 for females and 0.9 for males
- a is -0.329 for females and -0.411 for males
- min indicates the minimum of SCr/k or 1
- max indicates the maximum of SCr/k or 1

b. eGFR (ml/min/1.73 $m^2$) = 141 x $\min(SCr/k,1)^a$ x $\max(SCr/k,1)^{-1.209}$ x
$0.993^{Age}$ x
1.018 [if female] x
1.159 [if African American]

Where:
- SCr is serum creatinine in µmol/L
- k is 61.9 for females and 79.6 for males
- a is -0.329 for females and -0.411 for males
- min indicates the minimum of Scr /k or 1
- max indicates the maximum of Scr /k or 1

## A.7.5 Estimated Glomerular Filtration Rate(eGFR) Using Schwartz Equation for Children

Patient age less than 18 years: Creat Displayed in mg/dL

GFR = k * (height) / Creat

where:

height is in cm
Creat is in mg/dL
k = 0.33 when age < 1 preemie
k = 0.45 when age < 1
k = 0.55 when 1 ≤ age < 13
k = 0.55 when 13 ≤ age < 18 and sex is female
k = 0.65 when 13 ≤ age < 18 and sex is male

Patient age less than 18 years: Creat Displayed in µmol/L

GFR = k * (height) / (Creat / 88.4)

where:

height is in cm
Creat is in µmol/L
k = 0.33 when age < 1 preemie
k = 0.45 when age < 1
k = 0.55 when 1 ≤ age < 13
k = 0.55 when 13 ≤ age < 18 and sex is female
k = 0.65 when 13 ≤ age < 18 and sex is male

### A.7.6 Estimated Glomerular Filtration Rate(eGFR) Using Counahan-Barratt Equation for Children

Patient age less than 18 years: Creat Displayed in mg/dL

GFR = 0.43 * (height) / Creat

where: height is in cm
Creat is in mg/dL

Patient age less than 18 years: Creat Displayed in µmol/L

GFR = 38 * (height) / Creat

where: height is in cm
Creat is in µmol/L

## A.8 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails under warranty after delivery to the customer because of defective material or workmanship. This warranty does not include (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. Nova 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 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. The item must be placed into service 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 reagents or controls are used, as follows: Nova will not be responsible for any warranty on a Nova StatSensor-i Creatinine 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 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.