



Nova StatSensor® Xpress-i™ Creatinine Hospital Meter Instructions for Use Manual

For Export Only

nova®
biomedical

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Symbols

The following are symbols that are used in this manual, on insert sheets, and on the meter.



In vitro diagnostic medical device



Electronic Waste



Authorized Representative
in the European Community



Catalog number



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



Discard 90 days after opening



Caution, consult accompanying
documents



Temperature limitation



Consult instructions for use



Upper Limit of Temperature



Biological risk



Manufactured by

About This Manual

This manual is for the Nova Biomedical StatSensor® Xpress-i™ Creatinine Meter.

Unit of Measure Information

The unit of measure of the Nova StatSensor Xpress-i Creatinine Meter is factory set to the standards in the country of use. The Meter either reports creatinine results in mg/dL or $\mu\text{mol/L}$ and can not be changed. Separate Result screens and specifications are shown in the Instructions for Use Manual for each unit of measure.

Throughout this manual:

NOTES *provide important or helpful operating information.*

CAUTIONS *provide information that is important for instrument protection.*

WARNINGS *provide information that is important for user protection or about risk for inaccurate results.*

Safety

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

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. The meter should be cleaned only as recommended by the manufacturer.

Electrical Safety

1. Battery powered: 3-volt coin battery

Chemical and Biological Safety

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

Disposal of Used Batteries for customers in Europe:

- This symbol  on the battery label indicates that the battery provided with the meter should not be treated as household waste. To ensure the used battery is treated properly, remove the used battery from the meter and hand over the used battery to the

Safety

applicable collection point for the recycling of electrical and electronic equipment.

Disposal of Used Meters for customers in Europe:

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

Environmental

- The operating temperature range for Meter operation: 59°F to 104°F (15°C to 40°C)
- The relative humidity range for Meter operation: 10% to 90% non-condensing
- The maximum altitude for Meter operation: Up to 15,000 feet (4572 meters)

Intended Use

Dimensions:

Height: 91.4mm (3.6in)

Width: 58.4mm (2.3in)

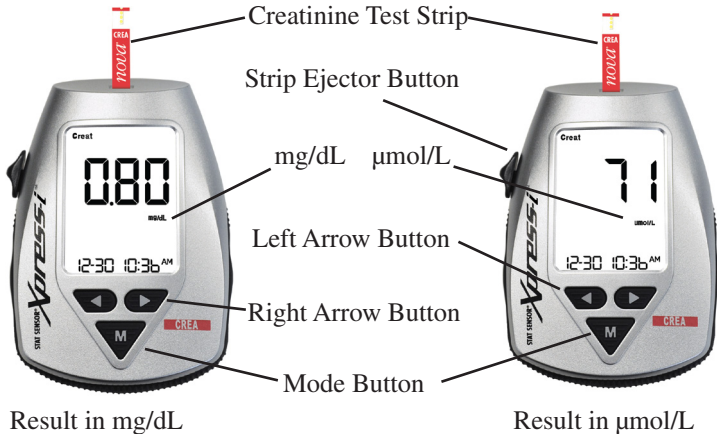
Depth: 22.9mm (0.9in)

Weight:

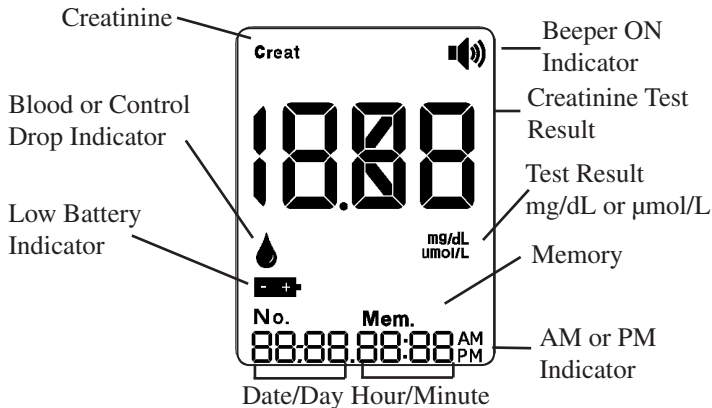
75 g (2.65 oz)

Intended Use

The Nova StatSensor Xpress-i Creatinine Meter System is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of Creatinine (Creat) 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.



Nova StatSensor Xpress-i Creatinine Meter



Nova StatSensor Xpress-i Creatinine Meter Screen

Introduction



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

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

- Prior to use, read the StatSensor Xpress-i Creatinine Meter Instructions for Use Manual.
- DO NOT reuse test strips. Strips are designed to be disposed after a single use.

- Discard used test strips according to local regulations.
- Use only the Nova StatSensor-i Creatinine Test Strips for testing with the Nova StatSensor Xpress-i Creatinine Meter.
- If test result is higher or lower than expected, run a control solution test.
- 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.

Introduction

Additional Information for Healthcare Professionals

- The Nova StatSensor-i Creatinine Test Strips are calibrated against plasma.
- The Nova StatSensor-i Creatinine Test Strips are used for whole blood testing only.

Introduction

The Nova StatSensor Xpress-i Creatinine Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical creatinine electrochemical test strips to measure creatinine in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. The meter can store up to 400 patient and/or quality control test results. The user can review all stored test results on screen. Functions and data selection are accomplished by 3 push buttons. The meter has a built-in beeper for audible alerts and prompts.

Clinical Utility

The StatSensor Xpress-iCreatinine Meter is intended for *in vitro* diagnostic use by health care professionals and for 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.

The Sample

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

Introduction

Interfering Substances

Creatinine Interferences:

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

Substances	Conc mg/dL(mmol/L)	Substances	Conc mg/dL(mmol/L)
Acetaminophen	10.0 (0.66)	D(+) Maltose Mono	100.0
Ascorbic Acid	3.5 (0.20)	Oxygen	All Conc
Bilirubin	15.0 (0.26)	Salicylate	30.0 (1.87)
Cholesterol	1000.0(25.8)	Triglycerides	1000.0(8.78)
Creatine	4.0 (0.35)	Uric Acid	20.0 (11.4)
Dopamine	10.0 (0.53)		
Glucose	500.0 (27.8)		
Hematocrit (RBC)	30%-60%		
Heparin	120 units/dL		
L-Dopa	300.0 (15.21)		

Introduction

Operation Overview

- To perform a test, the operator inserts a test strip into the test strip port. Touch the end of the strip to a drop of blood, QC solution, or linearity solution. The results are obtained in 30 seconds.
- Prior to analysis, the operator may designate the test sample as a quality control sample (level C1, C2, or C3).
- Test results are automatically stored into non-volatile memory.
- The operator can recall and review all stored test results.
- There are automatic electronic function checks to verify proper meter operation.
- The meter stores up to 400 patient, quality control, linearity, and proficiency test data.

- A coin-size battery provides power to operate the meter. The battery provides sufficient power to operate for approximately 600 tests. A low-battery warning on the meter display alerts the operator to change the battery. An auto sleep feature conserves power when the meter is not in use.

Meter Sleep/Wakeup

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

- Pressing a button
- Inserting a test strip

Introduction

If the meter goes into sleep mode, the following conditions should be expected:

- If blanking occurs when a Patient Result screen is displaying, the result is automatically saved.
- If the currently displayed screen is a Setup screen, any unconfirmed input data or menu selection are discarded prior to blanking.

Wakeup

To wake the meter, one of the following can be done:

- Press any button.
- Insert a strip.

Setup

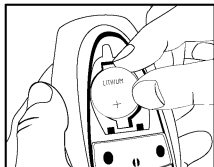
This section describes how to setup the Nova StatSensor Xpress-i Creatinine Meter. The operator can set the meter for local time and date, have the beeper On or Off, enable the sample counter, and set the date display format.

Setup

Installing the Battery (Replacing)

The meter is powered by a single 3V coin cell battery, 2450. Install/Replace the battery as follows:

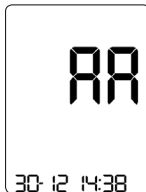
1. Remove the back battery cover on the meter.
2. Install the coin cell battery with the + side facing up.
(If replacing the battery, remove the used battery and replace with a new one.)
3. Replace the battery cover. All segments flash 3 times.



Setup

The software version and the current date and time will appear for 3 seconds then the screen will go blank.

CAUTION: Upon installing the battery, the meter software version is displayed for 3 seconds. Software versions are alpha characters.



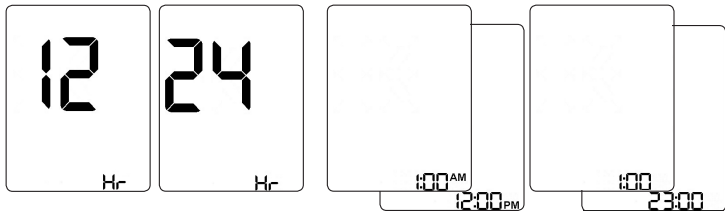
Setup

4. If this is the initial installation, go to setup.
If this is a battery replacement and the battery was replaced successfully within the time limit (30 seconds), all setup settings will be saved.
If this is a battery replacement and the battery was not replaced within the time limit (30 seconds), the time and date settings may be lost. The software version and the default date and time will appear for 3 seconds. Go to setup to configure the meter.

Set the Time

1. Press the MODE  button for longer than 3 seconds. The meter if in Sleep Mode wakes up and enters the SETUP Mode.

Setup



2. Select the hour (flashing) format: either 12 Hr or 24 Hr. Press the Right/Left Arrow   buttons to toggle between the 2 time format options.
3. Press the MODE  button to accept the Hour Format.
4. The meter displays the current time or the default time with the hour digits flashing.
5. Press the Right/Left Arrow   buttons to scroll from 1AM to 12PM (for 12 Hr Clock) or 0 to 23 (for 24 Hr Clock).

Setup

6. Press the MODE  button to accept the displayed Hour choice.
7. Next set the minutes (digits flashing). Press the Right/Left Arrow   buttons to scroll from 00 to 59 minutes.

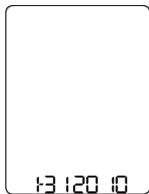


8. Press the MODE  button to accept the displayed Minutes choice.

Setup

Set Date Format

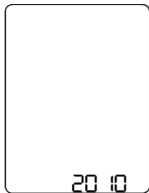
1. Next set the date format. The display is 1-31 2010 or 31.01.2010.
2. You can choose to have the date displayed as DD.MM or MM-DD. Press the Right/Left Arrow   buttons to toggle between DD.MM or MM-DD.



3. Press the MODE  button to accept the displayed Date Format.

Setup

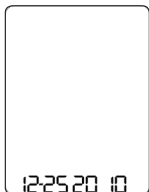
4. The year should be flashing. Press the Right/Left Arrow   buttons to select the current year.



5. Press the MODE  button to accept the displayed Year.

Setup

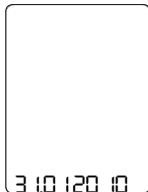
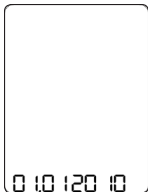
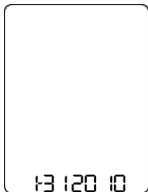
6. The month should be flashing. Press the Right/Left Arrow   buttons to scroll through the 12 months (1 to 12).



7. Press the MODE  button to accept the displayed Month.

Setup

8. The day should be flashing. Press the Right/Left Arrow   buttons to scroll through the days of the month.



9. Press the MODE  button to scroll the displayed Day.

Beeper On or Off

1. Press the Right/Left Arrow   buttons to toggle between Beeper ON or OFF (flashing).



2. Press the MODE  button to accept the displayed ON or OFF.

Setup

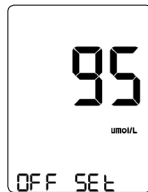
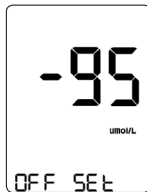
Set Offset: Blood Creatinine Result Only

1. For **mg/dL** meters, press the Right/Left Arrow   buttons to set the offset from -0.95 to 0.95 mg/dL in increments of 0.05 mg/dL.

For **μmol/L** meters, press the Right/Left Arrow   buttons to set the offset from -95 to 95 μmol/L in increments of 5 μmol/L.

NOTE: *The Meter stores the offset value in non-volatile memory. The offset value is applied to blood samples only (marked controls are excluded).*

Setup



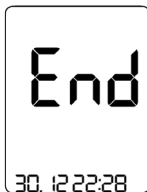
**Minimum to Maximum
Offset Screens for mg/dL
Meters**

**Minimum to Maximum
Offset Screens for μmol/L
Meters**

2. Press the MODE  button to accept the displayed **Offset for Creatinine Blood Result Only.**

Setup

End is displayed with the entered date and time. Press the Mode button for 1.5 seconds to exit Setup or the meter will time out in 1 minute.



Testing: QC/Linearity/Proficiency/Blood Samples

This section describes how to run QC (Quality Control), Linearity Solution, Proficiency Solution, and blood samples.

When to Perform a QC Test

The Nova StatSensor Xpress-i Creatinine Meter 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 StatSensor Xpress-i Creatinine Meter. These StatSensor Creatinine 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.

Testing a Quality Control Solution

StatSensor Creatinine Control Solution



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

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

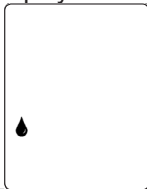
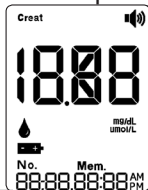
Testing a Quality Control Solution

- Each new operator
- Before using the StatSensor Meter for the first time
- When opening a new vial of test strips
- If a patient test has been repeated and the blood creatinine results are still lower or higher than expected
- After cleaning the test strip port on the meter
- 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

Testing a Quality Control Solution

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. This section describes how to run QC (Quality Control), Linearity Solution, Proficiency Solution, and blood samples.

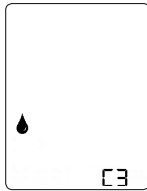
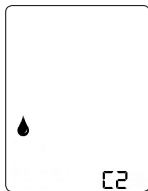
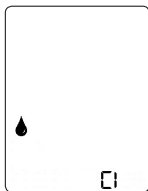
1. Insert a test strip into the meter. All segments of the screen will display for 2 seconds. Then a flashing blood drop will display.



NOTE: *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

Testing a Quality Control Solution

- Identify the sample as a Control; use the Left or Right button to find the desired control level: C1, C2, or C3.



- Touch the end of the test strip to a drop of control solution until the test strip fills and the meter beeps.

NOTE: A quick beep sounds when sufficient control solution has been added to the test strip.



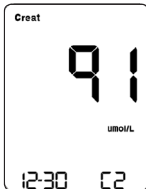
Testing a Quality Control Solution

4. Creatinine quality control test results are available on-screen in 30 seconds.

Result Displayed
in **mg/dL**



Result
Displayed
in **μmol/L**



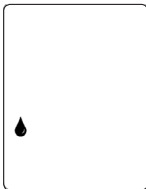
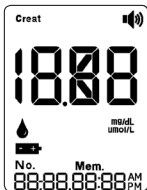
5. There is one long beep when the results are ready.
There are 3 short beeps if test results are outside the measurement range of the test strip.



Testing a Blood Sample

NOTE: Do not test patient samples until control solution test results are within expected range.

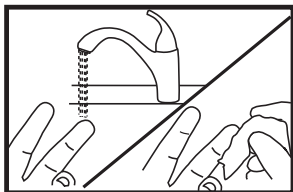
1. Insert a test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.



NOTE: If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.

Testing a Blood Sample

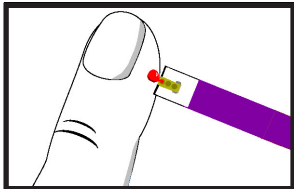
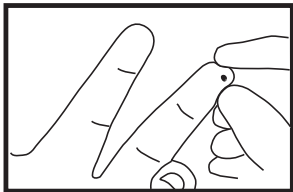
2. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.



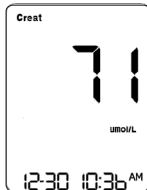
3. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
4. Use a lancet to puncture the finger.

Testing a Blood Sample

5. Squeeze the finger to form a drop of blood.
6. When the blood drop appears, touch the end of the test strip to the blood drop until the test strip fills and the meter beeps.
7. Creatinine test results are available on-screen in 30 seconds.



Testing a Blood Sample



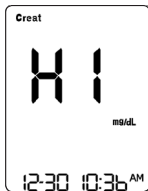
Result in mg/dL Result in $\mu\text{mol/L}$

8. There is one long beep when the results are ready.
There are 3 short beeps if test results are outside the range of the test strip.



Testing a Blood Sample

If result is LO (less than the measurement range) or HI (greater than the measurement range) repeat the test.



HI in mg/dL
(>12.0 mg/dL)



LO in μ mol/L
($<27\mu$ mol/L)

NOTE: Test results are automatically saved. If no activity for 1 minute, the meter will time-out: screen goes blank.

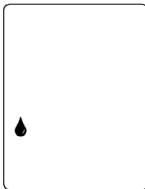
Testing a Linearity/Proficiency Solution

This section describes how to perform Linearity tests with the StatSensor Xpress-i Creatinine Meter. There are 5 levels in the StatSensor Creatinine Linearity kit.



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

1. Insert a test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.



NOTE: If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.

Testing a Linearity/Proficiency Solution

2. Touch the end of the test strip to a drop of linearity solution or proficiency solution until the test strip fills and the meter beeps.

NOTE: *Linearity/Proficiency test results are stored in memory as a blood sample.*

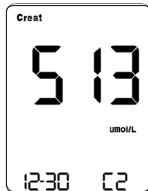
NOTE: *A quick beep sounds when sufficient linearity/*



proficiency solution has been added to the test strip.

3. Linearity or proficiency test results are available on-screen in 30 seconds.

Testing a Linearity/Proficiency Solution



Result in mg/dL Result in $\mu\text{mol/L}$

4. There is one long beep when the results are ready.
There are 3 short beeps if test results are outside the measurement range of the test strip.



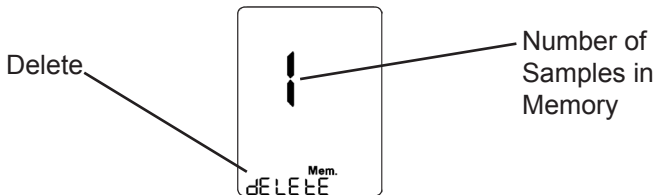
Reviewing Stored Test Results

The meter is able to store up to 400 test results.

1. To review test results, press the Mode button once for less than 3 seconds.
2. If there are no results in memory, the screen displays --- on the mem (memory) screen.
If there are tests saved, the most recent test is displayed first.
3. Press the left arrow button to scroll backward thru results. Press the right arrow button to scroll forward thru results.
4. If you scroll past the first or last stored result, the screen displays END.
5. After 400 test results, the new result will override the oldest result in memory.

You can delete all stored test and QC results. Proceed as follows to delete all results:

1. Press the Mode button once to display the number of stored test results.
2. Press the Right and Left arrow button simultaneously for longer than 3 seconds.
3. The screen displays the number of samples in memory with delete flashing at the bottom of the screen.



Deleting Stored Test Results

4. When the Screen displays dELEtE (flashing), press the left and right buttons simultaneously for greater than 3 seconds. All results are deleted. The screen will display OK and dELEtEd as shown below.
5. To exit without deleting results. press the MODE  button once.



Troubleshooting

This section describes Battery status, Error Codes, and Actions for the Nova StatSensor Xpress-i Creatinine Hospital Meter.

Battery Check

The battery provides sufficient power to operate for approximately 600 tests. A battery low warning will alert the user to replace the battery. Test results are stored in non-volatile memory to prevent test result loss.

Troubleshooting

How to view the battery status of the meter:

- Insert a test strip to the meter when it is turned off.
- All segments will display for 2 seconds.
- **Battery is OK:** a flashing blood drop appears at the lower left corner of the screen.
Continue with testing as usual.

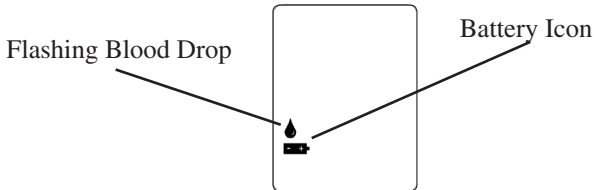


Flashing Blood
Drop



Troubleshooting

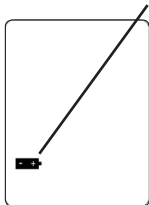
- **Battery is Low:** a flashing blood drop and battery icon appear at the lower left corner of the screen: battery charge sufficient for up to 10 tests. Continue with testing as usual. Battery icon remains on the screen.



Troubleshooting

- Battery is very Low:** battery icon at the lower left corner of the screen: battery charge insufficient for testing.
Meter will not operate and battery icon disappears when the test strip is removed. Replace the battery.

Battery Icon



CAUTION: Attempts to perform creatinine testing with a low battery could result in the software rebooting. Upon rebooting, the software version is displayed for 3 seconds. Software versions are displayed as alpha characters.

Troubleshooting

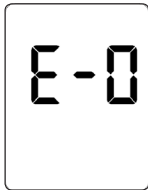
Error Codes

There are 7 Error Codes to inform you of problems with the meter. This section provides action procedures when these Error Codes are displayed. The error code displays after the test strip is inserted and the all segments screen displays for 2 seconds. If the beeper is enabled, there are also 3 quick beeps. Then the Error Code is displayed on the screen.

E0 Software Error

A software error has been detected.

Action: Perform the test again. If you get the same error again, remove and reseal the battery. If the error continues, call Nova Technical Support.



Troubleshooting

E1 System Hardware Error

A system hardware error has been detected.

Action: Perform the test again. If you get the same error, call Nova Technical Support.

A rectangular box with a thin black border containing the text "E-1" in a large, black, digital-style font.

E2 Operating Temperature Error

The Meter temperature is outside of the range for testing.

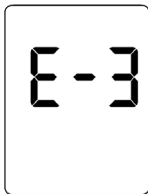
Action: Move the meter to an area where the temperature is acceptable (59°-104°F or 15°-40°C), allow meter to adjust to the temperature. Repeat the test.

A rectangular box with a thin black border containing the text "E-2" in a large, black, digital-style font.

E3 Used Strip Error

The test strip was previously used.

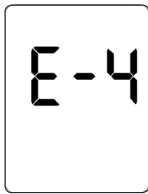
Action: Repeat the test with a new test strip.



E4 Short Sample Error

An insufficient sample volume (Control or blood) was drawn into the test strip.

Action: Repeat the test with a new test strip.



Troubleshooting

E8 Bad Strip Error

The test strip is defective or bad.

Action: Repeat the test with a new test strip.



E-8

E9 Bad Sample Error

A problem was detected with the sample.

Action: Repeat the test with a new test strip.



E-9

Appendix

The Appendix includes solution and reagent specifications, accuracy and precision, consumable list, reference information, and warranty.

Appendix

A.1 Specifications

Tests Measured	Blood Creatinine
Creatinine Methodology	Enzyme, Amperometric
Creatinine Test Results	mg/dL, $\mu\text{mol/L}$
Sample Type	Whole Blood: Capillary, Arterial, and Venous
Creatinine Test Range	0.30 to 12.0 mg/dL 27 to 1056 $\mu\text{mol/L}$
Test Time	30 seconds
Test Strip Volumes	1.2 μL
Memory storage	400 Tests
Battery Life (nominal)	600 Tests
Battery Type	2450 3V coin cell
Data Cable	Serial or USB

Appendix

Operating Ranges:

Temperature	59° to 104°F (15° to 40°C)
Humidity	10% to 90% relative humidity
Altitude	15,000 ft (4572 meters)
Hematocrit	20% to 65%
Weight	2.65 oz (75 g)
Size	3.6x2.3x0.9 in(91.4x58.4x22.9 mm)

A.2 Reference Values

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

Creatinine (male)¹ 0.7 - 1.3 mg/dL (61.9 - 114.9 μ mol/L)

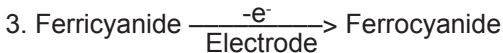
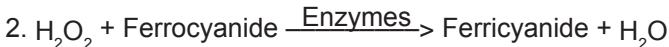
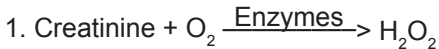
Creatinine (female)¹ 0.6 - 1.1 mg/dL (53.0 - 97.2 μ mol/L)

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1998. *Tietz Textbook of Clinical Chemistry*. Philadelphia, PA: W. B. Saunders Co.

Appendix

A.3 Creatinine Methodology

The creatinine measurement is based on the following methodology:



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

Appendix

A.4 Quality Control Solution

QC Solutions

Levels 1, 2, 3

Linearity Solutions

Levels 1, 2, 3, 4, 5

A.5 Chemistry Measurement

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

Creatinine Levels (mg/dL)	Creatinine Levels (μ mol/L)	CV%
1	88	8%
5	440	6%
10	880	4%

Appendix

A.6 Ordering Information

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

DESCRIPTION	REF
Instructions for Use Manual	49011
Quick Reference Guide.....	49018
StatSensor-i Creatinine Test Strips.....	43272
Creatinine Control Solution, Level 1	43921
Creatinine Control Solution, Level 2	43922
Creatinine Control Solution, Level 3	43923
Creatinine Linearity Solution, Levels 1-5	44037
Battery (DL2450).....	41221

A.7 Cleaning and Care

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.*

CAUTION: *Do Not attempt to open the meter to make any repairs. Your warranty and all claims will be void! Only Nova Biomedical authorized service personnel can repair the meter. Call Nova Biomedical or an authorized dealer if the meter needs to be repaired or checked.*

Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair of 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 which cause shortened life, erratic behavior, damage or poor analytical performance; (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. All requests for

Warranty

warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure. 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 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 Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranty on Nova StatSensor Xpress-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.

Warranty

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.

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