INSTRUCTIONS FOR USE

NOVA MAX PRO CREATININE and eGFR METER SYSTEM

nova® biomedical

Nova Max Pro™ Creatinine and eGFR Meter System Instructions for Use Manual

Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454-9141 U.S.A.
Customer Service Telephone: 1-781-647-3700
or contact your local distributor
Supplies:
Web Site: www.novabiomedical.com
or contact your local distributor

Made in the U.S.A. by Nova Biomedical Corporation

PN 64322 Rev. A 01/2022

nova® biomedical

EC REP Nova Biomedical GmbH

Hessenring 13A
Geb. G
64546 Mörfelden-Walldorf Germany

nova® biomedical

Symbols

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

IVD	*In vitro* diagnostic medical device
EC REP	Authorized Representative in the European Community
	Caution
	Consult instructions for use
	Biological risk
	Use By
LOT	Lot Number
Rx Only	Prescription Use Only
	Electronic Waste
REF	Catalog number
	Temperature limitation
	Manufactured by
	Date of Manufacture
	For Near Patient Testing
SN	Serial Number
CONTROL	Control
	Contains sufficient for <n>tests
	Device complies with Part 15 of the FCC rules
	Bluetooth

nova® biomedical

Important Information!

- Before you begin using your new Nova Max Pro Creat and eGFR Meter, please read all of the instructions provided in this Instructions for Use Manual as well as the instructions provided in the Nova Max Pro Creat eGFR Creatinine Test Strips and the Nova Max Pro Creat eGFR Control Solutions.
- Your Meter uses a rechargeable, 3.7 V Li-Polymer battery. To begin using your Meter, you need to charge the battery. See the section on Battery Charging in this guide for details.
- Perform all quality control checks recommended in this Instructions for Use Manual.

Notes, Cautions, and Warnings:

NOTES *provide helpful operating information.*

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

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

nova® biomedical

Table of Contents

nova® biomedical

Table of Contents

Intended Use

The Nova Max Pro Creatinine and eGFR Meter System is intended for in vitro diagnostic use for the quantitative measurement of creatinine in capillary whole blood obtained from the fingertip for screening of kidney health by calculating Estimated Glomerular Filtration Rate (eGFR). It is intended for multiple patient use in Near-Patient/Point of Care and professional healthcare settings. The system should only be used with the Nova Max Pro Creat eGFR Creatinine Test Strips and Nova Max Pro Creat eGFR Creatinine Control Solutions and with single-use, auto-disabling lancing devices. It is not intended to diagnose a specific kidney disease or condition. The system should not be used to alter kidney disease treatment by changing any medication schedule or dosage unless specifically instructed by a healthcare professional.

Limitations

The Nova Max Pro Creat eGFR Creatinine Test Strips give accurate results when the following limitations are observed:

- Blood – Use only capillary whole blood. Do not use serum or plasma.
- Do not use the Nova Max Pro Creatinine and eGFR System for testing neonates.
- Test results are best obtained when used within an operating relative humidity of 10% to 90% (non-condensing). Testing outside this range may cause inaccurate results.
- Altitude – There is no effect of altitudes up to 12,000 feet (3658 meters) above sea level.
- Meter operational temperature range: 59°F to 104°F (15°C to 40°C)

Interfering Substances

A study was conducted to examine Creatinine and eGFR measurement using the Nova Max Pro Creatinine and eGFR Meter System. The following substances were tested and determined to have no clinical interference:

Tested Interfering Substances	Tested Concentration Level
Acetaminophen	20.0 mg/dL
Ascorbic acid	2 mg/dL
Bilirubin	20 mg/dL
Cholesterol	500 mg/dL
Creatinine	15 mg/dL
L-Dopa	1 mg/dL
Dopamine	5 mg/dL
Glucose	600 mg/dL
Heparin	500 units/dL
Ibuprofen	48 mg/dL
D(+) Maltose Monohydrate	500 mg/dL
Methyl Dopa	2 mg/dL
Salicylate	48 mg/dL
Tolazamide	25 mg/dL
Tolbutamide	25 mg/dL
Triglyceride	750 mg/dL
Uric Acid	20.0 mg/dL

Important Safety Instructions

WARNING: *Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products with care. Wear gloves when performing measurements on another person. Items that are used to measure Creatinine and eGFR, i.e., Test Strips, lancets, and alcohol swabs, must be disposed of in accordance with local regulations.*

Healthcare professionals and others must wear gloves while using this system on multiple patients and 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.

Important Safety Instructions

Blood-Borne Pathogens Safety

1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the Nova Max Pro Creatinine and eGFR Meter System.
2. Healthcare professionals should be aware that all parts of the Nova Max Pro Creatinine and eGFR Meter System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
3. The Nova Max Pro Creatinine and eGFR Meter System may only be utilized for testing on multiple patients when Standard Precautions are followed and when the system is cleaned and disinfected after use on each patient following the Cleaning and Disinfecting Procedure. Healthcare professionals should wear a new pair of protective gloves before testing each new patient.

Important Safety Instructions

4. Only auto-disabling, single-use lancing devices may be used with this system.
5. For more information, refer to the following references:
   "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," http://www.cdc.gov/hicpac/2007ip/2007isolationprecautons.html. Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/.
   "Protection of Laboratory Workers From Occupationally Acquired Infection ; Approved Guideline - Fourth Edition," Clinical and Laboratory Standards Institute (CLSI) M29-A4. CDC Clinical Reminder: Use of Fingerstick Devices. https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html

Important Safety Instructions

Federal Communications Commission (FCC) Notice

FCC ID: QYY-61721 IC: 4562A-61721

This device complies with Part 15 of the FCC Rules: Operation is subject to the following conditions:

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

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

Important Safety Instructions

Radio Standards Specifications (RSS) Notice

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

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

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Important Safety Instructions

Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens." (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

General 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.

Important Safety Instructions

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

This symbol () on 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 on " cleaning and disinfecting the meter" of this manual and hand over the product to the applicable collection point for the recycling of electrical and electronic equipment.

Introduction

Before Testing

Before testing and to ensure accurate Creatinine and eGFR results, the patient must wash the hands and the test site; then thoroughly dry these areas.

Test Strips

The Nova Max Pro Creat eGFR Creatinine Test Strips are designed for use with the Nova Max Pro Creat and eGFR Meter. Use each Test Strip only once, then discard. **DO NOT** reapply blood to a Test Strip.

Important Nova Max Pro Creat and eGFR Test Strip Information

- Use only Nova Max Pro Creat eGFR Creatinine Test Strips when testing.
- Remove the Test Strip from the vial only when ready to test.

Introduction

- Storage temperature for the Nova Max Pro Creat eGFR Test Strips: 35.6°F to 46.4°F (2°C to 8°C)
- Do not freeze.
- Do not store near heat or moisture.
- Store the Test Strips in their original vial only: do not transfer strips between vials.
- After removing a Test Strip from the vial, immediately replace the vial cap and close it tightly.
- Do not use Test Strips beyond the expiration date printed on the package as this may cause inaccurate results.
- Use an opened Test Strip vial only for 3 months after the first opening.

Controls

- Storage temperature for the Nova Max Pro Creat eGFR Control Solution: 35.6°F to 46.4°F (2°C to 8°C)

Introduction

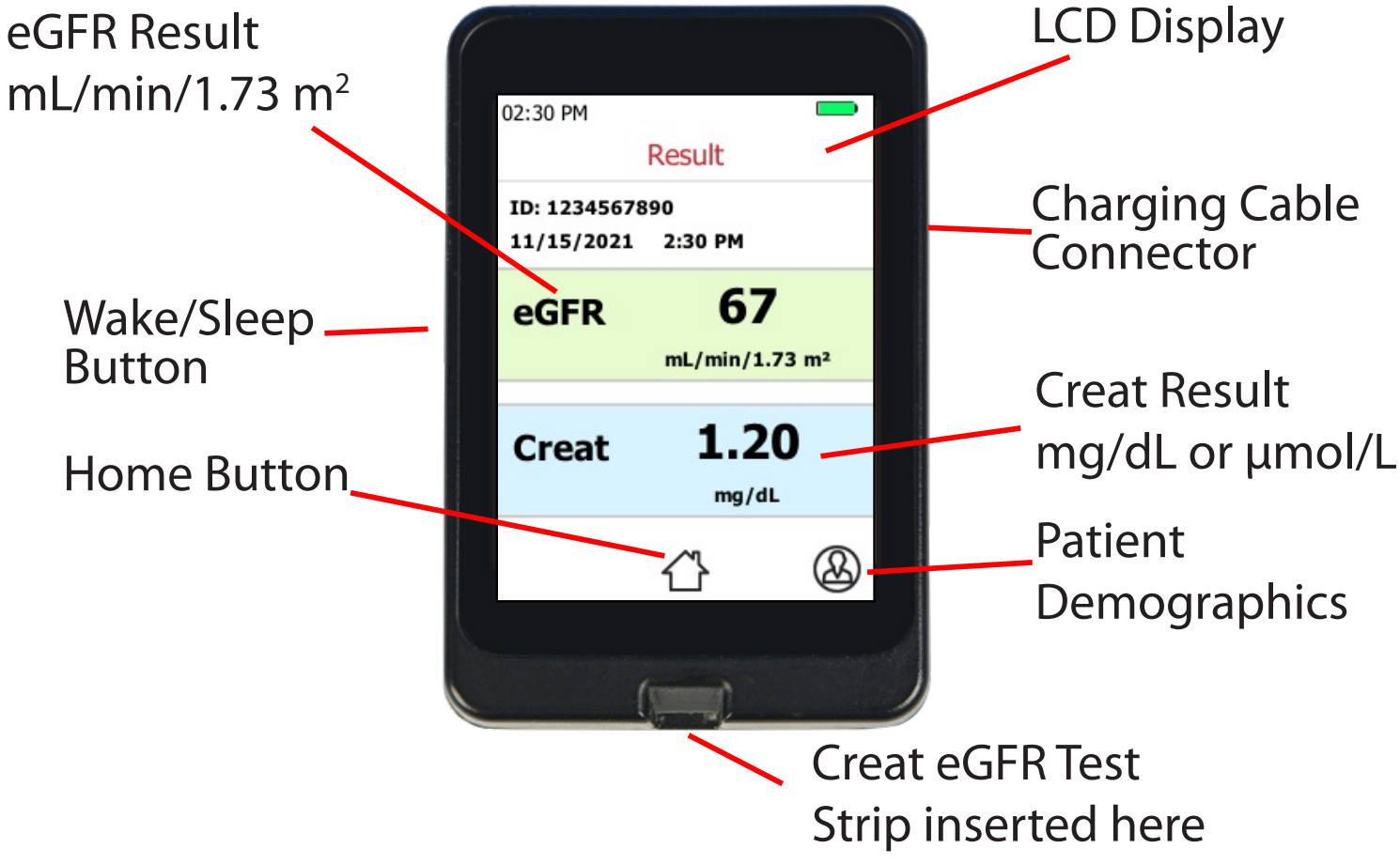
The Nova Max Pro Creat and eGFR Meter

The Meter is a hand-held testing device that measures Creatinine and eGFR levels in capillary whole blood obtained from the finger-tip.

- A simple one-step process provides a Creatinine and eGFR blood test result.
- Test results are available in 30 seconds.
- There is a memory for a minimum of 400 test results.

CAUTION: *The Meter should be handled with care. Dropping, rough handling, etc. may damage the Meter. Also, protect the Meter from moisture, prolonged direct sunlight, and extreme temperatures.*

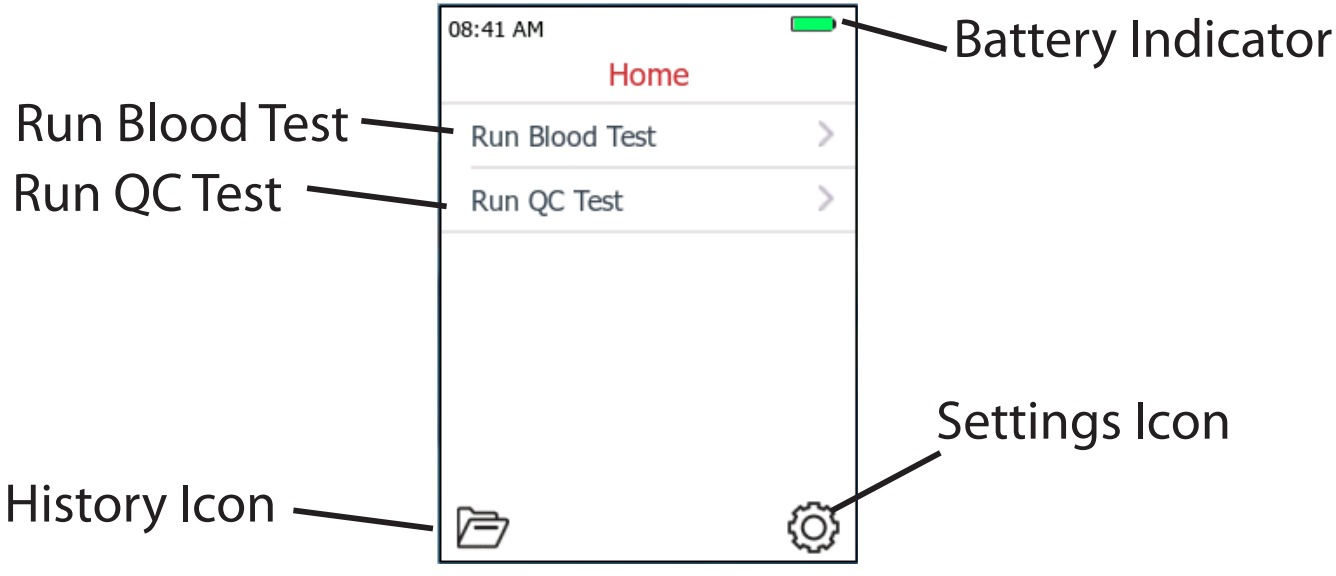
Introduction



Nova Max Pro Creat and eGFR Meter Components

Meter Display

When you turn the Nova Max Pro Creat and eGFR Meter on, the home screen displays. The Home screen is the default screen for the meter. It allows the user to navigate to all screens in the meter. To go to the meter settings press the Settings icon .



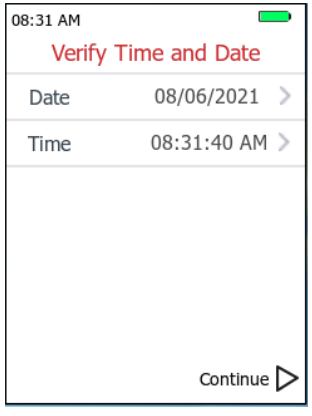
Nova Max Pro Creat and eGFR Meter Screen Display

Date & Time, Sound, Language, and Advanced Settings

The Meter Settings menu provides a means of setting the date and time to match the local time zone or adjust for daylight savings. An alert tone can be enabled for the user if desired and the Meter Software and Strip Reader version, as well as the serial number of the Meter, are displayed.

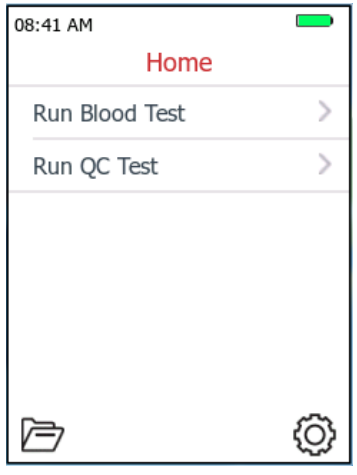
1. When the Meter is powered up, the Meter will display the **Nova Max Pro** splash screen followed by the Verify Time and Date screen.

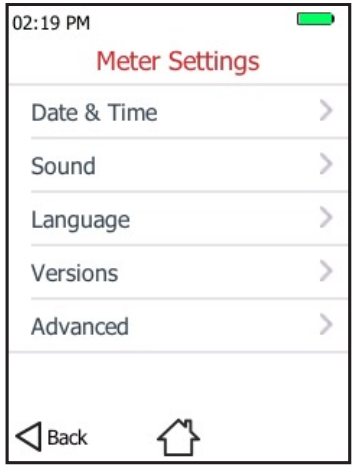
2. Verify the Time and Date, or set the Time and Date as explained in the next steps.



Date & Time, Sound, Language, and Advanced Settings

3. To access the Meter settings menu; from the Home screen, press the Settings icon .

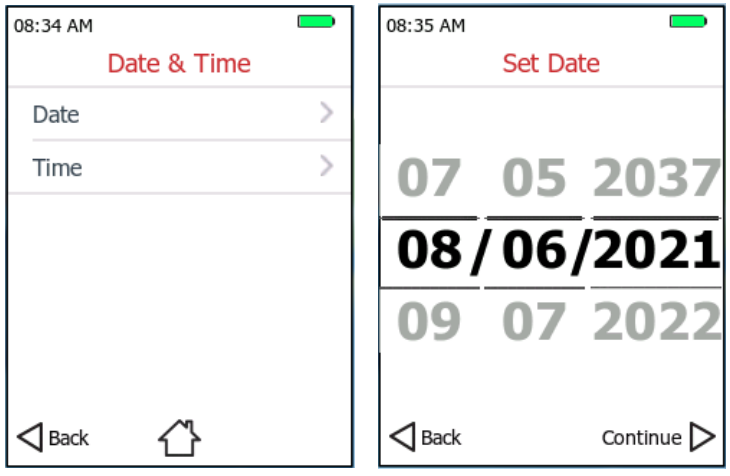




4. The Meter Settings screen is displayed.
5. To set the current Date or Time, press **Date & Time.**

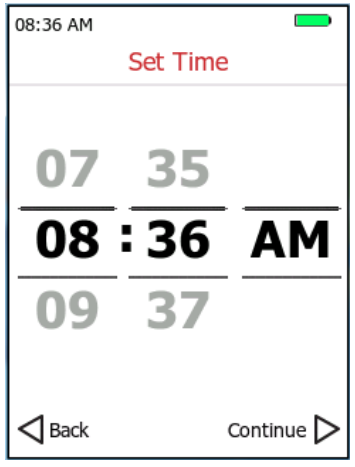
Date & Time, Sound, Language, and Advanced Settings

6. The Date & Time screen displays.
7. To set the current date, press **Date**.



8. The Set Date screen displays.
9. Set Date uses 3 scroll wheels for the month (1-12), day (1-31), and year (2019-2038). Scroll up or down to select the current month, day, and year. Press Continue to save the date and return to the Date & Time screen. Press Back to discard any changes and return to the Date & Time screen.

Set TIME



1. To set the current time, from the Date & Time screen press **Time**. The Set Time screen displays.
2. Set Time uses 3 scroll wheels for the hour (1-12), minute (0-59), and type (AM, PM, or 24H). The hour wheel will update (00-23) if 24H is selected. Press **Continue** to save the time and return to the Date & Time screen. Press Back to discard any changes and return to the Date & Time screen.
3. Press **Back** from the Date & Time screen to return to the Meter Settings screen.

Date & Time, Sound, Language, and Advanced Settings

Set Sound: On or Off

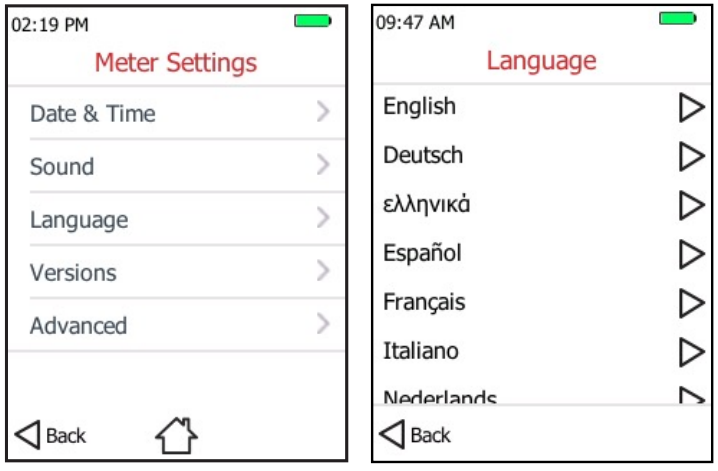
1. To enable or disable the alert sound, from the Meter Settings screen press **Sound**.

2. The Sound screen displays.
3. Touching the speaker icon will toggle the sound between On or OFF. Press **Continue** to save the Sound setting and return to the Meter Settings screen. Press Back to discard any changes and return to the Meter Setting screen.

Date & Time, Sound, Language, and Advanced Settings

Select Language

1. To select a Language and Units, from the Meter Settings screen press **Language**.

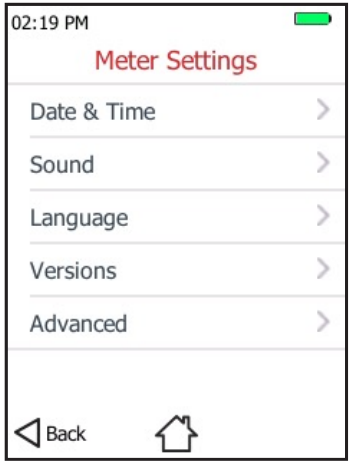


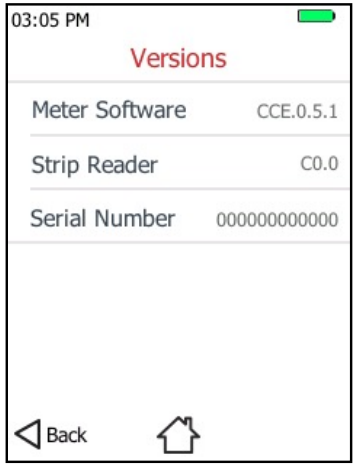
2. The Language with Units screen displays.
3. Select English, German, Spanish, French, Italian, Portuguese, Greek, Dutch, or Russian.
4. Press Back to return to the Meter Settings screen or press ⌂ to return to the Home screen.

Date & Time, Sound, Language, and Advanced Settings

View Versions

1. To view the Meter's Software version , Strip Reader version, and Serial Number, from the Meter Settings screen press **Versions**.



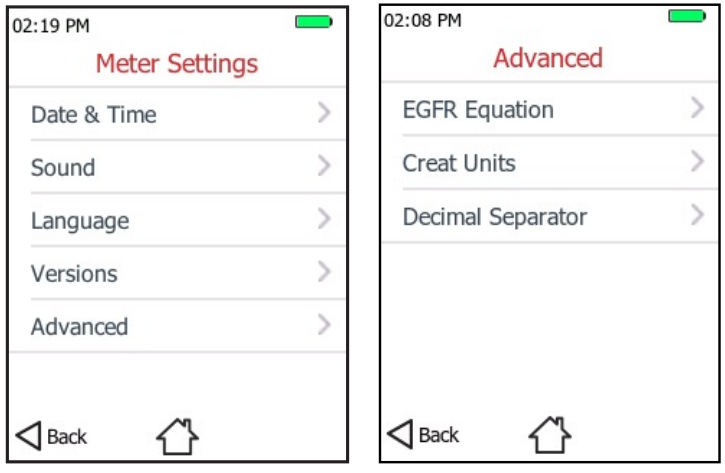


2. The Versions screen displays.
3. The Meter Software and Strip Reader version and the Meter's Serial Number are displayed.
4. Press Back to return to the Meter Settings screen or press ⌂ to return to the Home screen.

Advanced Settings

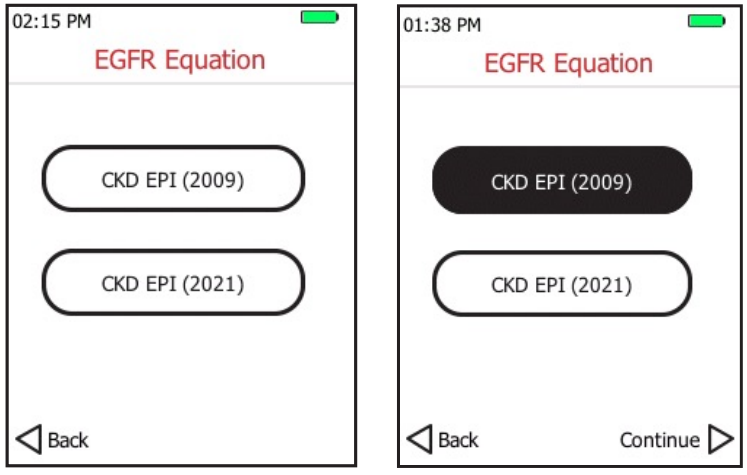
Advanced Settings allow the meter to be configured to use a selected eGFR Equation, Creatinine Unit of Measurement, and Decimal Separator.

To access the Advanced settings, from the Meter Settings screen press Advanced.



Date & Time, Sound, Language, and Advanced Settings

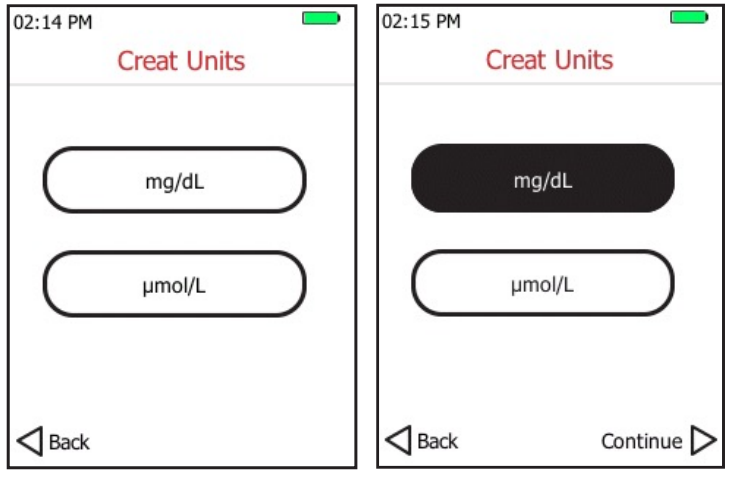
1. Select eGFR Equation, then select either CKD EPI (2009) or CKD EPI (2021). The selected equation will be displayed with a dark background.



2. Press Continue to keep your selection and return to the Advanced screen or press Back to discard any changes and return to the Advanced screen.

Date & Time, Sound, Language, and Advanced Settings

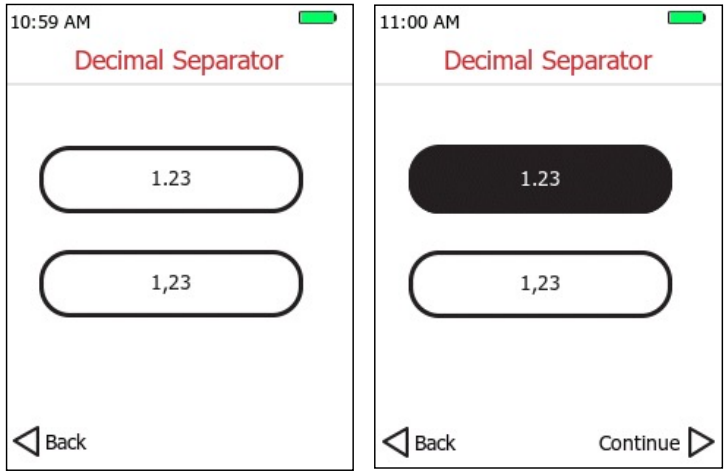
3. Select Creat Units, then select the appropriate Creatinine unit of measure, either mg/dL or µmol/L. The selected equation will be displayed with a dark background.



4. Press Continue to keep your selection and return to the Advanced screen or press Back to discard any changes and return to the Advanced screen.

Date & Time, Sound, Language, and Advanced Settings

5. Select Decimal Separator, then select the appropriate separator, either a decimal point or comma. The selected separator will be displayed with a dark background.



6. Press Continue to keep your selection and return to the Advanced screen or press Back to discard any changes and return to the Advanced screen.

Running Nova Max Pro Creat eGFR Control Solution

Nova Max Pro Creat eGFR Control Solution

NOTE: *Read the package insert sheets for Nova Max Pro Creat eGFR Control Solution for complete instructions, indications, precautions, and limitations of the system.*

Nova Max Pro Creat eGFR Control Solution is a liquid control that contains a fixed amount of Creatinine.

- Use this solution to test that the Meter and Test Strips are working properly as a system.
- If the Meter reading is within the range printed on the Control Solution vial label, the Meter and test strips are working properly as a system.

Running Nova Max Pro Creat eGFR Control Solution

Perform a Control Solution Test

The Control Solution test confirms that the Meter and Test Strips are working correctly. A Control Solution test is similar to a blood test, except the Nova Max Pro Creat eGFR Control Solution is used instead of a blood sample.

When to Perform a Quality Control Test

- Before using the Nova Max Pro Creat and eGFR Meter for the first time.
- As required by your institution's quality control policy or local regulatory requirements.
- If a patient test has been repeated and the blood Creatinine results are still lower or higher than expected.
- If there are other indications that the system is not working properly.
- If you drop the meter.

Running Nova Max Pro Creat eGFR Control Solution

The Nova Max Pro Creat eGFR Control Solution should produce results that fall within the range of results printed on the vial label of the Control being used. If the Control Solution test result is outside the range (is either higher or lower), the Meter and Test Strip may not be working properly as a system.

Important Information for Control Solution

- Use only Nova Max Pro Creat eGFR Control Solution.
- Check the expiration date on the Control Solution vial. Do not use Control Solution past the expiration date, or you may get inaccurate results.
- Use the Control Solution vial only for 90 days after the first opening. When you open a new vial of Control Solution, count forward 90 days and write that date on the label of the Control Solution vial.

Running Nova Max Pro Creat eGFR Control Solution

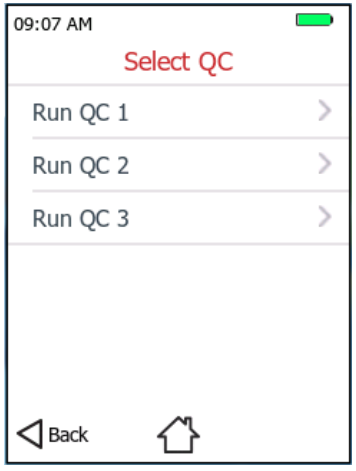
- Store the Control Solution tightly closed and refrigerated between 35.6°F and 46.4°F (2°C and 8°C). Do not freeze.
- Shake the Control Solution well before using.

If your Control Solution test results continue to fall outside the range printed on the Control Solution vial label:

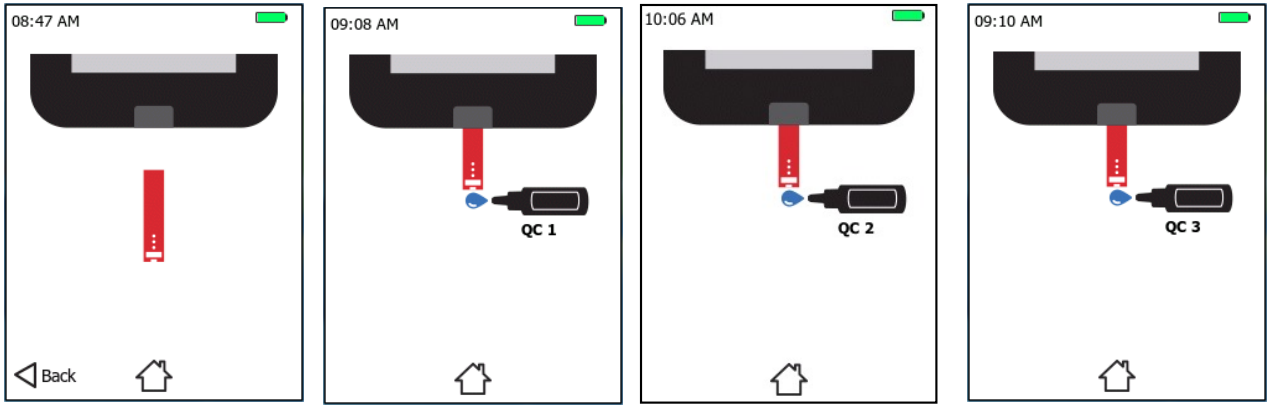
- The Nova Max Pro Creat eGFR Meter may not be working properly.
- Do not use the Meter to test the patient's blood.
- Contact Customer Service.

Running Nova Max Pro Creat eGFR Control Solution

Testing a Control Solution

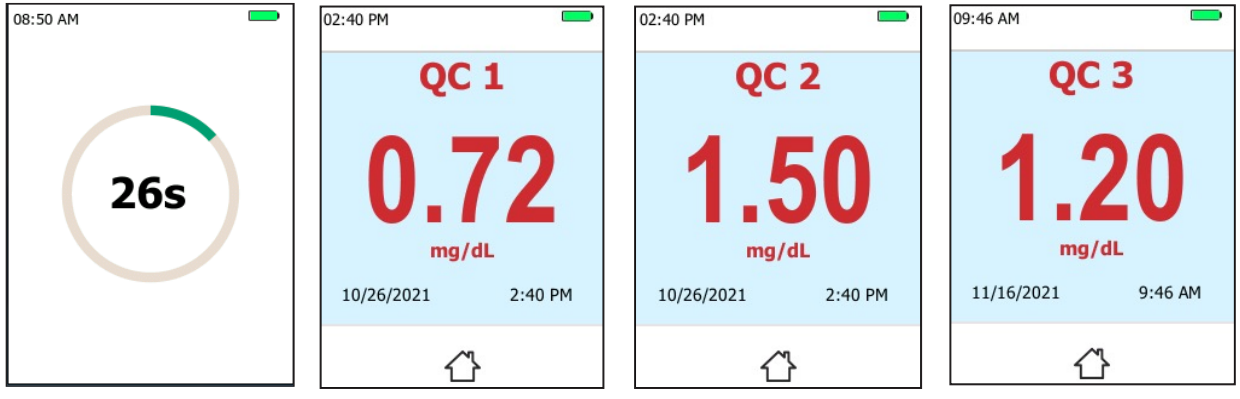


1. From the Home screen, press Run QC Test. The Select QC screen displays. Select Run QC 1, Run QC 2, or QC 3.
2. Once the QC test is selected, the Insert Test Strip screen displays. Insert a test strip.
3. The Add QC 1, QC 2, or QC 3 screen displays. Add the QC solution as shown on the display to the strip.



Running Nova Max Pro Creat eGFR Control Solution

4. The countdown waits 30 seconds for the strip reader to process results. It displays the count down in the middle of a progress wheel that shows how much time is remaining. Once the countdown reaches 0, the meter displays the Results screen.
5. The QC Result Screen displays Creatinine for the QC test. At this point, the test is finished. Press the Home button to return to the Home screen. The result can be viewed later in the Result or QC History screens.



Running Nova Max Pro Creat eGFR Control Solution

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

NOTE: *A quick beep sounds when sufficient Control Solution has been added to the Test Strip.*

NOTE: *Nova Max Pro Creat eGFR Control Solution test results are available on-screen in 30 seconds.*

Out-of-range results may be caused by the following:

- You may not be doing the test properly. Retest and follow the instructions carefully.
- The control solution may have expired or have been contaminated. Check the expiration date on the control solution vial. The control solution is good for only 90 days after opening. Make sure the control solution vial is closed when not in use.

Running Nova Max Pro Creat eGFR Control Solution

- The test strip may have expired. Check the expiration date on the test strip vial.
- The test strip may have been damaged. Retest using a new test strip.
- The Nova Max Pro Creat eGFR Meter may not be working properly.
- Acceptable quality control ranges may differ at your institution from the ranges reported by Nova Biomedical. Follow your institution's guidelines for quality control results.

NOTE: *If the Control Solution test result is outside the range (is either higher or lower), the Meter and Test Strip may not be working as a system. Repeat the process using a new Test Strip. Do not use the Meter until test results fall within the appropriate range. If the problem continues, call Customer Service.*

Nova Max Pro Creat eGFR Control/Linearity Material are traceable to NIST Standard Reference Material.

Testing a Blood Sample

Important Safety Instructions

Standard Precautions should be adhered to when handling or using the Nova Max Pro Creatinine and eGFR Meter System to reduce the risk of disease transmission.

All parts of the Nova Max Pro Creatinine and eGFR Meter System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.

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

The Nova Max Pro Creatinine and eGFR Meter System may only be utilized for testing on multiple patients when Standard Precautions are followed and when the system is cleaned and disinfected after use on each patient following the procedure in the Cleaning and Disinfecting the Meter section.

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

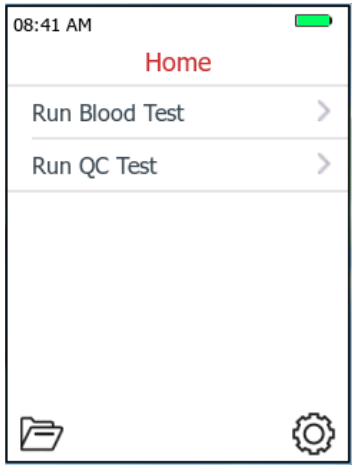
Testing a Blood Sample

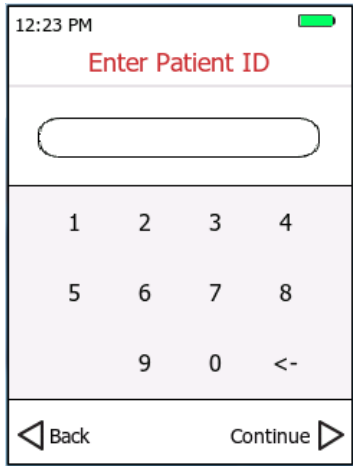
For more information, refer to the following references:

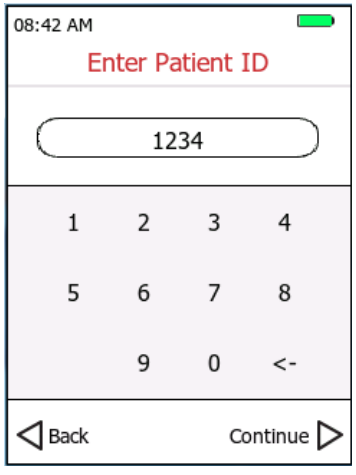
- "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," http://www.cdc.gov/hicpac/2007ip/2007isolationprecautons.html.
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/. "Protection of Laboratory Workers From Occupationally Acquired Infection ; Approved Guideline - Fourth Edition," Clinical and Laboratory Standards Institute (CLSI) M29-A4.
- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication." (2010) http://www.fda.gov/Medicaldevices/Safety/AlertsandNotices/ucm224025.html.
- "CDC Clinical Reminder: Use of Fingerstick Devices. https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html.

Testing a Blood Sample

1. From the Home screen, press Run Blood Test.
   This starts the process to run a patient test.
2. The Enter Patient ID screen displays. You can enter the ID by number only.

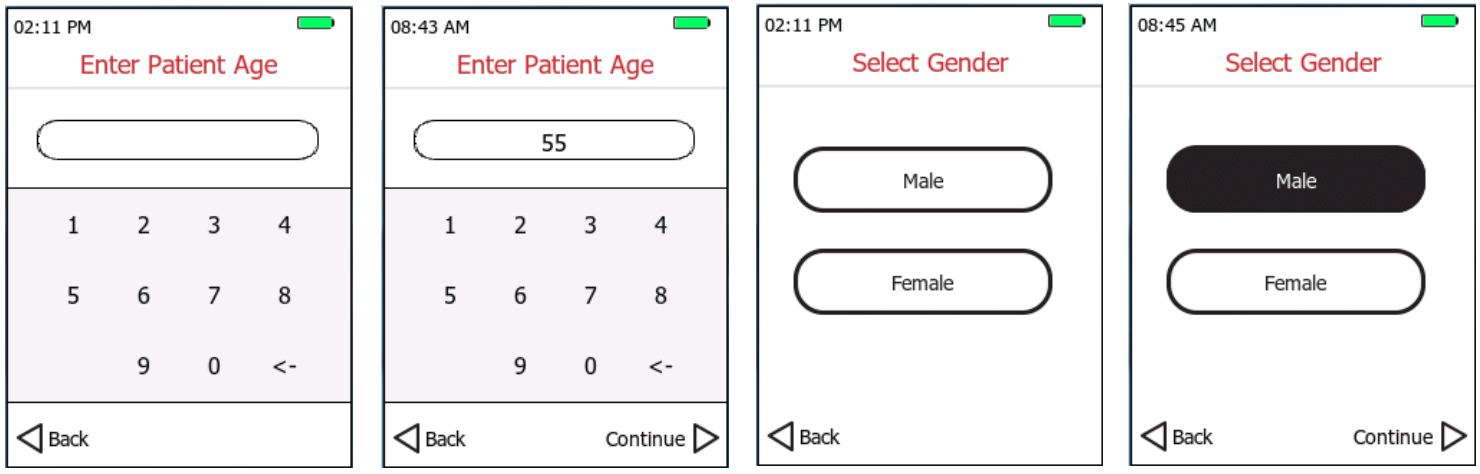






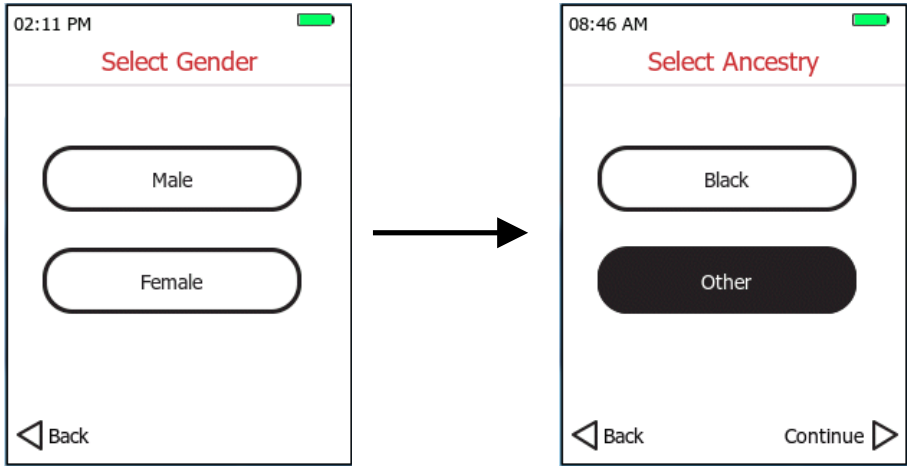
Testing a Blood Sample

3. Enter Patient ID allows the patient's ID to be stored with their data.
4. Press the Continue button to display the Enter Patient Age screen. Enter the patient's age for this test from 18-130 years.
5. Press the Continue button to display the Select Gender screen: press Male or Female.



Testing a Blood Sample

6. Press the Continue button to display the Select Ancestry screen: press Black or Other.

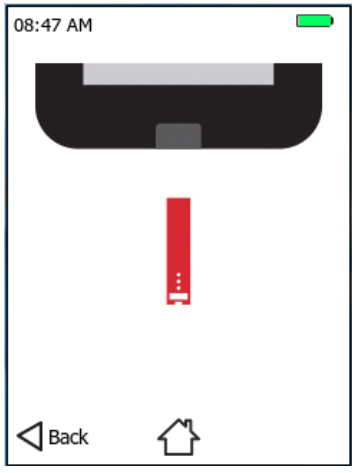


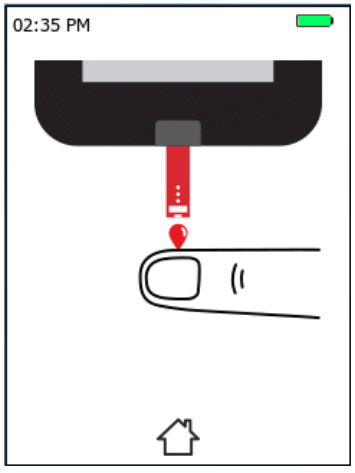
NOTE: *Both radio buttons are unchecked on the initial startup for Select Gender and Select Ancestry screens. This data is used to calculate eGFR and is stored with the result. If you navigate back to this page through settings, one will already be selected.*

Testing a Blood Sample

7. Press the Continue button to display the Insert Strip screen. The meter waits for you to insert a strip. Once the test strip is inserted the meter transitions to the Apply Sample screen.
8. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.
9. Holding hand downward, massage finger with thumb toward the tip to stimulate blood flow.
10. 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.
11. Squeeze the finger to form a drop of blood. Wipe away the first drop of blood then squeeze the finger again to form a second drop of blood.

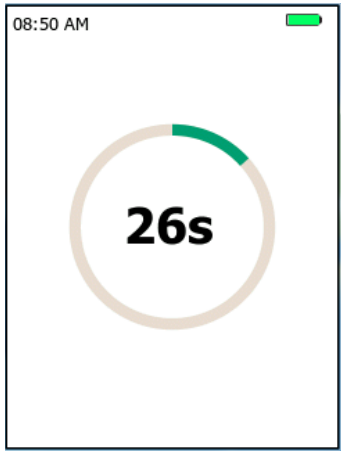
Testing a Blood Sample





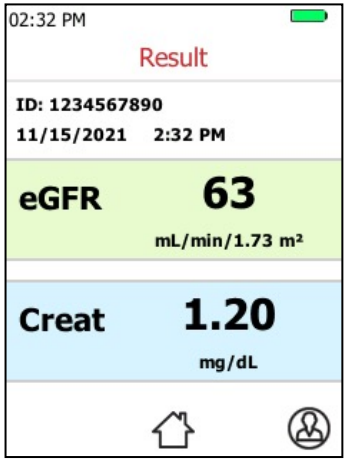
12. Touch the end of the Test Strip to the fresh blood drop until the Test Strip fills and the on-screen countdown timer begins. (Beeper sounds if enabled.)

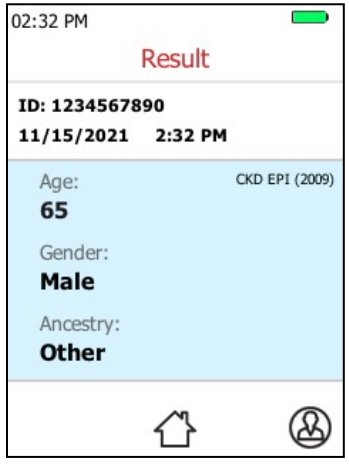
13. A countdown on the screen appears while the test is in progress. The eGFR and Creat results are available on-screen in 30 seconds.



Testing a Blood Sample

14. The Result Screen displays the eGFR and Creat results. At this point, the test is finished. The result can be viewed later in the Result screens. You can also click on the patient demographics icon which shows their settings for eGFR. Press the Home button to return to the Home screen.





Testing a Blood Sample

15. The result is automatically stored in memory.

16. Wash your hands thoroughly with soap and water after handling the Meter, Lancet, or Test Strips.

NOTE: *Do not press the Test Strip directly against the skin. Touch the Test Strip gently to the blood drop.*

NOTE: *Discard used Lancets and Test Strips in a puncture-proof container such as a biohazard container.*

Test Result

Red	Orange	Yellow	Green
>30 mL/min/1.73m^2	30-45 mL/min/1.73m^2	45-60 mL/min/1.73m^2	60>90 mL/min/1.73m^2

NOTE: *The meter flags calculated eGFR values into four categories: Red, Orange, Yellow and Green. The eGFR number indicates how well the kidneys are functioning. As kidney disease progresses, eGFR goes down.*

Test Result

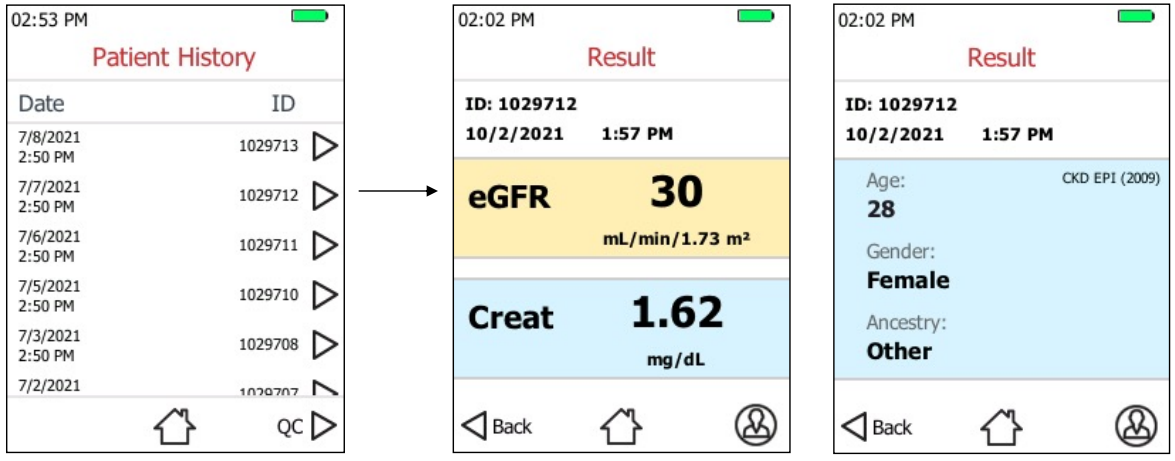
The Stages of Chronic Kidney Disease vs the eGFR value is shown in the table below.

Stages of Chronic Kidney Disease		eGFR	% of Kidney Function
Stage 1	Kidney damage with normal kidney function	90 or higher	
Stage 2	Kidney damage with mild loss of kidney function	89-60	
Stage 3a	Mild to Moderate loss of kidney function	59-45	
Stage 3b	Moderate to severe loss of kidney function	44-30	
Stage 4	Severe loss of kidney function	29-15	
Stage 5	Kidney Failure	Less than 15	

Review Test Results in Memory

To review test results that are stored in memory, start with the Meter displaying the Home screen. The Home screen has a History button.

1. Pressing this button displays the Patient History screen.



2. The Result History screen displays a scroll wheel with all available results based on Date and Patient ID. Pressing a Patient ID displays the patient's test results and demographics.

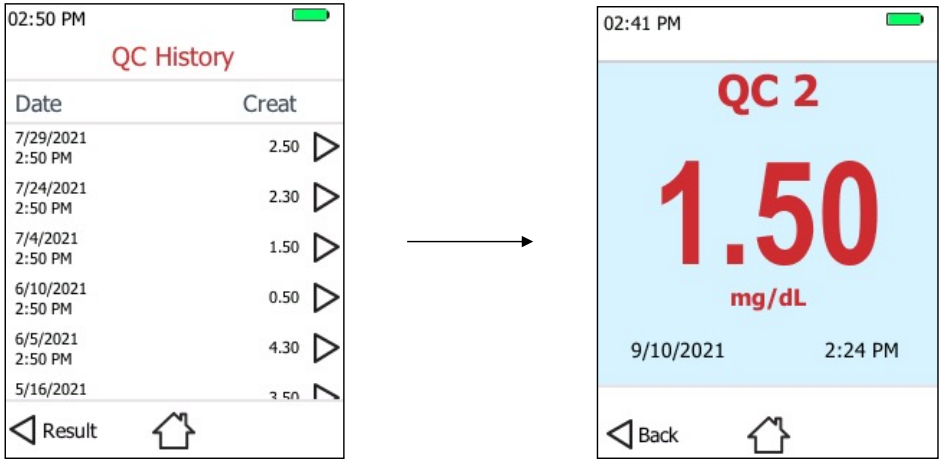
Review Test Results in Memory

3. Press the Patient Settings icon  to open the Patient demographics screen for that patient , press the Back button to go back to the Patient History screen, or press the Home button to return to the Home screen.

4. To review QC History, press the QC button at the bottom right of the Patient History screen.

Review Test Results in Memory

5. The QC History screen displays a scroll wheel with all available QC results based on Date and Creatinine.
6. Select a QC result by date or a Creat result to display the Result screen.



7. At the bottom left of the QC Result screen, press the Result button to return the Result History screen.

Basic Upkeep

Battery Check

The Meter displays a green battery status bar when the battery charge is >33%. The status bar changes color from green to yellow to red to remind the user to recharge the battery. Test results are stored in non-volatile memory to prevent test result loss.

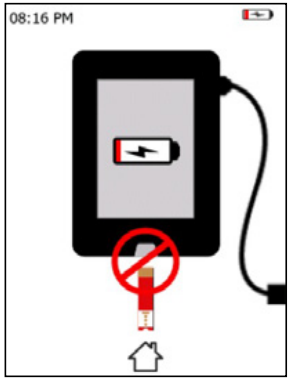
How to view the battery status of the Meter:

- **Battery is Low:** The Meter displays a yellow battery status bar when the battery charge is >10% and ≤33 %.
  Continue with testing as usual. If possible, recharge the battery.

- **Battery is Very Low:** The Meter displaya a red battery status bar when the battery charge is ≤10%. It is best to recharge the battery as soon as possible.

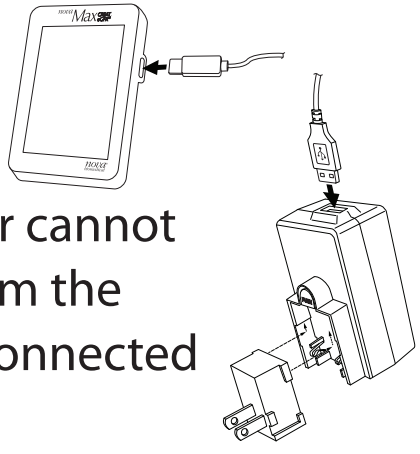
Basic Upkeep

Charging the Battery



The Meter is charged like a cell phone, using an external power supply connected to an electric outlet, and a charging cable connecting the power supply to the meter. The meter should be recharged when the battery icon changes color from green to yellow or red.

Patient and QC sample analysis cannot be performed while the meter is charging, and a No Testing, charging screen is displayed if a test strip is inserted. The remaining meter functions, Patient and QC history and Meter Settings, are fully accessible while the meter is charging.



Charge the meter for several hours or until the battery icon is displayed completely in green, the meter cannot be overcharged. The meter can be disconnected from the charger at any time to run sample analysis, then reconnected to the charger to complete the charging cycle.

Basic Upkeep

Cleaning and Disinfecting the Meter

WARNING: Cleaning is not the same as disinfecting. Cleaning means removing protein or other contaminants from the surface. Disinfecting means to kill or prevent the growth of disease-carrying microorganisms.

The Nova Max Pro Creat and eGFR Meter should be cleaned and disinfected after each patient use over the intended use-life of the Meter. The cleaning and the disinfecting procedure was validated a total of 10,950 times by Nova Biomedical to simulate a 3-year use-life of the Meter. The validation testing corresponded to cleaning and disinfecting 10 times a day for 3 years.

Basic Upkeep

Meter Cleaning and Disinfection Procedure

Clean and disinfect after each patient use by following this protocol to help ensure effective cleaning and disinfection. Cleaning is not the same as disinfecting. Cleaning is intended to remove protein, visible blood, bodily fluids, and soils from the external surfaces. Disinfecting means killing or preventing the growth of disease-carrying microorganisms.

The Nova Max Pro Creat and eGFR Meter should be cleaned and disinfected after each patient use to minimize the risk of transmission of blood-borne pathogens between patients and healthcare professionals.

Healthcare professionals and others should follow Good Laboratory Practice guidelines and these important safety instructions. Healthcare professionals should ensure they are wearing protective gloves when disinfecting the meter and should wash their hands thoroughly with soap and water after handling the Meter.

Basic Upkeep

IMPORTANT: *Nova recommends cleaning and disinfecting the Meter with the following EPA Registered product - Clorox® Germicidal Wipes, EPA Registration #67619-12, or Super Sani-Cloth® Germicidal Disposable Wipes, EPA Registration #9480-4. Clorox Germicidal Wipes are available from the following suppliers: Amazon.com: http://www.amazon.com Clorox Healthcare: 1-800-234-7700 Office Depot: http://www.officedepot.com.*

NOTE: *Cleaning and disinfection may in rare cases damage the device(s). Meter damage may include plastic housing cracks, cloudiness, or frosting of the display, legibility or response issues with the keypad, or battery compartment fluid leakage. Signs of Meter performance deterioration may include failure to recover proper control results or the inability to perform a blood test. If you observe damage due to cleaning and disinfecting, please stop using the Meter and contact Customer Service.*

Basic Upkeep

Cleaning and Disinfecting the Meter

NOTE: *To properly clean and disinfect the Meter, steps 1 to 5 should be performed together before testing on each patient.*

1. **Clean the Meter.**
   - Wipe the external surface of the Meter thoroughly with a fresh Germicidal Wipe.
   - Discard the used wipe per Step 4.

2. **Disinfect the Meter.**
   - Remove another fresh Germicidal Wipe from the canister. Thoroughly wipe the top, bottom, left, and right sides of the Meter avoiding the Test Strip port by wiping the surface a minimum of 3 times horizontally followed by 3 times vertically.

Basic Upkeep

3. Observe surface contact time.

- Ensure the Meter surface stays wet **for the recommended time** and is allowed to air dry for an additional **1 minute**.

NOTE: *If you must rewet the surface of the Meter, use a new, fresh wipe.*

4. Dispose of wipes

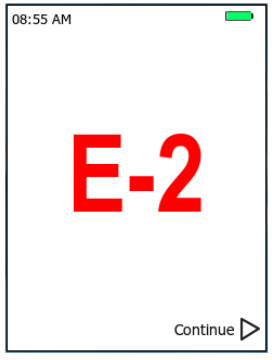
- Dispose of the used germicidal wipes in a standard waste container.

5. Wash and sanitize hands.

- Wash your hands thoroughly with soap and water.

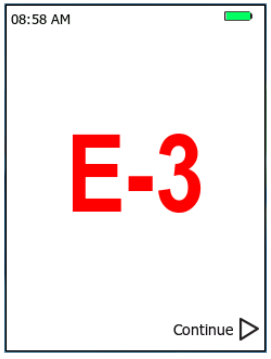
Displays, Meanings, Actions

This section addresses the messages that appear on your displays, what they mean, and what action you need to take.

Display	What it Means	What to Do
	**Temperature Error** When the test strip was inserted, the Meter detected operating temperature out of range. The Meter shall generate 3 short beeps.	The Meter is outside the required temperature range 59°F to 104°F (15°C to 40°C). Move the Meter to a warmer or cooler area and wait a few minutes.

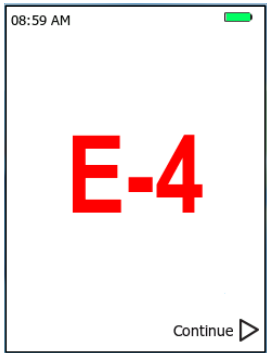
Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.

Displays, Meanings, Actions



Test Strip Error
The Meter detected the inserted test strip is defective. The Meter shall generate 3 short beeps.

Replace with a new strip. Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.



Sample Error
The Meter detected a sample flow problem when applying a sample on the test strip. The Meter shall generate 3 short beeps.

An insufficient sample volume was drawn into the Test Strip. Repeat the test with a new strip. Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.

Displays, Meanings, Actions

Display	What it Means	What to Do
The Meter does not turn on after inserting Test Strip.	• Test Strip inserted upside down or not completely in.	Insert the Test Strip correctly with the Creat name and white tip facing up and out.
	• The battery is dead.	Recharge the battery. Call Customer Service.

Displays, Meanings, Actions

The Meter does not begin test countdown after applying a blood sample	• Not enough blood sample	Repeat the test with a new Test Strip.
	• Sample applied after Meter automatically turned off	Repeat the test with a new Test Strip.
	• Test Strip may be damaged	Repeat the test with a new Test Strip.
	• The Meter may not be working properly	After 3 attempts, call Customer Service.

Appendix

Specifications

Test Measured	Creatinine and eGFR
Creat Methodology	Enzyme, Amperometric
Creat Blood Test Results	0.30-7.00 mg/dL or 27-619 µmol/L (Plasma values)
Sample type	Capillary whole blood from the fingertip
eGFR Test range	15 - >90 mL/min/1.73 m^2
Limit of Detection	0.119 mg/dL
Limit of Quantitation	0.160 mg/dL
Length of Test	30 seconds
Test Strip Volumes	1.2 µL

Appendix

Battery Life (normal)	400 Tests
Low Battery Life	About 10 Tests
Operating Ranges	
Temperature	59°F to 104°F (15°C to 40°C)
Humidity	10% to 90% relative humidity
Weight	3.17 oz (90 g)
Size	3.75 x 2.44 x 0.74 in (95.25 x 61.98 x 18.80 mm)
Meter data storage	400 Results

Appendix

Accuracy and Precision

Clinical Accuracy

Clinical accuracy was assessed within 3 Point-of-Care/Near Patient Testing (POC/NPT) settings on normal subjects and subjects previously diagnosed with chronic kidney disease (CKD). The clinical study compared the creatinine and eGFR results obtained from capillary whole blood specimens obtained by finger-stick measured on the Nova Max Pro Creatinine and eGFR Meter with venous, plasma creatinine and eGFR results measured on the IDMS traceable, Seimens Healthineers Dimension RxL Chemistry System (Seimens Healthineers, Erlangen Germany). The eGFR results reported in this study were derived using the CKD-EPI eGFR equation A sensitivity and specificity analysis were performed using the reported eGFR to assess the ability of the Nova Max Pro Creatinine and eGFR Meter System to correctly screen enrolled subjects for

kidney disease. Sensitivity is defined as the ability to correctly identify patients with a disease. Specificity is defined as the ability to correctly identify patients without a disease. The eGFR clinical cut-off level for normal/abnormal kidney function used for this assessment was 60 mL/min/1.73m2. Subjects with an eGFR above 60 mL/min/1.73m2 are considered to have normal kidney function. Subjects below 60 mL/min/1.73m2 are considered to have abnormal kidney function. Pooled eGFR data from all 3 clinical testing sites is shown below.

Sensitivity = 98.8% (342/346)

Specificity = 79.2% (57/72)

TN = 57

FN = 4

FP = 15

TP = 342

Appendix

Pooled creatinine data assessed using Linear Regression from all 3 clinical testing sites is shown below.

Capillary Whole Blood obtained from Finger-stick
Number of Samples:
Slope:
Y-intercept:
R squared (R2):

Appendix

Clinical Precision

Within-run precision was assessed using venous whole blood collected in lithium heparin within 3 POC/NPT settings at 3 different creatinine target levels. Typical creatinine within-run precision performance is shown in Table 1 below. Day-to-Day Precision was assessed using stabilized control solutions within 3 POC/NPT settings at 3 different creatinine target levels over 20 days: 4 measurements per day. Typical Day-to-Day results are shown in Table 2 below.

Table 1
Typical Within-Run Precision – Venous Whole Blood Results

Table 2
Typical Day-to-Day Precision – Control Solution Results

Appendix

Ordering Information

Supplies and parts for the Nova Max Pro Creatinine and eGFR Meter System are available from Nova Biomedical.

DESCRIPTION	**Part #**
Nova Max Pro Creat eGFR Creatinine Test Strips	63983
Nova Max Pro Creat eGFR Creatinine Control Solution Level 1	63941
Nova Max Pro Creat eGFR Creatinine Control Solution Level 2	63942
Nova Max Pro Creat eGFR Creat Linearity Level 1, 2, and 3	63946
PWR SUP SWI5 UNIV AC IN DC 5VO USB	61583
CABL ASSY USB-A TO USB-C M/M 1.2 METER	64006

Appendix

Warranty

Your Nova Max Pro Creat and eGFR Meter is warranted to be free of material and workmanship defects for 3 years from the date of purchase (except as noted below). If at any time during the first 3 years after purchase your Nova Max Pro Creat and eGFR Meter does not work for any reason (other than as described below), it will be replaced with a new Meter, or a substantial equivalent, free of charge.

Limitations on Warranty: This warranty is subject to the following exceptions and limitations:

1. This warranty applies only to the original purchaser.
2. This warranty does not apply to units which malfunction or are damaged due to obvious abuse, misuse, alteration, neglect, unauthorized maintenance, or failure to operate Meter in accordance with instructions.
3. We have no knowledge of the performance of the Nova Max

Pro Creat and eGFR Meter when used with Test Strips other than Nova Max Pro Creat and eGFR Test Strips. Therefore, we make no warranty as to the performance of the Nova Max Pro Creat eGFR Meter when used with any Test Strips other than Nova Max Pro Creat and eGFR Test Strips.

4. There is no other express warranty for this product. The option of a replacement, described above, is the warrantor's only obligation under this warranty.

For warranty service: Contact Nova Biomedical or your local distributor.

Privacy Policy: Nova Biomedical is committed to using your personal information responsibly and in compliance with the law. You have our pledge that we will not share or sell your personal information with marketers or third parties. The information you voluntarily share with us will be used to help us serve you better in the future.

Appendix

Serious Incidents/Adverse Advents

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

Revision History

PN 64322 Rev A: Initial Release

nova®
biomedical