INSTRUCTIONS FOR USE

NOVA MAX CREAT eGFR MONITORING SYSTEM

For Investigational Use Only

nova® biomedical

Nova Max® Creat eGFR Monitoring 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

IVD CE

PN 64548 Rev. A 12/2021

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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

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

 Caution, consult accompanying documents

 Consult instructions for use

 Biological risk

 Use By

LOT — Lot Number

℞ Only — Prescription Use Only

 Electronic Waste

REF — Catalog number

 Temperature limitation

 Upper Limit of Temperature

 Manufactured by

nova® biomedical

Important Information!

- Before you begin using your new Nova Max Creat 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 Creat eGFR Test Strips and the Nova Max Creat eGFR Control Solutions.
- Your Meter uses a rechargeable 3.7 V Li-Polymer battery. To begin using your Meter, you may 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.*

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Intended Use

The Nova Max Creatinine and eGFR Monitoring System is intended for *in vitro* diagnostic use for the quantitative measurement of creatinine in capillary whole blood obtained from the fingertip for monitoring of kidney health by calculating Estimated Glomerular Filtration Rate (eGFR).

The system should only be used with the Nova Max Creatinine and eGFR Test Strips and Nova Max Creatinine and eGFR 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.

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 Creat and eGFR, i.e., Test Strips, lancets, and alcohol swabs, must be disposed of in accordance with local regulations to avoid risk to anyone.*

Limitations

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

- Blood – Use only capillary whole blood obtained from the fingertip. Do not use serum or plasma.
- Do not use the Nova Max Creat eGFR Test Strips 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.

Blood-Borne Pathogens Safety

1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the Nova Max Creat eGFR Monitoring System.
2. Healthcare professionals should be aware that all parts of the Nova Max Creat eGFR Monitoring System are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
3. Only auto-disabling, single-use lancing devices may be used with this system.
4. For more information, refer to the following references:

Important Safety Instructions

"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 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) http://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.

Introduction

The Nova Max Creat 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

General Safety

Persons 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.

Introduction

Before Testing

To ensure accurate Creatinine and eGFR results, wash and thoroughly dry your hands before testing.

Test Strips

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

Introduction

Important Nova Max Creat eGFR Test Strip Information

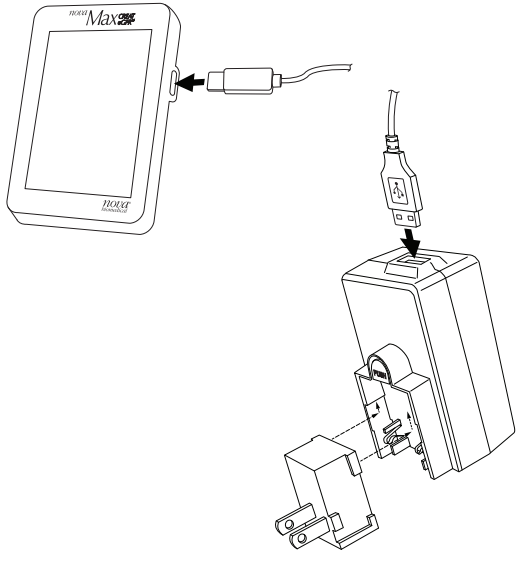
- Use only Nova Max Creat eGFR Test Strips when testing.
- Remove the Test Strip from the vial only when ready to test.
- Storage temperature for the Nova Max Creat eGFR Test Strips and Nova Max Creat eGFR Control Solution: 35.6°F to 46.4°F (2°C to 8°C).
- Do not freeze.
- Do not store near heat or moisture.
- 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.

Introduction

Nova Max Creat eGFR Meter Components

Getting Started

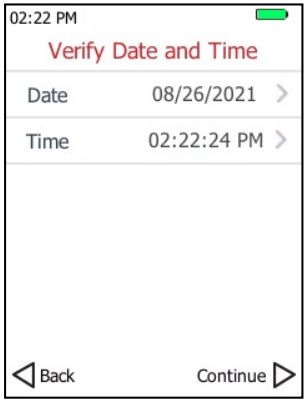
Charge the Meter's battery before use. Connect the included power supply to a wall outlet, then insert one end of the charging cable into the power supply and the other into the Meter's charging cable connector. The Meter may display the charging screen for several minutes. Once the battery is sufficiently charged the Meter will prompt you to configure it for use. In addition to selecting the Language, Date, and Time, the Meter asks you to enter your Age, Gender, and Ancestry for accurate eGFR results. These settings can be changed later in the Meter Settings menu if desired.



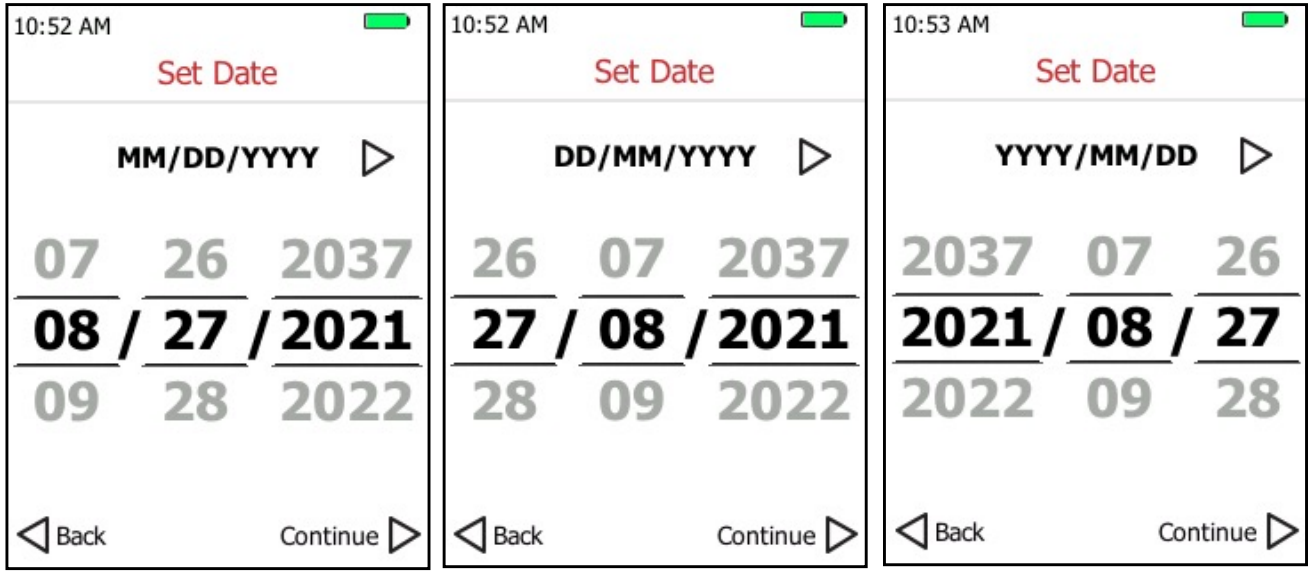
Getting Started

1. Set the desired language for use on the Meter. Press the ▷ button to the right of the desired language to select it for use. Once selected, the display will switch to the Verify Date and Time screen.

2. From the Verify Date and Time screen, to change the Date, touch the current date to display the Set Date screen.
   To change the Time, touch the current time to display the Set Time screen.
   When the correct Date and Time is displayed, press Continue to go to the Birth Date screen or press Back to return to the Language screen.



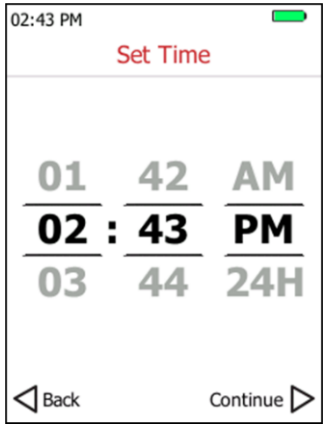
3. To set the current date, first select the date display order. Press the ▷ icon next to the date display order to scroll through the 3 available options, MM/DD/YYYY, DD/MM/YYYY, or YYYY/MM/DD.

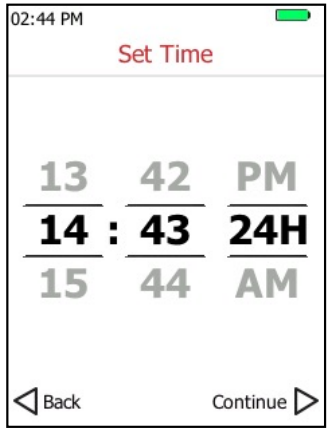


Set Date uses 3 scroll wheels for the month (1-12), day (1-31), and year (2021-2037). Scroll up or down to select the current month, day, and year. Press Continue to save the date and

return to the Verify Date and Time screen. Press Back to discard any changes and return to the Verify Date and Time screen.

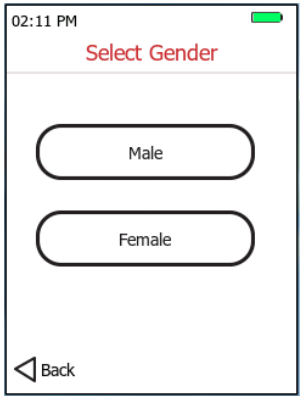
4. Set Time uses 3 scroll wheels for the hour (1- 12), minute (0-59), and type (AM, PM, or 24H). The hour wheel will update (00-23) if 24H is selected. Press Continue to save the time and return to the Verify Date and Time screen. Press Back to discard any changes and return to the Verify Date and Time screen.

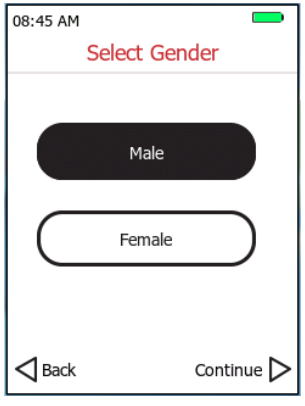




5. Select your Birth Date using the 3 scroll wheels for month (1-12), day (1-31), and year (allows for ages 18-120). The Day scroll wheel adjusts depending on how many days are in the month. Press Continue to advance to the Select Gender screen or press Back to return to the Verify Date and Time screen.

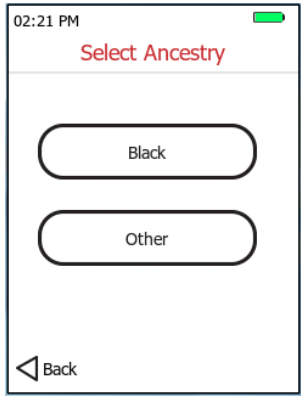
6. From the Select Gender screen, select Male or Female. The selection will turn dark to confirm your choice. Press Continue to advance to the Select Ancestry screen or press Back to return to the Select Birth Date screen.

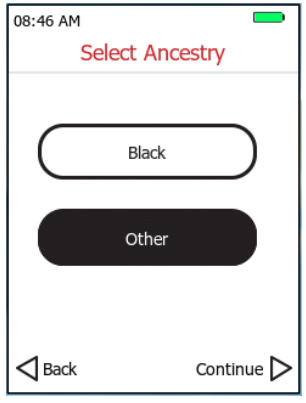




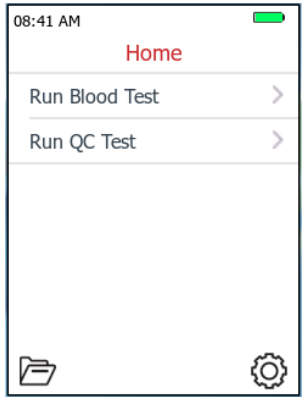
Getting Started

7. From the Select Ancestry screen, select Black or Other. The selection will turn dark to confirm your choice. Press Continue to review your settings or press Back to return to the Select Gender screen.



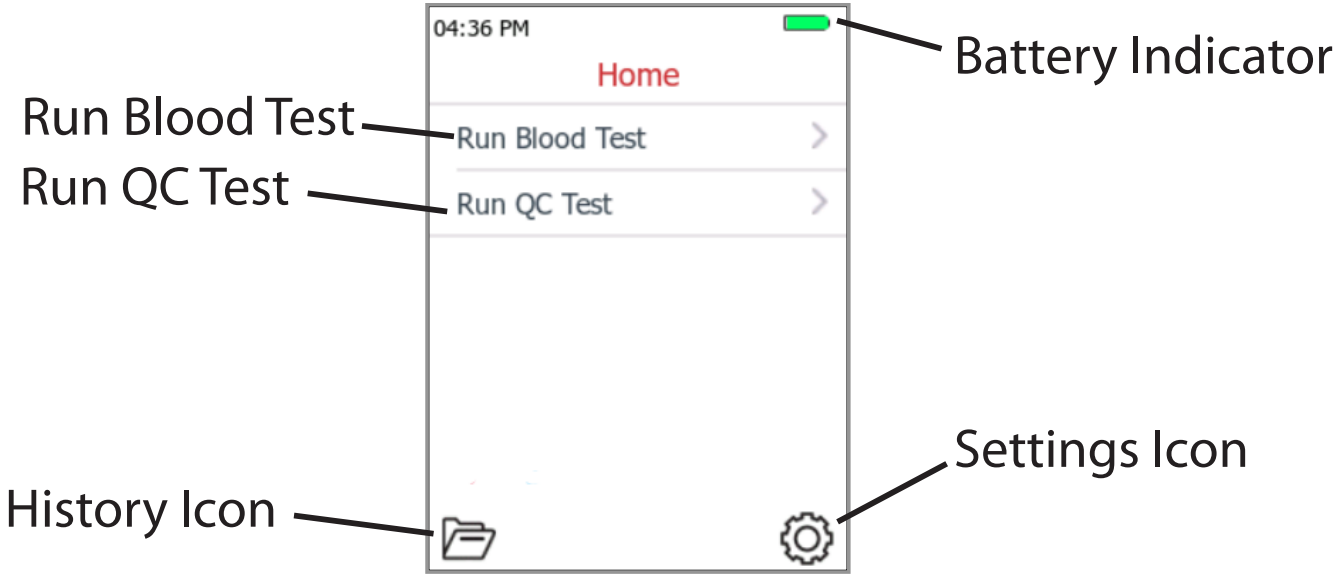


8. Your selections for Date of Birth, Gender, and Ancestry are displayed. If your selections are correct press Continue to advance to the Home screen. Use the Back button to return to any of the first-time setup settings if necessary.



Getting Started

Home Screen



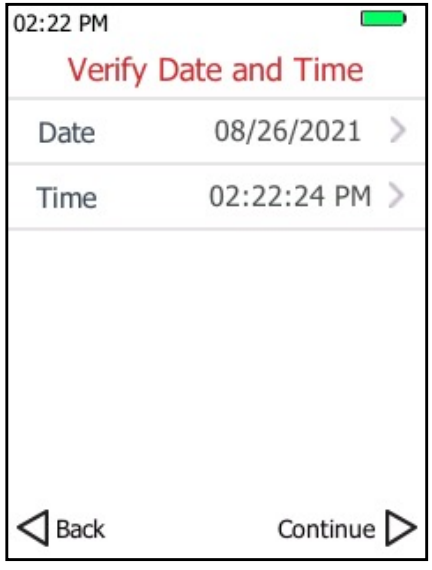
Nova Max Creat eGFR Meter Screen Display

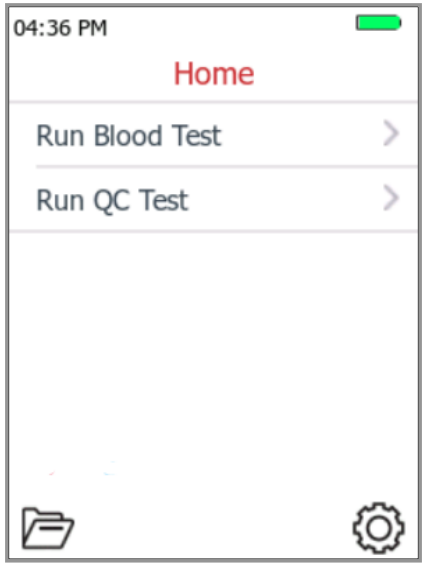
Getting Started

To conserve battery power, the Meter turns off the display after 60 seconds of inactivity (120 seconds if a test strip is inserted). After 30 minutes of inactivity, the Meter automatically turns itself off. To manually turn off the display, press the power button on the left side of the Meter briefly. To turn the Meter off, press and hold the power button down for 5 seconds until the display turns off.

Getting Started

To use the Meter, press the power button. If the Meter was off, the Meter will boot up and display the Verify Date/Time screen.





Press Continue to display the Home screen. If the Meter was in sleep mode, the screen shown when the Meter entered sleep mode is displayed.

Running Nova Max Creat eGFR Control Solution

Nova Max Creat eGFR Control Solution

Nova Max 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.
- If the Meter reading is within the range printed on the Control Solution vial label, the Meter and test strips are working properly.

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 Creat eGFR Control Solution is used instead of a blood sample.

Running Nova Max Creat eGFR Control Solution

When to Perform a Quality Control Test

- When opening a new vial of the Test Strips.
- If there are indications that the system is not working properly.
- If you drop the Meter.

The Nova Max 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.

Running Nova Max Creat eGFR Control Solution

Important Information for Control Solution

- Use only Nova Max 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 3 months after the first opening. When you open a new vial of Control Solution, count forward 3 months and write that date on the label of the Control Solution vial.
- 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.

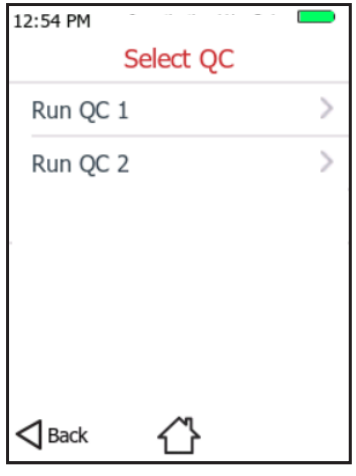
Running Nova Max Creat eGFR Control Solution

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

- The Nova Max Creat eGFR Meter and Test Strips may not be working properly.
- Do not use the Meter to test your blood.
- Contact Customer Service.

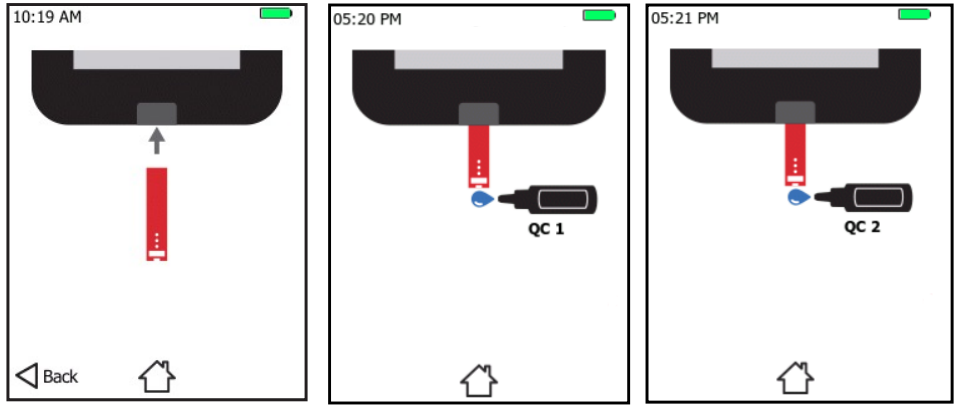
Testing a Control Solution

1. From the Home screen, press Run QC Test. The Select QC screen displays. Select Run QC 1 or Run QC 2.
2. Once the QC test is selected the Insert Test Strip screen displays. Insert a test strip.



Running Nova Max Creat eGFR Control Solution

3. The Run QC 1 or QC 2 screen displays. Touch the end of the Test Strip to the QC drop until the Test Strip fills and the on-screen countdown timer begins. (Beeper sounds if enabled.)



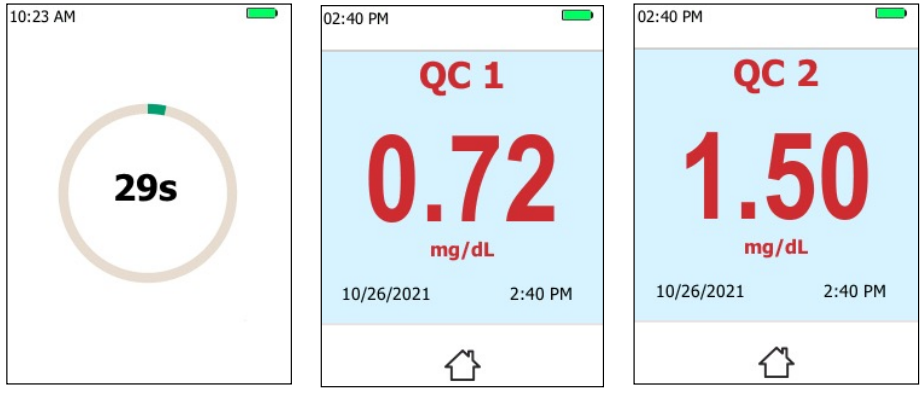
Arrow flashes.

Blue Drop flashes.

4. A countdown on the screen appears while the test is in progress. The QC result is displayed on-screen in 30 seconds and automatically stored in memory.

Running Nova Max Creat eGFR Control Solution

5. Press the Home button to return to the Home screen The result can be viewed later in the QC History screen.



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

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

- An error in performing the Control Solution test, retest and follow the instructions carefully.

Running Nova Max Creat eGFR Control Solution

- The Control Solution may have expired or have been contaminated. Check the expiration date on the Control Solution vial. Control Solution is good for only 3 months after the first opening. Make sure the Control Solution vial is closed when not in use.
- Expired Test Strip, check the expiration date on the Test Strip vial. Test Strips are good for only 3 months after the first opening. Make sure the Test Strip vial is closed when not in use.
- The Test Strip may have been damaged. Retest using a new Test Strip.
- The Meter may not be working properly.

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.*

Testing a Blood Sample

Important Safety Instructions

Standard Precautions should be adhered to when handling or using the Nova Max Creat eGFR Monitoring System to reduce the risk of disease transmission.

All parts of the Nova Max Creat eGFR Monitoring System are considered potentially infectious and can potentially transmit blood-borne pathogens.

Only auto-disabling, single-use, 21 gauge lancing devices may be used with this system.

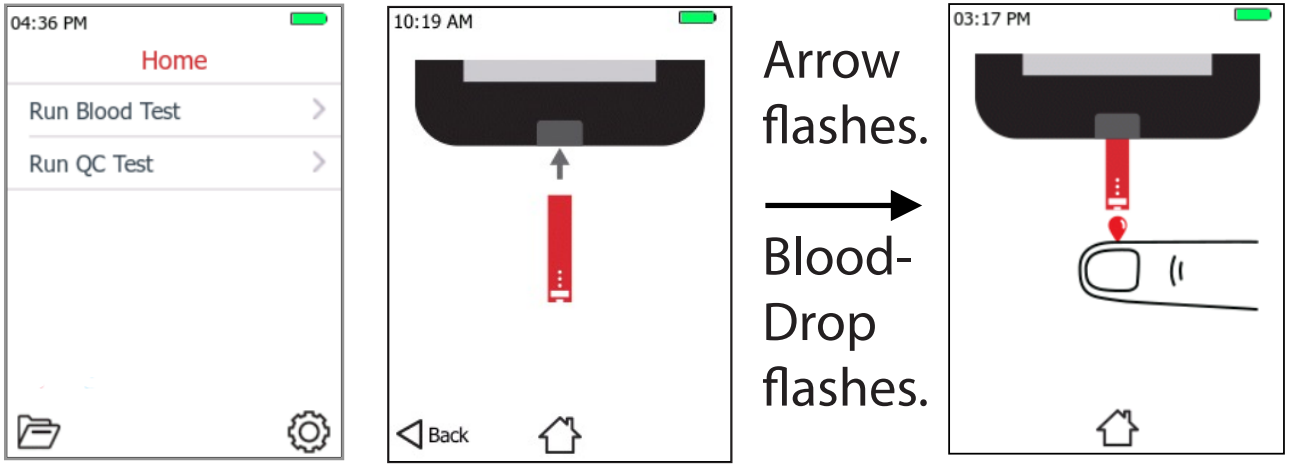
Testing a Blood Sample

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 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) http://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 your test.



2. Press the Continue button to display the Insert Strip screen. The Meter waits for you to insert a strip. Once done the Meter transitions to the Apply Sample screen.

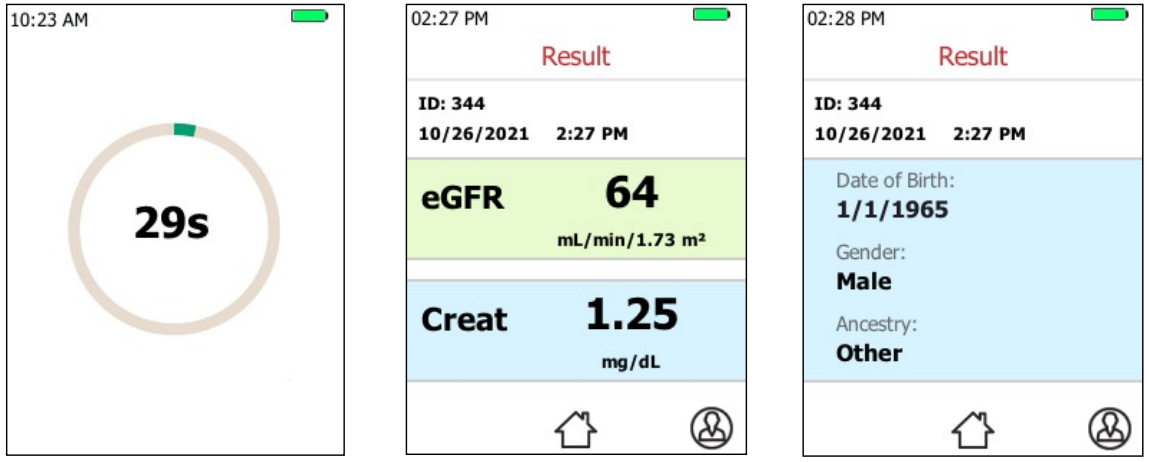
Testing a Blood Sample

3. Wash your hands with soap and warm water then dry thoroughly after cleaning.
4. Holding the hand downward, massage your finger with the thumb toward the tip to stimulate blood flow.
5. Use a single-use, disposable 21 gauge safety Lancet to puncture the finger.
6. Squeeze your finger to form a drop of blood. Wipe away the first drop of blood then squeeze your finger again to form a second drop of blood.

10. 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.)

Testing a Blood Sample

11. A countdown on the screen appears while the test is in progress. The eGFR and Creat results are displayed in 30 seconds and automatically stored in memory.



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

Testing a Blood Sample

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 eGFR number indicates how well the kidneys are functioning. As kidney disease progresses, eGFR goes down.*

Test Result

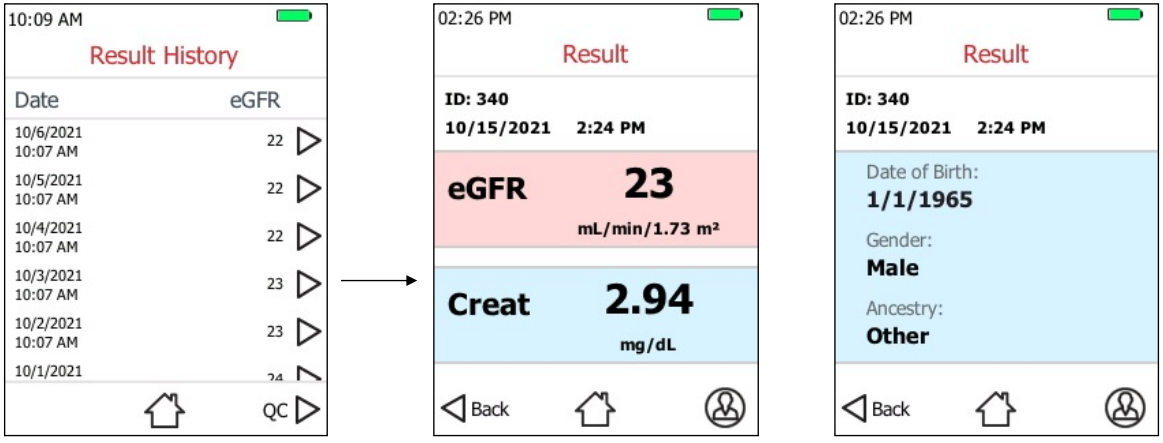
The Stages of Chronic Kidney Disease vs the eGFR value is shown in the table below. (National Kidney Foundation/Estimated Glomerular Filtration Rate (eGFR): kidney.org.)

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 your 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 Result History screen.

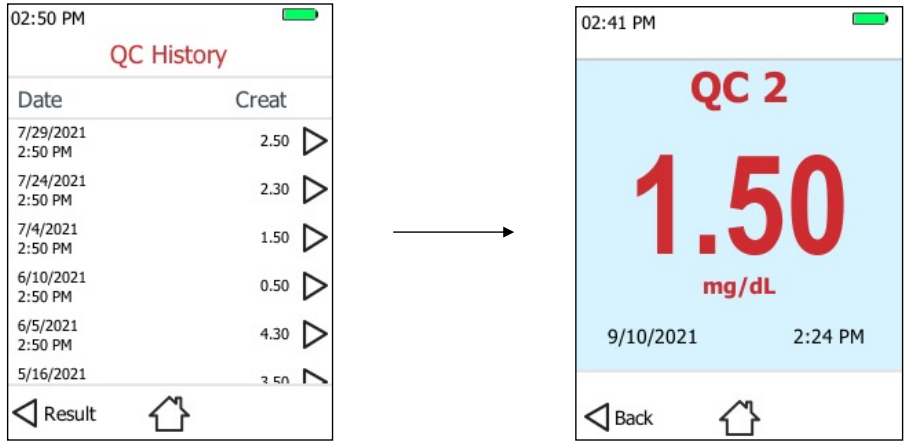


Review Test Results in Memory

2. The Result History screen displays a scroll wheel with all available results based on Date. Pressing the Right Arrow  button for one of your result dates displays that result.
3. Press the Personal Settings icon  to open your Result Settings screen.

Review Test Results in Memory

5. To review QC History, press the QC button at the bottom right of the Result History screen.
6. The QC History screen displays a scroll wheel with all available QC results based on Date.
7. Select a QC result by date or a Creat result to display the Result screen.

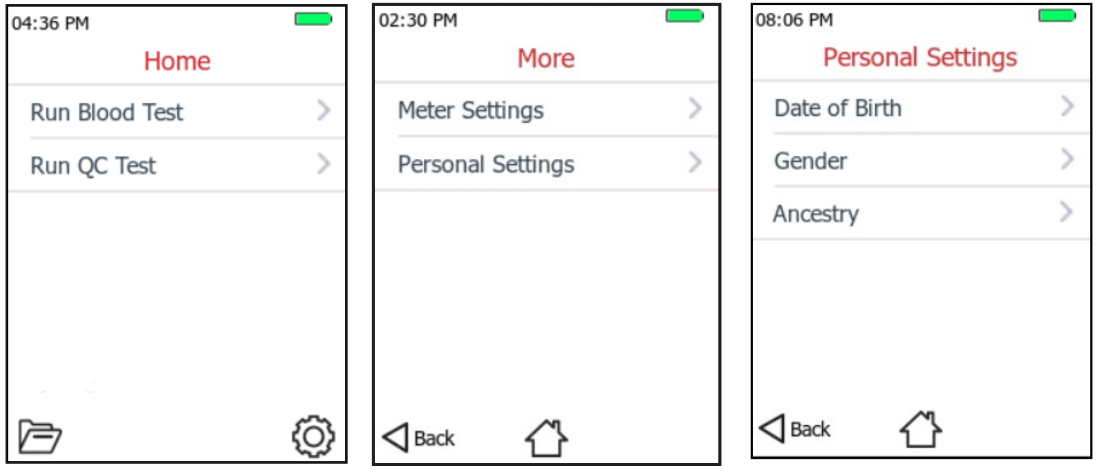


8. At the bottom left of the QC Result screen, press the Back button to return the Result History screen or Home button.

Setting: Time, Date, Beeper, Versions

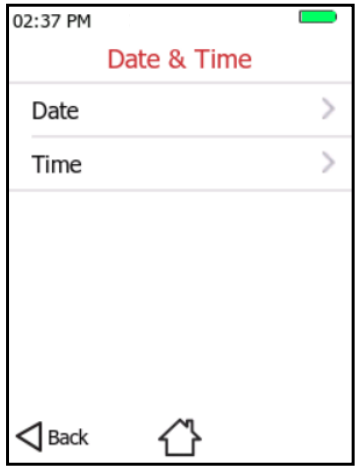
The Meter Settings menu provides a means of setting the date and time to match the local time zone or adjust for daylight savings. An alert tone can be enabled for the user if desired and the Meter Software and Strip Reader version, as well as the serial number of the Meter, are displayed.

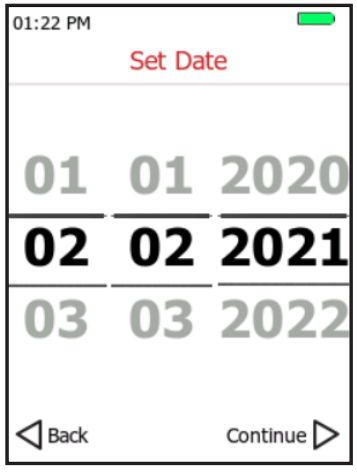
1. To access the Meter settings menu; from the Home screen, press the Settings icon .



Setting: Time, Date, Beeper, Versions

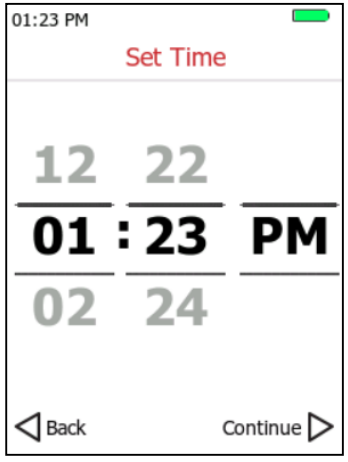
2. The More screen displays; press Meter Settings to display the Meter Settings screen.
3. To set the current Date or Time, press **Date & Time.**
4. The Date & Time screen displays.
5. To set the current date, press **Date**.





6. The Set Date screen displays.
7. 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.

Setting: Time, Date, Beeper, Versions



8. To set the current time, from the Date & Time screen press **Time**. The Set Time screen displays.
9. 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.
10. Press **Back** from the Date & Time screen to return to the Meter Settings screen.

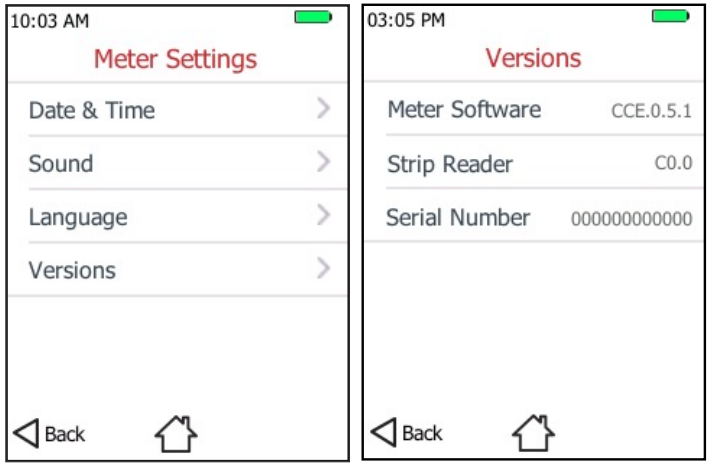
Setting: Time, Date, Beeper, Versions

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

12. The Sound screen displays.
13. 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.

Setting: Time, Date, Beeper, Versions

14. To view the Meter's software version and serial number, from the Meter Settings screen press **Versions**.

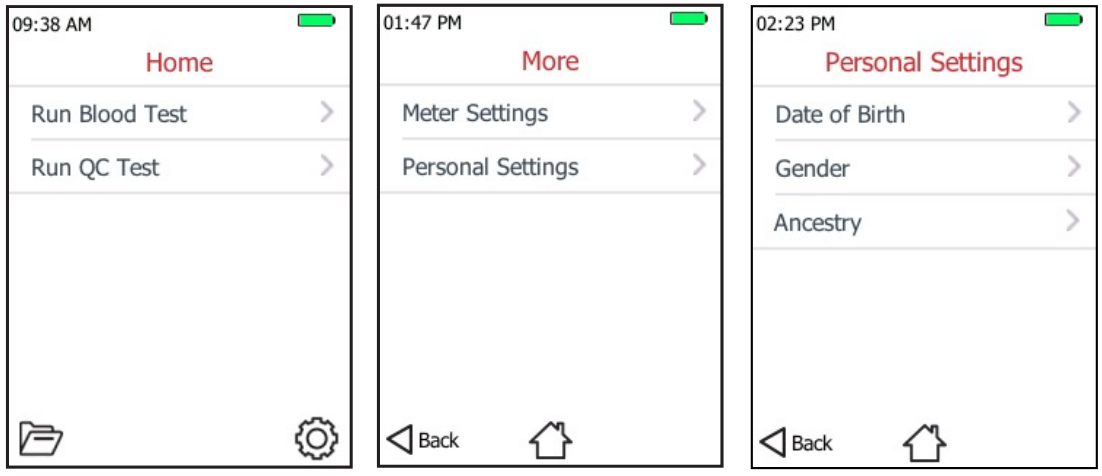


15. The Versions screen displays.
16. The Meter Software and Strip Reader version and the Meter's Serial Number are displayed.
17. Press Back to return to the Meter Settings screen or press ⌂ to return to the Home screen.

Personal Settings

The Meter can be personalized for your information that is needed to give an accurate eGFR calculation. Access Personal Settings from the following screens.

1. To access the Personal Settings menu; from the Home screen, press the Settings icon .



4. The More screen displays; press Personal Settings to display the Personal Settings screen.

Personal Settings

5. Press Date of Birth on the Personal Settings screen.

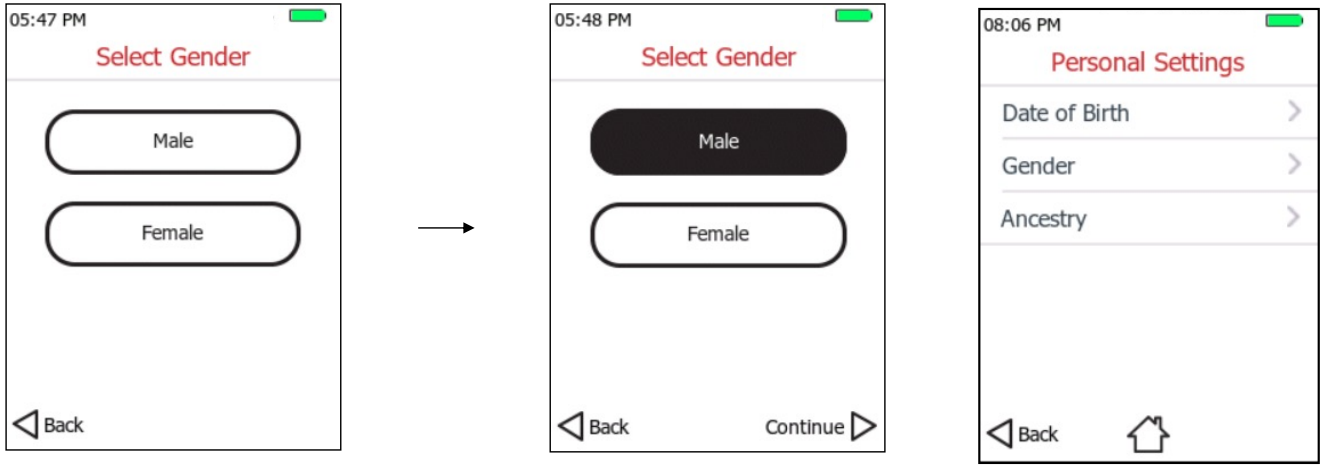
6. 

Select Birth Date using the 3 scroll wheels for month (1-12), day(1-31), and year (allows for ages 18-120). The Day scroll wheel adjusts depending on how many days are in the month.

7. Press the Continue button to save the Date of Birth and redisplay the Personal Settings screen.

Personal Settings

8. Press Gender to display the Select Gender screen and select Gender.

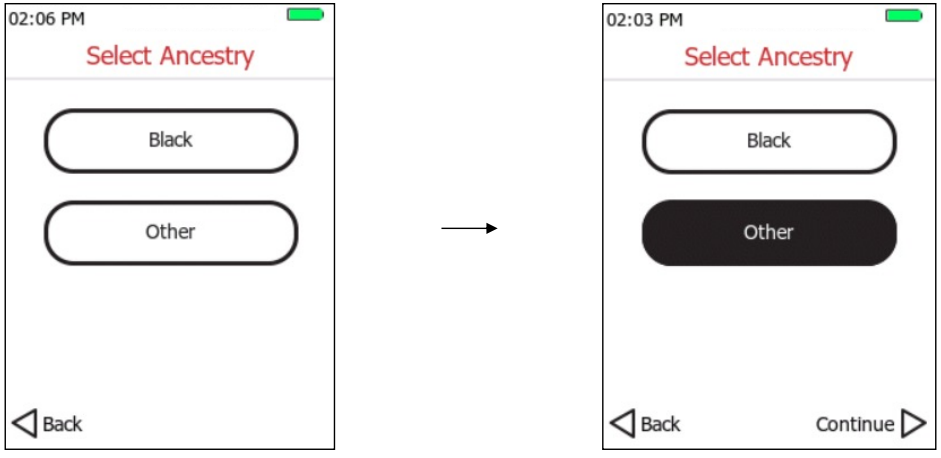


9. Press the Continue button to save gender and redisplay the Personal Settings screen.

10. Press Ancestry to display the Select Ancestry screen.

Personal Settings

11. Select Black or Other.



12. Press continue to save then on the Personal Settings screen press ⌂ to return to the Home screen.
13. The meter is now set up for your personal use.

Basic Upkeep

Battery Check

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

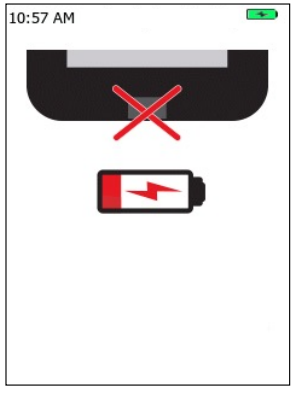
How to view the battery status of the Meter:

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

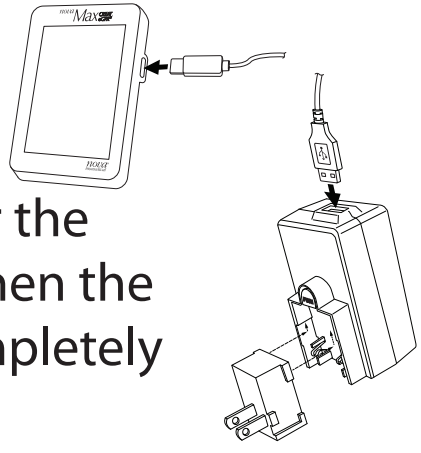
- **Battery is Very Low:** The Meter shall display a red battery progress bar when the battery charge is ≤10%. It is best to recharge the battery now.

Basic Upkeep

Charging the Battery



The Meter battery is charged like a cell phone with a special cable that is provided with a wall plug for USB. Plug the small end of the cable into the right side port and the USB into the USB port of the provided plug. Plug into a wall outlet and allow the Meter to fully charge. The Charging screen is displayed on the Insert Strip and Apply Sample screens while the Meter is plugged into anything through the USB Port. The Meter prevents the user from using the device while it is plugged in. This is just an icon, not a representation for battery charge (as displayed in the upper right-hand corner). The lightning bolt over the battery icon will be displayed on every screen when the Meter is charging. The battery icon becomes completely green when charging is complete.



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 Creat eGFR Meter should be cleaned and disinfected weekly over the intended 3-year use-life of the Meter. The Nova eGFR cleaning and the disinfecting procedure was validated a total of 10,950 times by Nova Biomedical. 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 your personal Meter weekly 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 Creat eGFR Meter should be cleaned and disinfected weekly to minimize the risk of transmission of blood-borne pathogens between the owner and other persons.

End users and others should follow Good Laboratory Practice guidelines and these important safety instructions.

Basic Upkeep

IMPORTANT: *Nova recommends cleaning and disinfecting the Meter with the following EPA Registered products - Clorox® Germicidal Wipes, EPA Registration #67619-12 or Super Sani-Cloth® Germicidal Disposable Wipes, EPA Registration #9480-4. These products are widely available at numerous retail and wholesale providers .*

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.*

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** (1 minute for the Clorox® Germicidal Wipes or 2 minutes for the Super Sani-Cloth® Germicidal Disposable Wipes) 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.

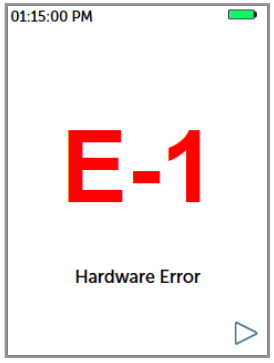
- Wash your hands thoroughly with soap and water.

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
	**Software Error** The Meter detected an internal software error. The Meter shall generate 3 short beeps.	Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip. **Call Customer Service.**

Displays, Meanings, Actions



Hardware Error
The Meter detected an internal hardware error. The Meter shall generate 3 short beeps.

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

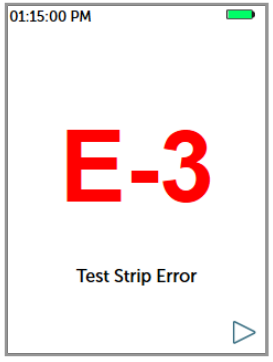
Displays, Meanings, Actions

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.

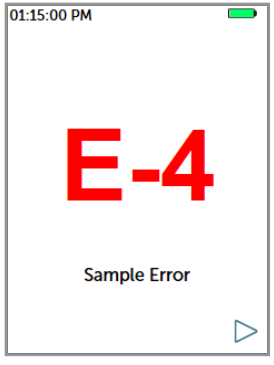
Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.

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.

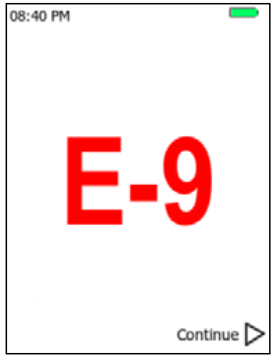
An insufficient sample volume was drawn into the Test Strip. Repeat the test with a new strip. Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.

Displays, Meanings, Actions

Defective/Bad Strip Error

The test strip is defective or bad. The Meter shall generate 3 short beeps.

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.

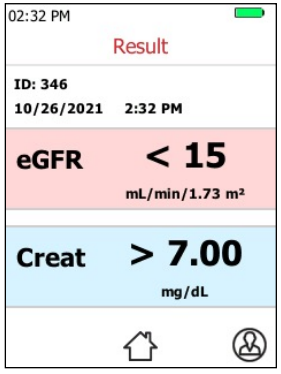


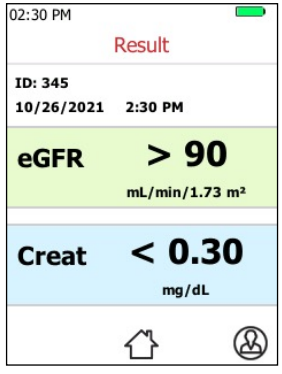
Sample Error

A problem was detected with the sample. The Meter shall generate 3 short beeps.

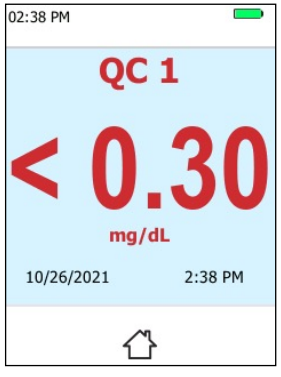
An insufficient sample volume was drawn into the Test Strip. Repeat the test with a new strip. Pressing the right arrow on any error will bring you back to the insert strip screen to run another strip.

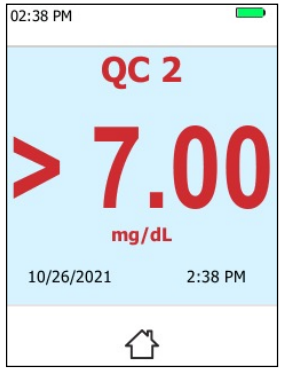
Displays, Meanings, Actions





These Result Screens will show if eGFR or Creatinine values are out of the specified range for the Meter. The current range is 15 - 90 ml/min/1.73 m^2 for eGFR and 0.30 - 7.00 for Creatinine(mg/dL).





These QC Result Screens will show if Creatinine values are out of the specified range for the Meter. The current range is 0.30 - 7.00 for Creatinine(mg/dL).

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 (Plasma values)
Sample type	Capillary whole blood from the fingertip
eGFR Test range	15 - >90 mL/min/1.73 m^2
Limit of Detection	
Limit of Quantitation	
Length of Test	30 seconds
Test Strip Volumes	1.2 µL

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	Minimum of 400 Results

Appendix

Ordering Information

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

DESCRIPTION	**Part #**
Nova Max Creat eGFR Creatinine Test Strips	64147
Nova Max Creat eGFR Creatinine Test Strips (Dual Pack)	64154
Nova Max Creat eGFR Creatinine Control Solution Level 1	64148
Nova Max Creat eGFR Creatinine Control Solution Level 2	64149
PWR SUP SWI5 UNIV AC IN DC 5VO USB	62135
CABL ASSY USB-A TO USB-C M/M 1.2 Meter	63422
21 Gauge Safety Lancet, 200 per box	64480

Appendix

Warranty

Your Nova Max Creat 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 Creat 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 Creat eGFR Meter when used with Test Strips other than Nova

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