
# Quick Reference Guide

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*Refer to the StatSensor Creatinine Meter Instructions for Use Manual and Package Inserts for complete instructions for use, indications, precautions, and limitations of the system.*

StatSensor®

# Creatinine Hospital Meter

# StatSensor Creatinine Hospital Meter

## Table of Contents


The StatSensor Creatinine Hospital Meter ..... QR-1
Barcode Scanning ..... QR-2
Quality Control Test ..... QR-3
Add Comment to a Result (Patient, QC, Linearity)..... QR-11
Running a Patient Sample..... QR-12
Docking/Charging Station..... QR-23
Changing the Battery..... QR-24
Cleaning the Meter ..... QR-27
Troubleshooting..... QR-29


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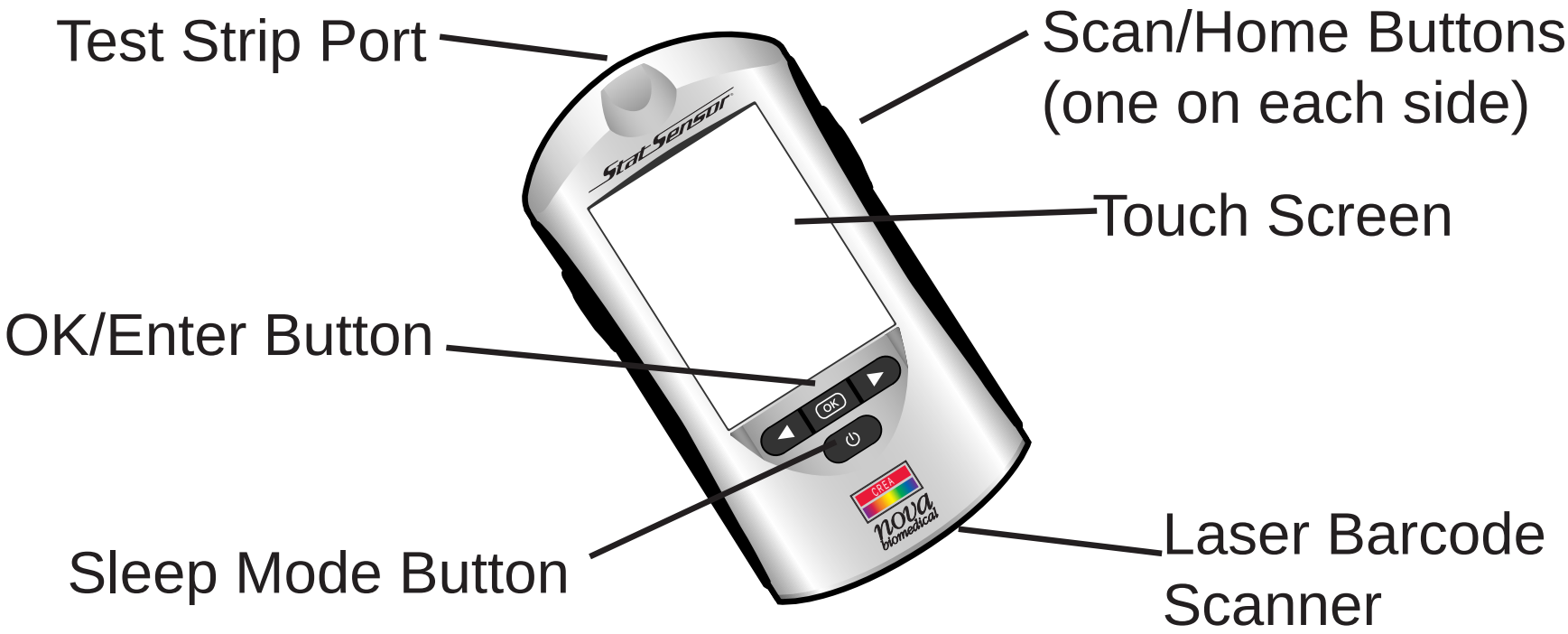
## Disclaimer

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

## The StatSensor® Creatinine Hospital Meter

Refer to this Quick Reference Manual only after you have become familiar with all of the instructions in the Instructions for Use Manual.



## Barcode Scanning

A built-in barcode scanner provides automated data entry. Patient ID's and lot numbers may be scanned into the meter.

To scan a barcode, hold the barcode label parallel to and approximately 2 to 6 inches from the scanner. Press either the left or right side scan button. If the information appears on the screen at the top (Screen Title), the barcode has been successfully scanned. Press the OK button.

***WARNING:*** Do Not stare into the laser light or point the light towards anyone's eyes while scanning a barcode.

## Quality Control Test

The following section explains how to run a Quality Control Test with one of the 3 StatSensor Creatinine Control Solutions.

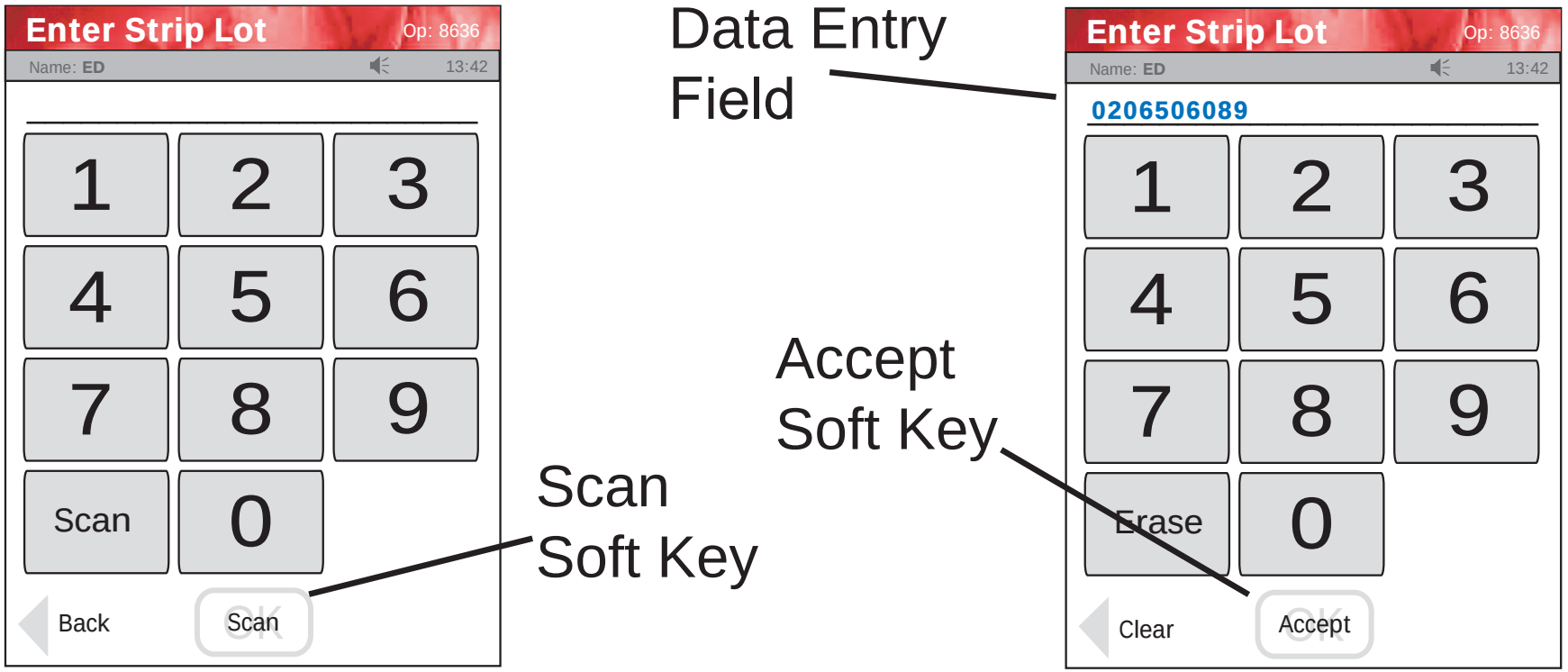
**Read the StatSensor Creatinine Solution package insert sheet for complete instructions, indications, precautions, and limitations of the system.**

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

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

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

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



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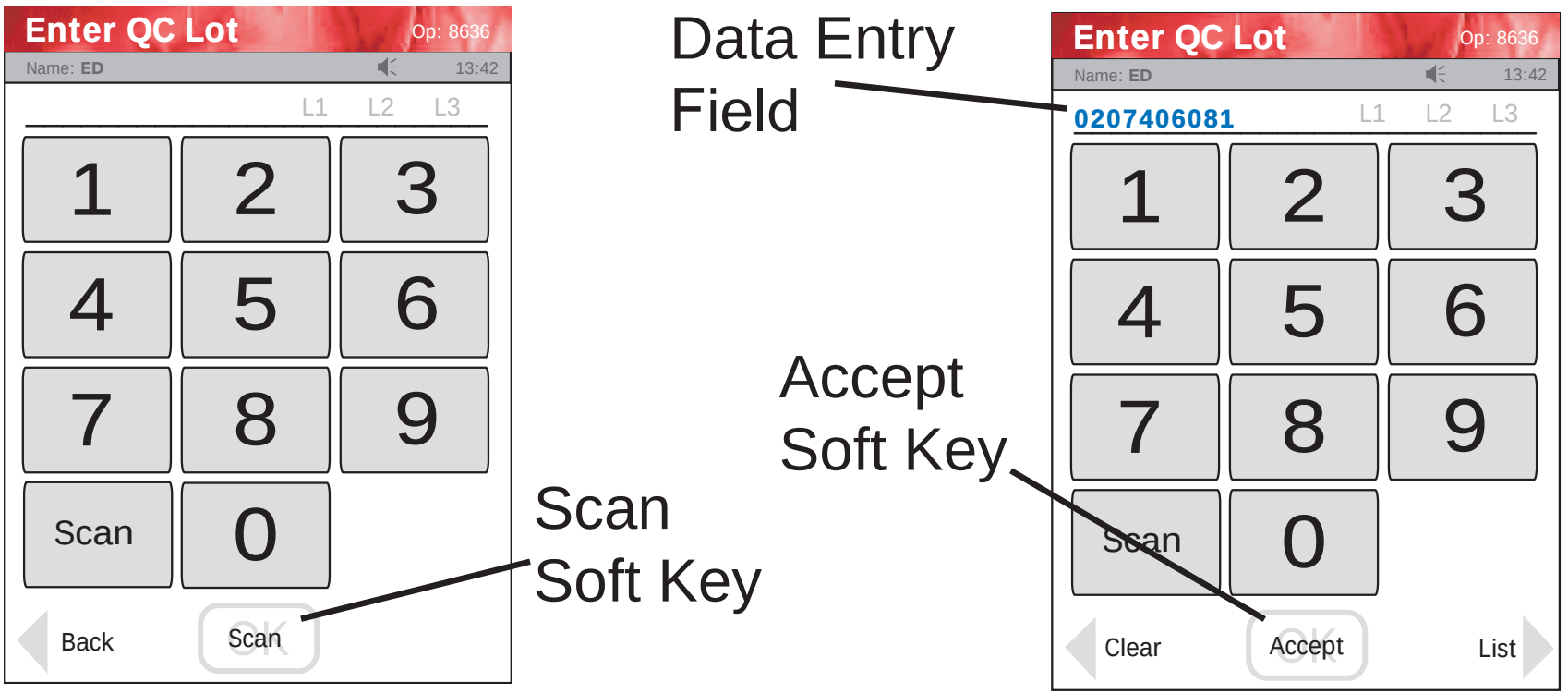
4. The Enter QC Lot screen displays. Enter the QC lot number, select from the QC Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key.

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

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



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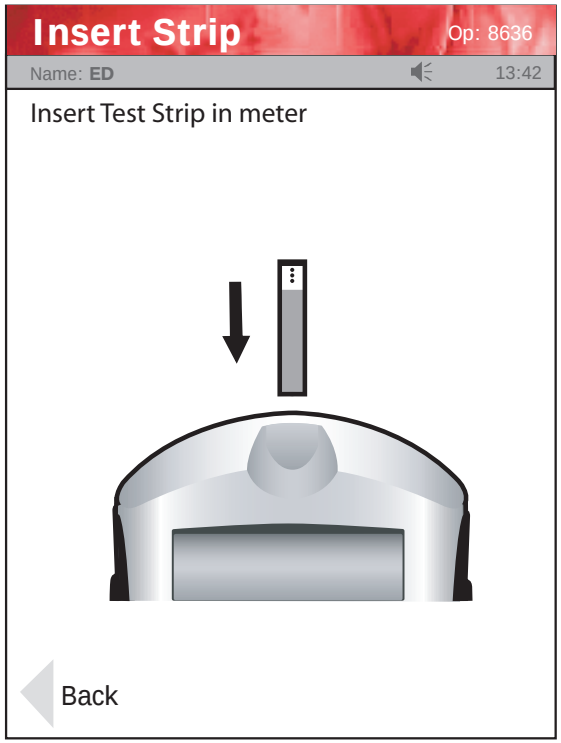
6. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.



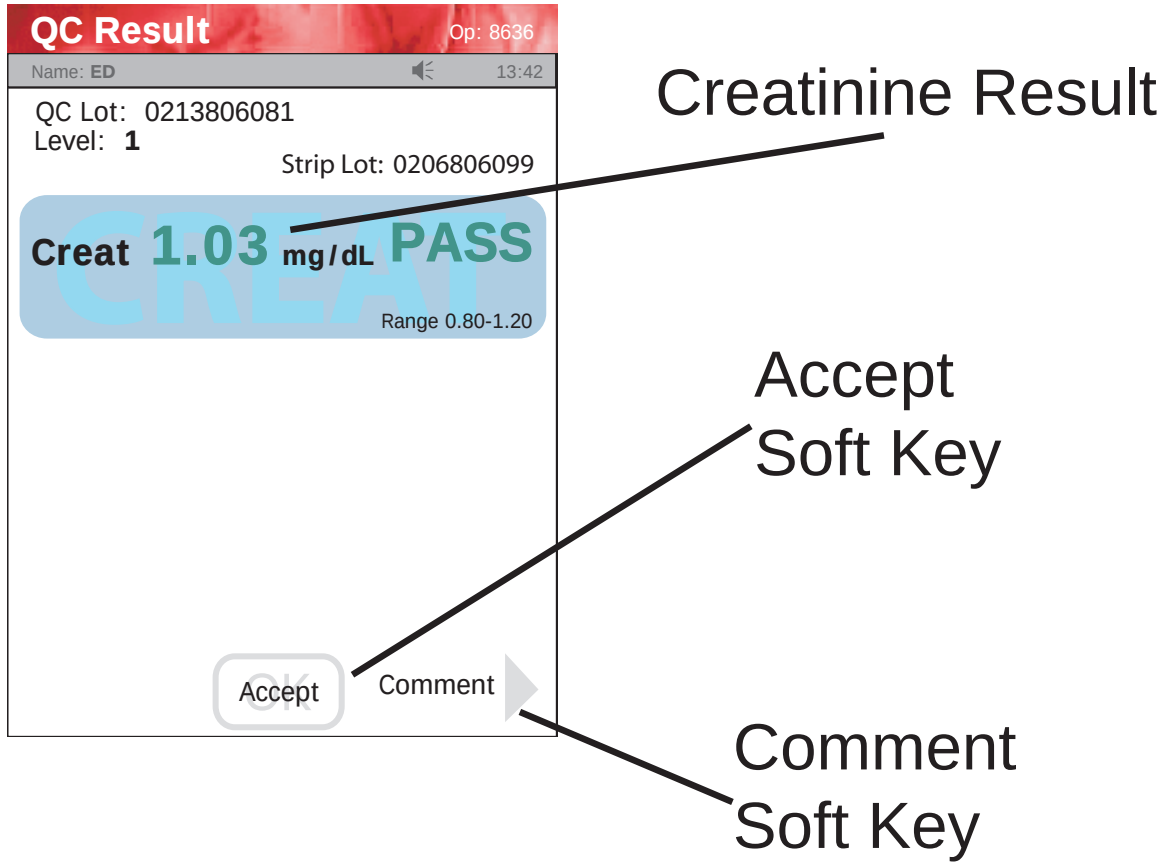

7. With the test strip correctly inserted, the Apply Sample screen displays.

8. Gently mix the StatSensor Creatinine Control Solution before each use.

9. Discard the first drop of control solution from the bottle to avoid contamination.

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

11. Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.




12. When the meter completes the test, the QC Result screen displays with the results in mg/dL or µmol/L.

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

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

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

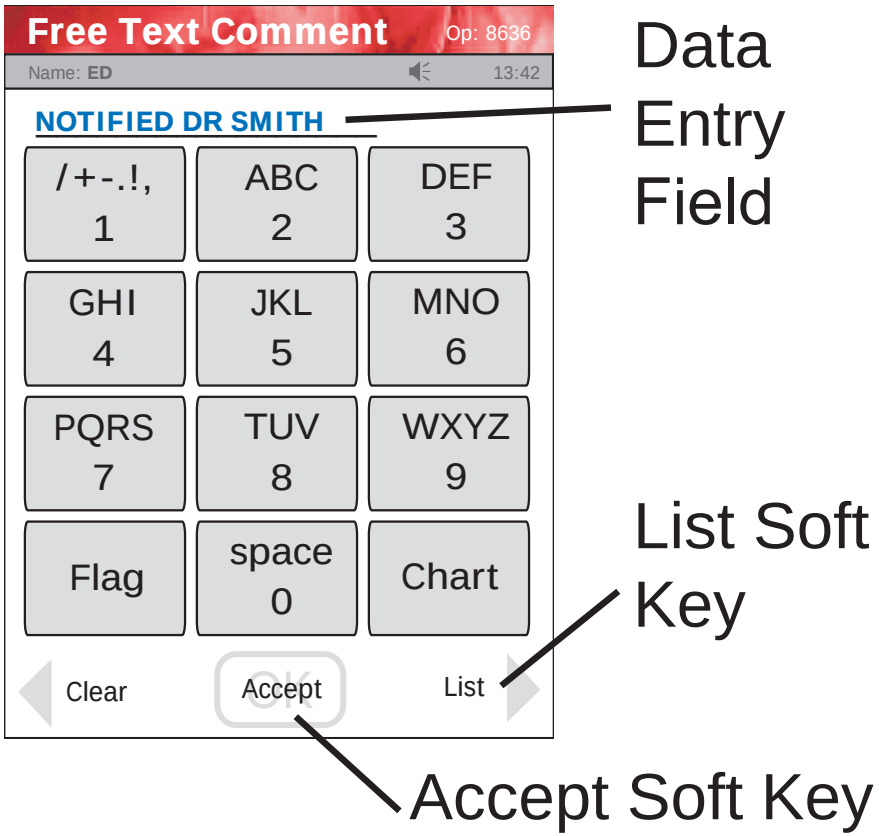
14. To accept the results, press the Accept soft button.

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

To add a comment to a result, press the Comment soft key on the Result screen.

The Free Text Comment screen displays. Add a comment to this screen, e.g., Notified Dr. Smith or press the List soft key for list of comments.

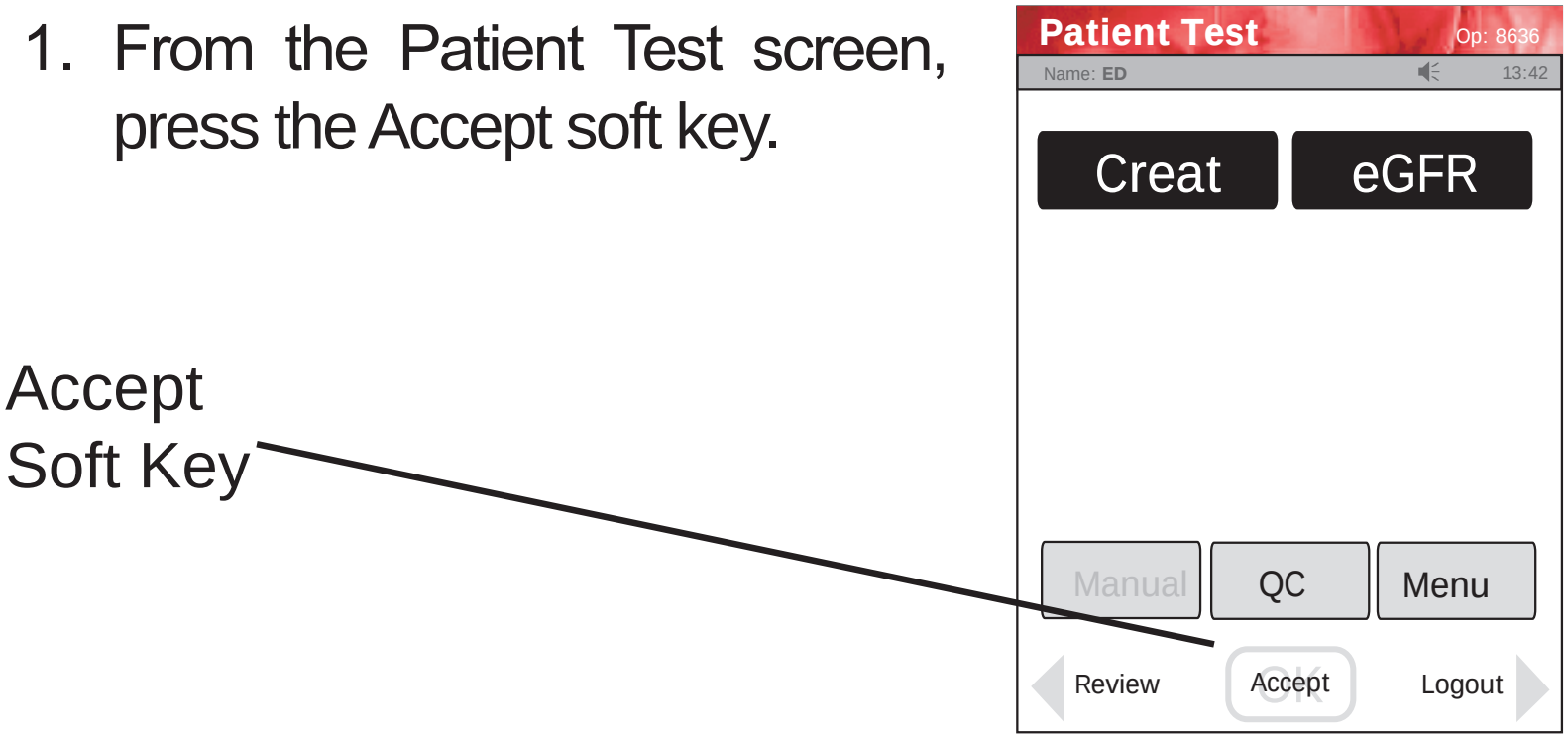
To add the comment to the result and have it become part of the record, press the Accept soft key.



# Running a Patient Sample

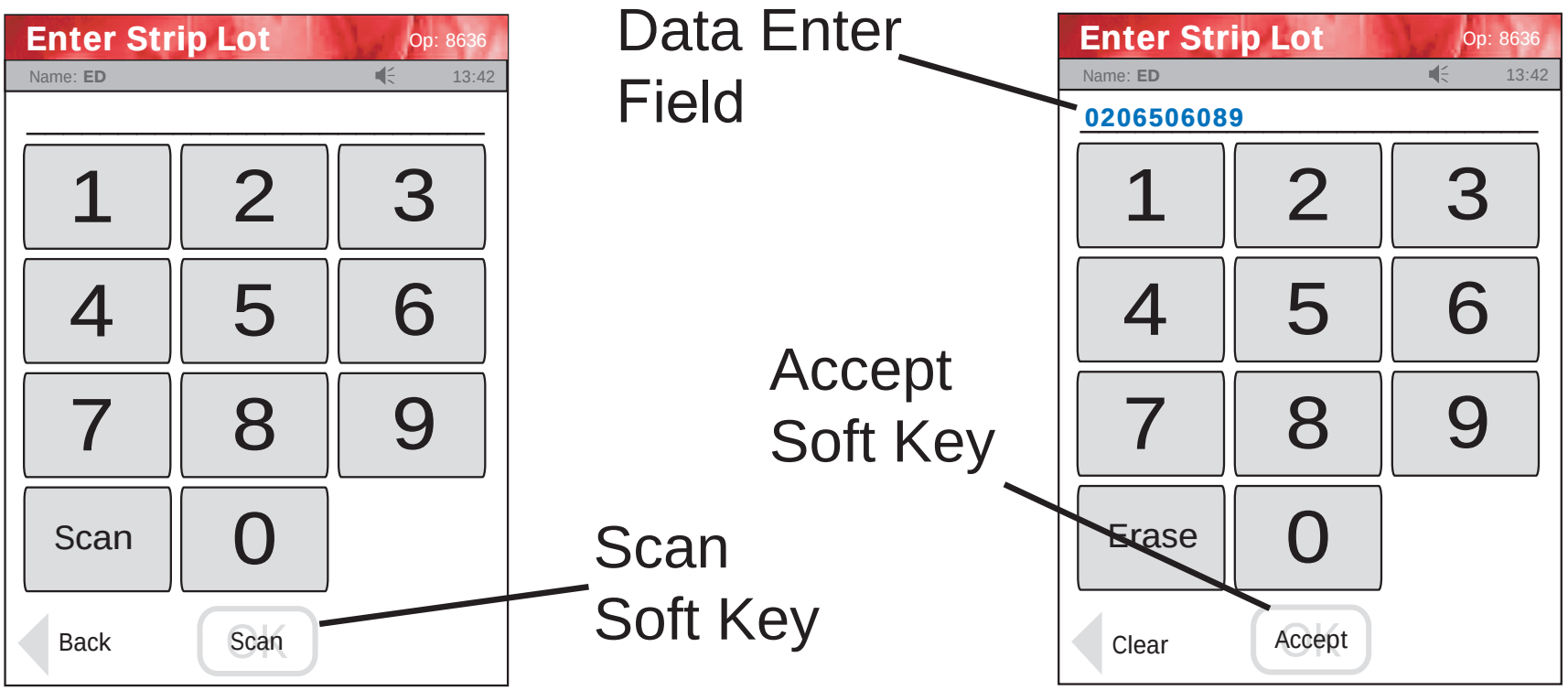
**Read the Test Strip package insert sheet for complete instructions, indications, precautions, and limitations of the system.**

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



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

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



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

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

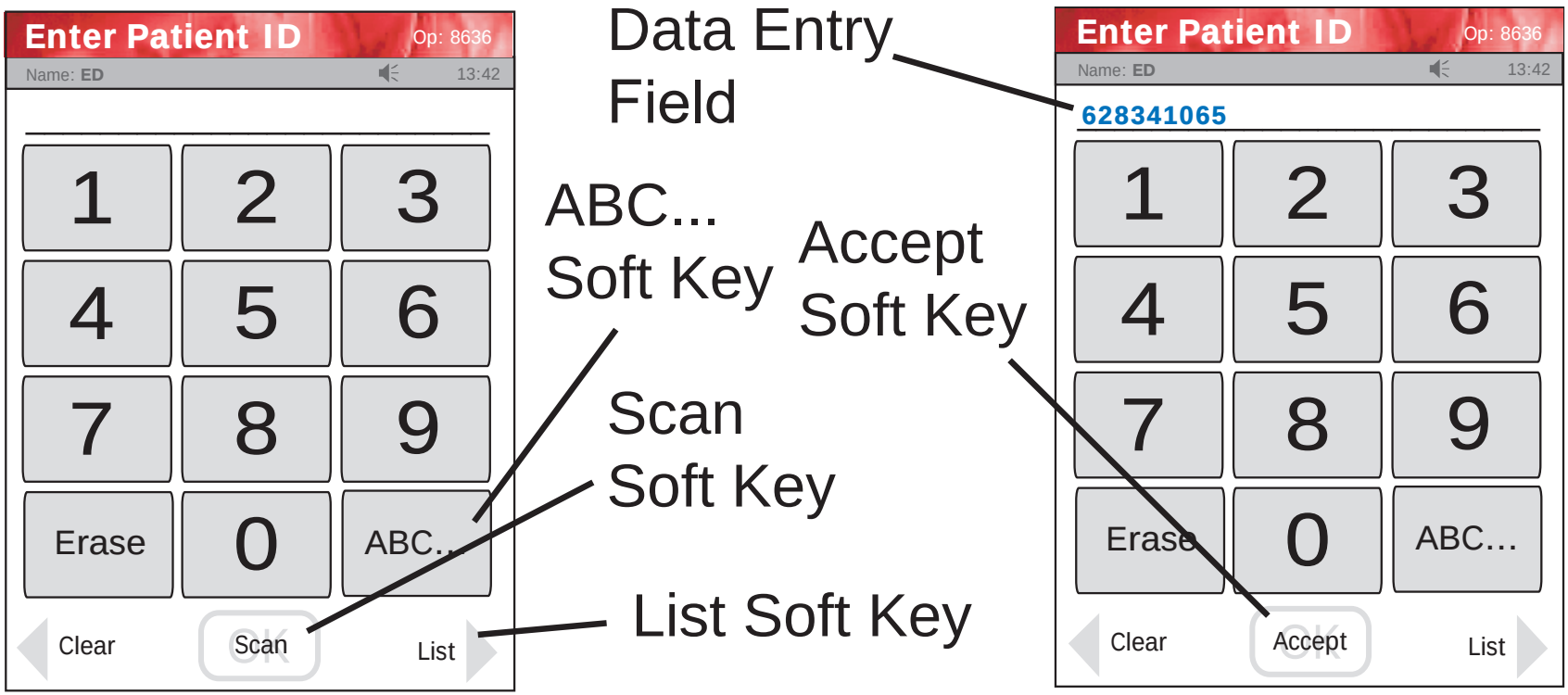
6. Depending on what is enabled to the meter, one of 3 screens will display: Enter Patient ID, Enter Accn Num, or Sample ID Type.

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

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

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

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

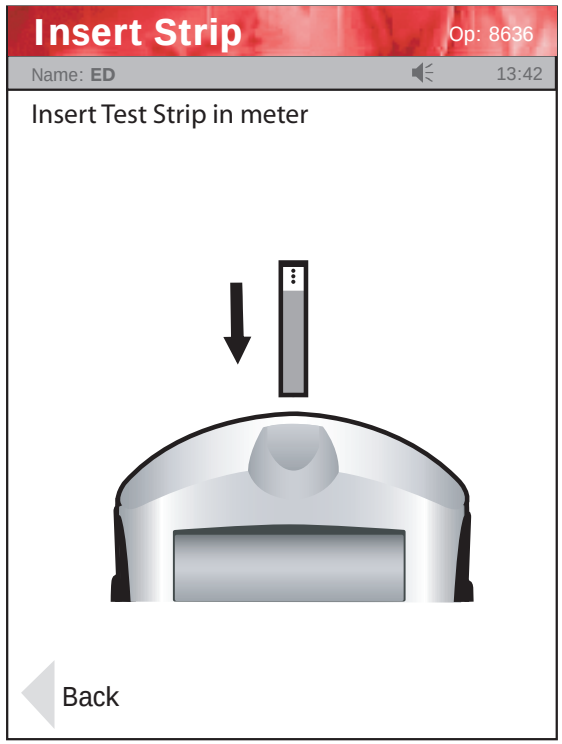



10. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.

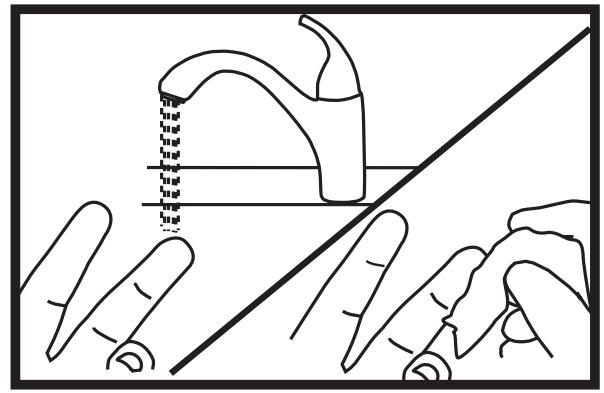
11. If eGFR is not selected, go to Step 12.
    If eGFR is selected, complete Step a or b.
    a. Using the MDRD equation (modified to include adjustment for race) to calculate an estimated Glomerular Filtration Rate (eGFR), as an indicator of creatinine clearance (CrCl)
       Enter the patients Age in years (18-130).
       Select the patient's sex (Male or Female).
       Select the patient's Race (African American or All Other Races).
       eGFR values above 60 are reported as >60 mL/min/1.73 $m^2$.

b. Using the Cockcroft-Gault equation to calculate an estimated Glomerular Filtration Rate (eGFR) as an indicator of Creatinine Clearance (CrCl)
Enter the patients age in years (18-130).
Select the patients sex (Male or Female).
Enter the patients weight in pounds or kilograms.
eGFR values above 60 are reported as >60 mL/min.

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



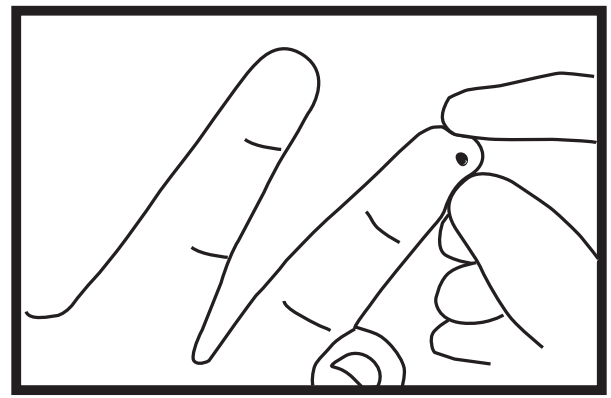
13. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.



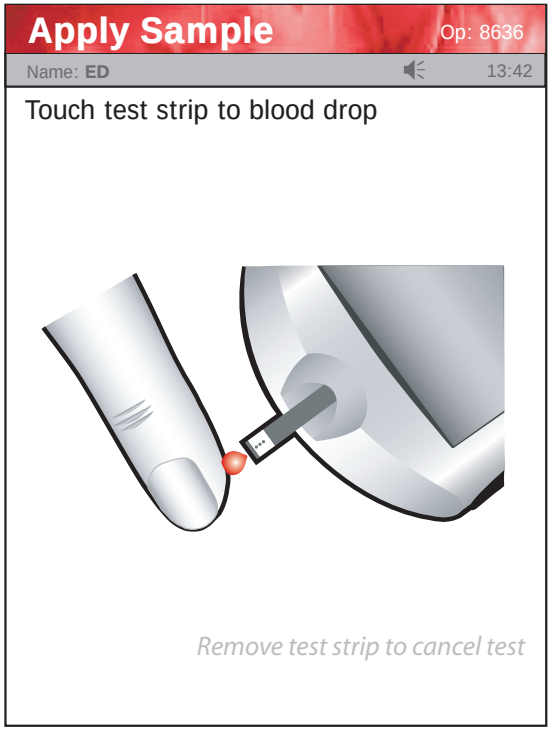
14. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

14. Use the Safety Lancet to puncture the finger.

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



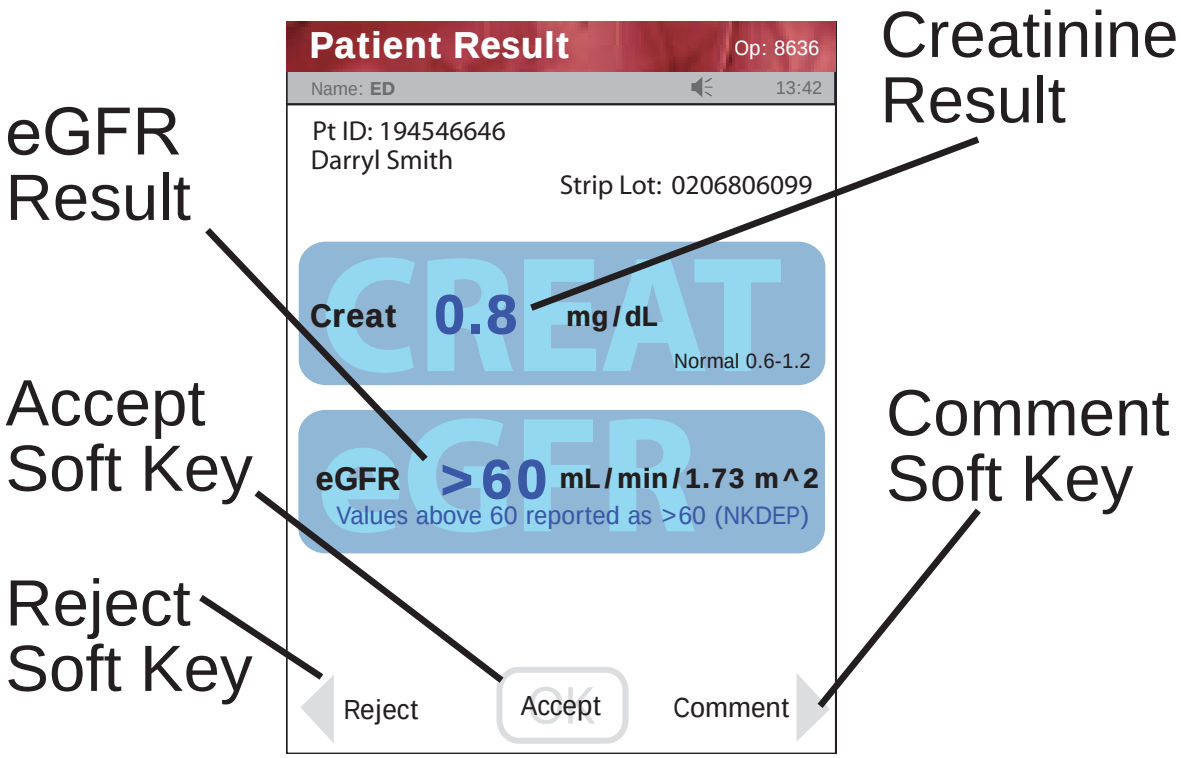
16. The Apply Sample screen should be displaying. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.




**WARNING:** *The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely,* ***do not touch the test strip to the blood droplet a second time.*** *Discard the test strip and repeat the test with a new strip.*

17. The test results will appear in 30 seconds.

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




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

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

## Docking/Charging Station

When the meter is not in use, place it into the Docking/Charging Station. This enables the meter to stay fully charged and connects the meter to the computer network. When the Battery LOW symbol displays on the screen, place the meter into the Docking/Charging Station. If you have a spare battery that is already fully charged, change the battery.

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

## Changing the Battery

***NOTE:*** *Each StatSensor Battery has an expiration date printed on the outside of the battery case. A battery beyond its expiration date indicates the maximum charge of the battery may be less than 60% of its original capacity. The battery will function well beyond that date, but with lower maximum charge. Replace the battery when battery life is no longer acceptable for clinical use.*

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

***WARNING:*** Replace the battery with Nova P/N 46827 only. Using another battery may present a risk of fire or explosion. If discarding,

dispose of the battery promptly. Keep the battery away from children.

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

***NOTE:*** *If it takes longer than 20 seconds to change the battery, power up the meter, relogin, and set the date and time: see the Creatinine Meter Instructions for Use Manual.*

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

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

4. Replace with a fully charged battery.

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

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

6. Place the drained battery into the Charging Station.

## Cleaning the Meter

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

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

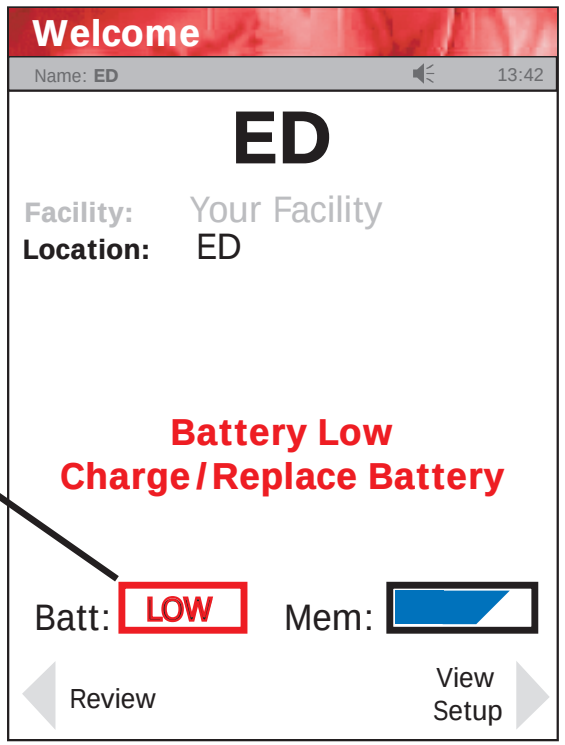
***CAUTION:*** ***DO NOT*** immerse the meter or hold the meter under running water.
***DO NOT*** spray the meter with a disinfectant solution.

## Troubleshooting

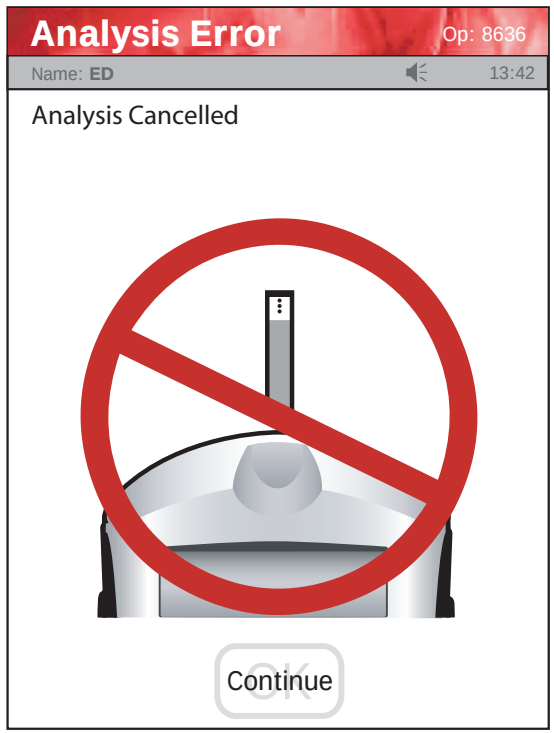
The StatSensor Meter displays screen alerts.

1. **Battery Low** - Change the battery or place the meter onto the Charging Station.

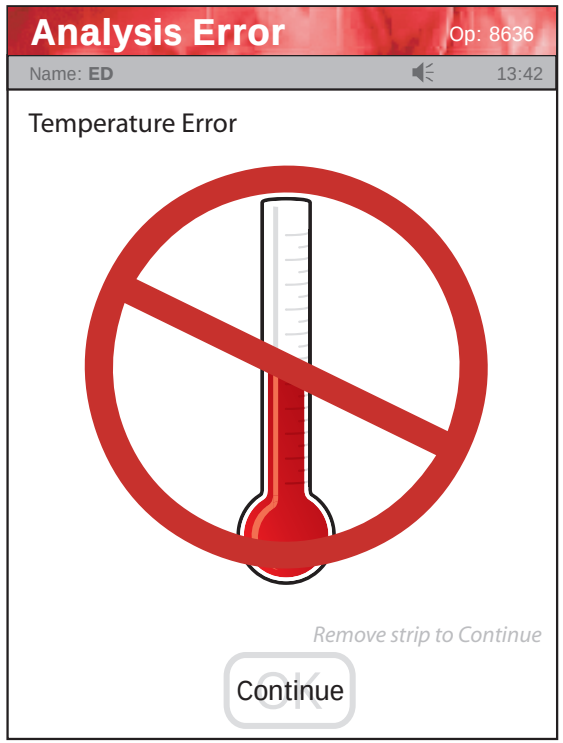
Battery Low Icon



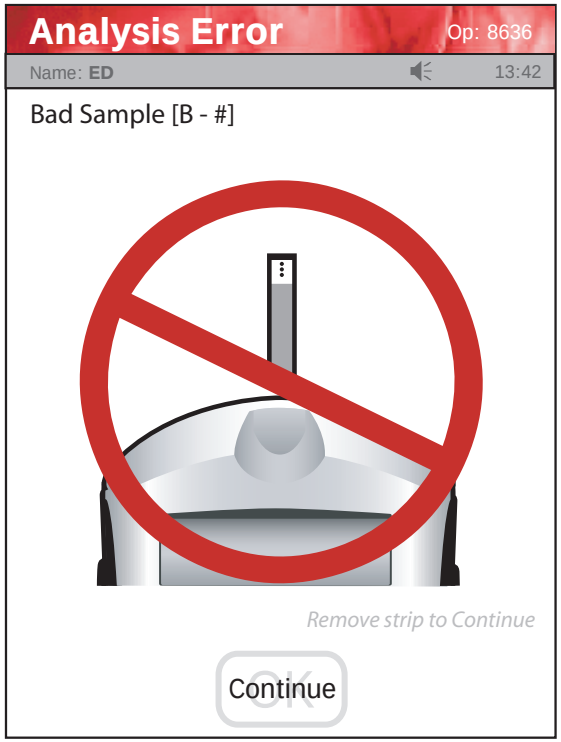
2. **Analysis Cancelled** - Test Strip Was Removed. The test has been cancelled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.



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

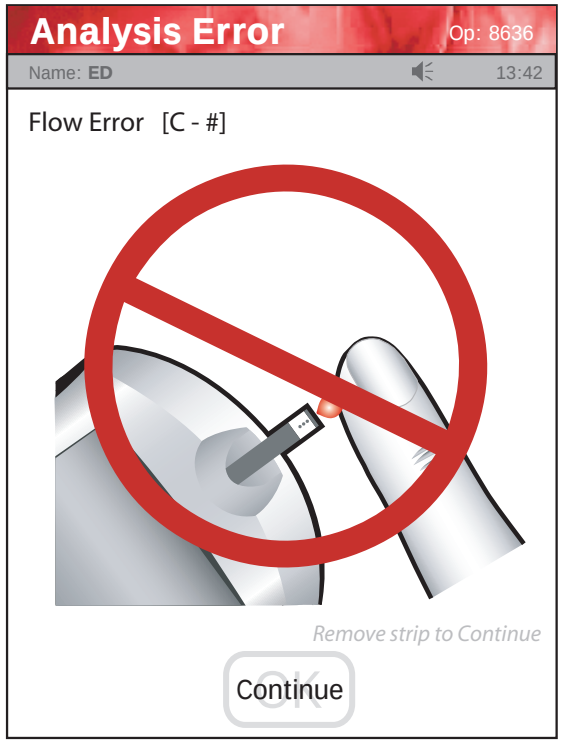


4. **Bad Sample** - Insert a new strip and rerun the test. If the error code persists, perform the test using an alternate test strip vial or alternate method.

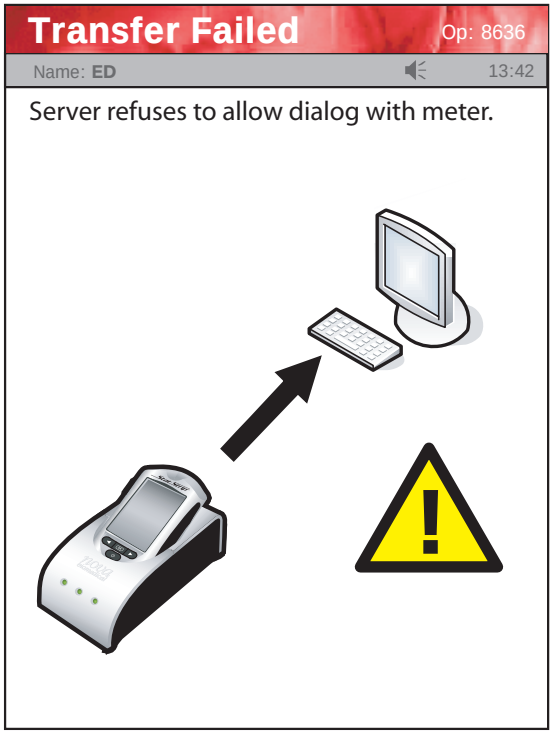


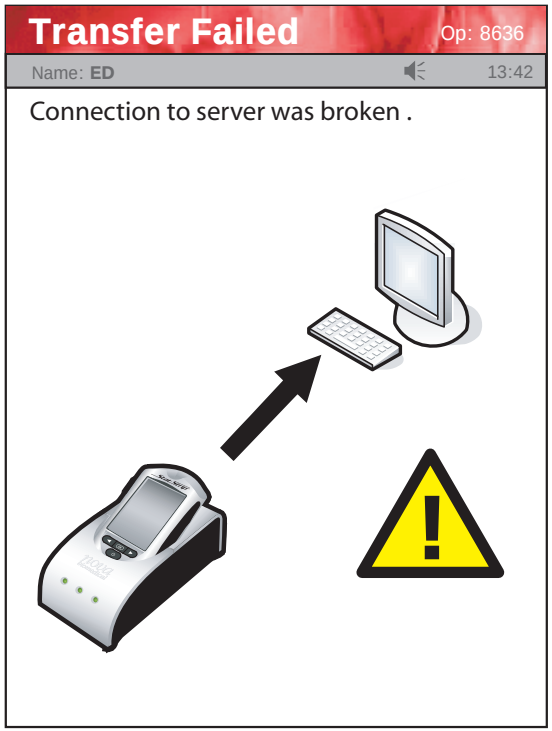
5. **Bad Strip** - Occurs after insertion of strip or occurs during analysis. Insert another strip and retest. If the error code persists, perform the test using an alternate test strip vial or alternate method.

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

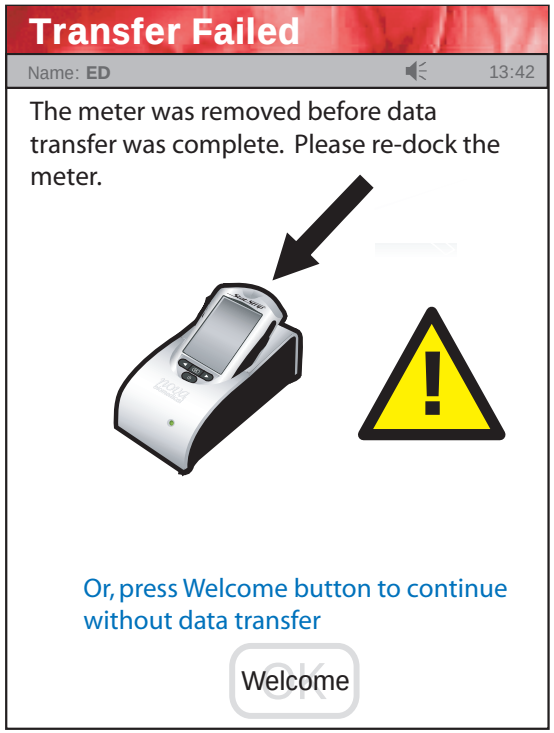


7. **Transfer Failed** - Server refuses to allow dialog with meter, or Connection to server was broken. Please check the network settings, status of your network, or contact your administrator for assistance.



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



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# StatSensor® Creatinine Meter

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