



Quick Reference Guide

nova[®]
biomedical



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

StatStrip[®]

Lactate Hospital Meter

StatStrip Lactate Hospital Meter

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Intended Use

The Nova StatStrip Lactate Hospital Meter System is intended for *in vitro* diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.

Important Safety Instructions

Blood-Borne Pathogens Safety



Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the Nova StatStrip Lactate Hospital Meter system. Healthcare professionals should be aware that all parts of the Nova StatStrip Lactate Hospital Meter system are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals. The Nova StatStrip Lactate Hospital Meter system should be disinfected after use on each patient following the cleaning and disinfection procedure in section 6.3 of the Instructions for Use Manual.

The Nova StatStrip Lactate Hospital 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.

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

For more information, refer to the following references:

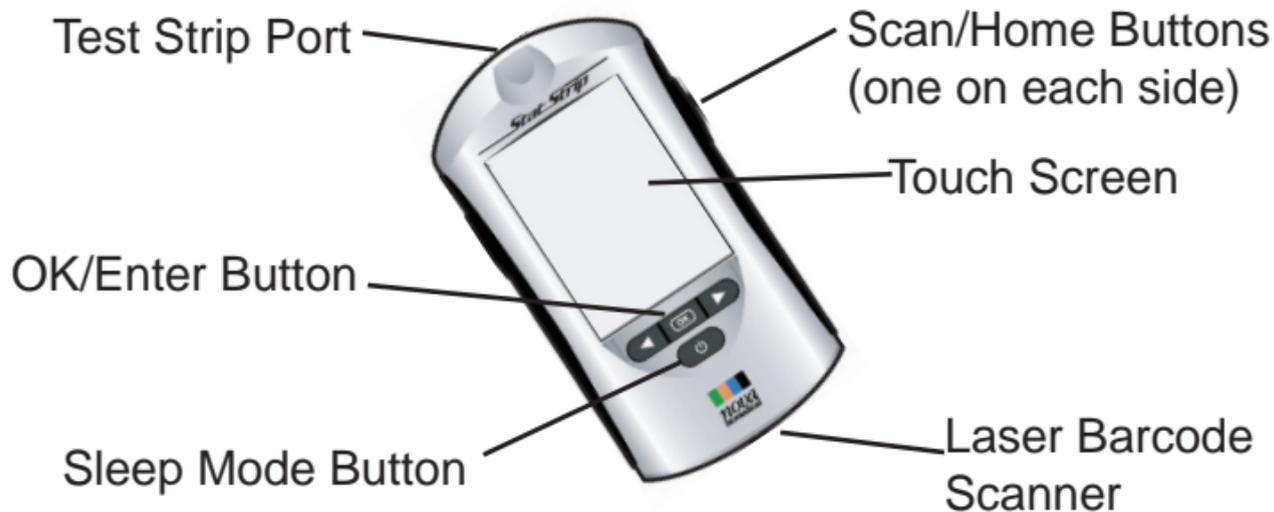
“Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007,” <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmb15/>.

“Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition” Clinical and Laboratory Standards Institute (CLSI) M29-A3.

The StatStrip Lactate 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 2 Nova StatStrip Lactate Control Solutions.

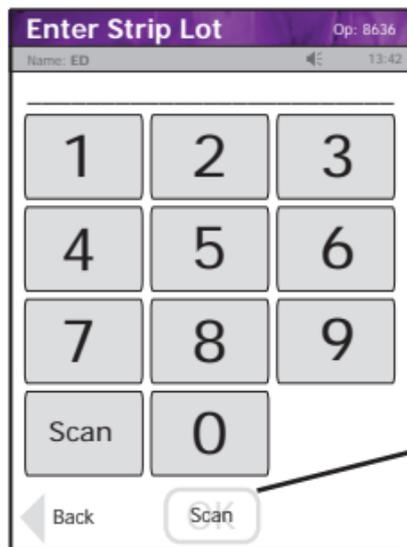


Read the StatStrip Lactate Control Solution package insert sheet for complete instructions, indications, precautions, and limitations of the system.

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.



Data Entry Field



Scan Soft Key

Accept Soft Key

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."*

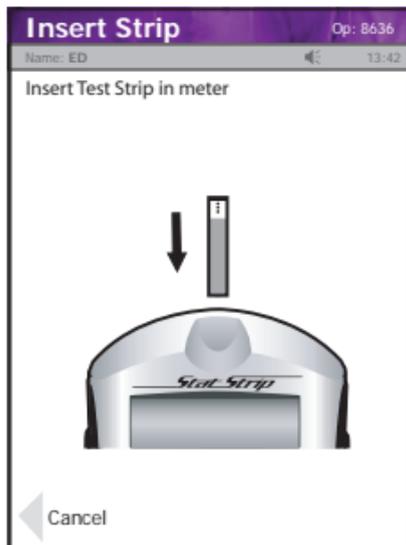


Data Entry Field



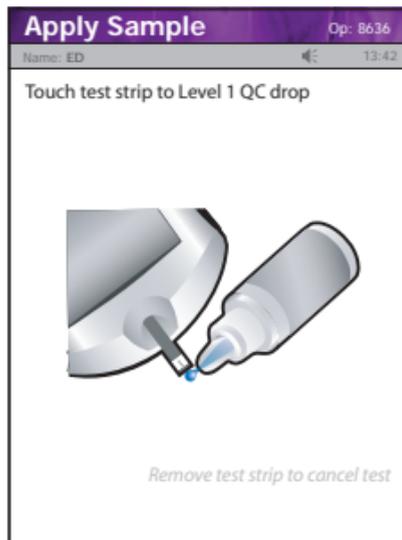
5. Press the Accept soft key if the lot number is correct.

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 shake the StatStrip Lactate Control Solution before each use.

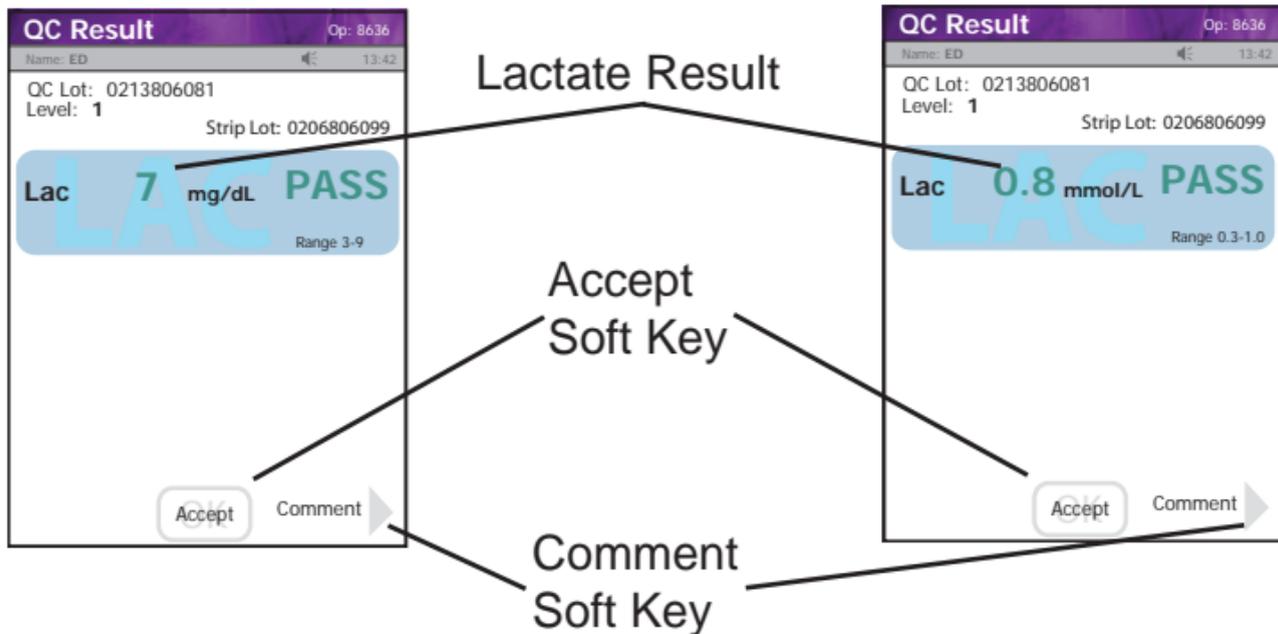


9. Discard the first drop of control solution from the bottle to avoid contamination.

10. Place a drop of control solution from the bottle to the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter.



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 mmol/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.

The screenshot shows the 'Free Text Comment' screen. At the top, it displays 'Name: ED' and 'Op: 8636' with a back arrow. Below this is the text 'NOTIFIED DR SMITH'. A keyboard is displayed with the following layout:

/+-.!, 1	ABC 2	DEF 3
GHI 4	JKL 5	MNO 6
PQRS 7	TUV 8	WXYZ 9
Flag	space 0	Chart

At the bottom, there are three soft keys: 'Clear' (left arrow), 'Accept' (center button with a checkmark), and 'List' (right arrow).

Data
Entry
Field

List Soft
Key

Accept Soft Key

Running a Patient Sample



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

Important Safety Instructions

Blood-Borne Pathogens Safety



Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the Nova StatStrip Lactate Hospital Meter system. Healthcare professionals should be aware that all parts of the Nova StatStrip Lactate Hospital Meter system are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.

The Nova StatStrip Lactate Hospital Meter system should be

disinfected after use on each patient following the cleaning and disinfection procedure in section 6.3 of the Instructions for Use Manual.

The Nova StatStrip Lactate Hospital 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.

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

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

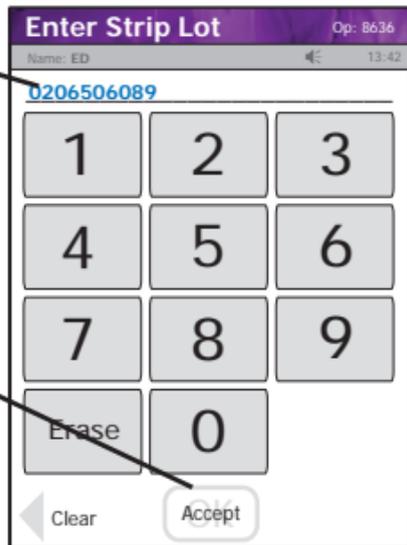
Accept
Soft Key



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.



Data Enter Field

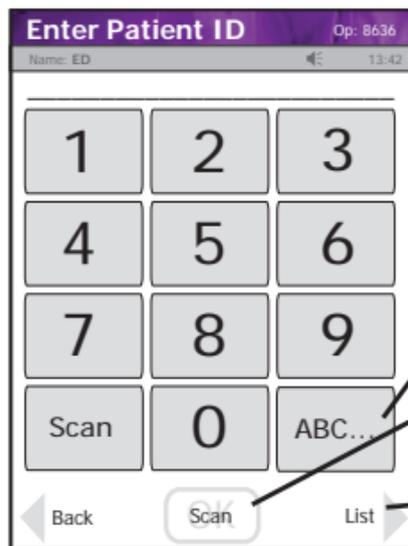


Accept Soft Key

Scan 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.



Data Entry Field

ABC... Soft Key

Accept Soft Key

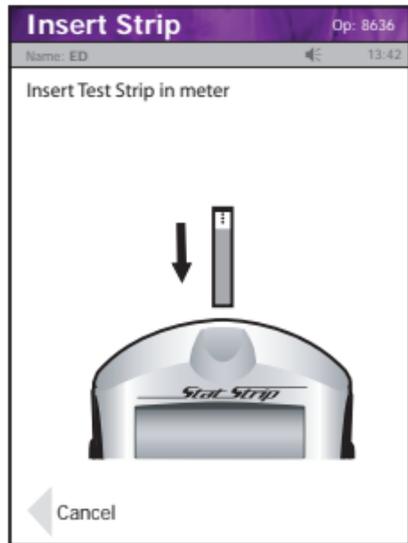
Scan Soft Key

List Soft Key



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

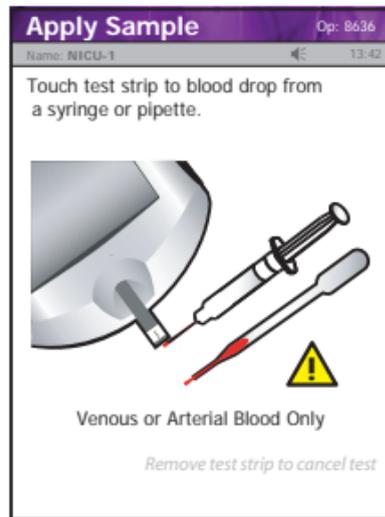
10. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.
11. The Insert Strip screen displays. Insert a test strip as shown on the meter screen.



12. Draw a fresh blood sample from an artery or a vein.

CAUTION: Has not been characterized for use with capillary specimens.

13. Use either the syringe or a pipette to add a fresh venous or arterial blood drop to the Lactate test strip.



14. 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 into a biohazardous container and repeat the test with a new strip.

15. The test results will appear in 13 seconds.

NOTE: *Do not remove the test strip while the count-down is in progress.*

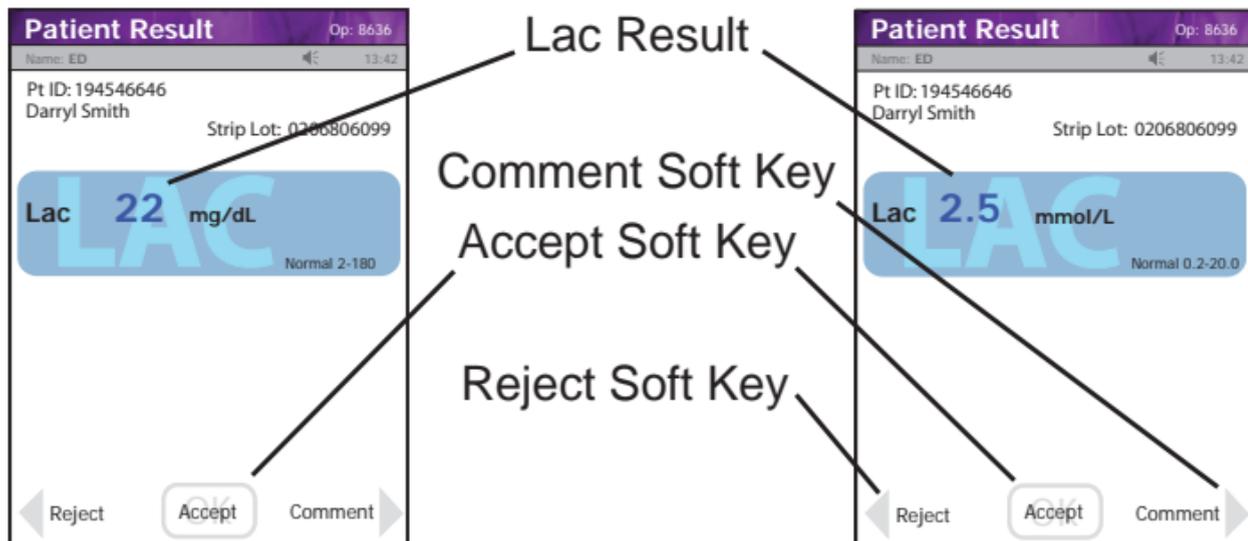
NOTE: *A single up arrow displays for abnormal high result and 2 up arrows for critical high value. A single down arrow displays for abnormal low result and 2 down arrows for critical low value.*

16. 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.

17. When patient testing is completed, the Nova StatStrip Lactate Hospital Meter should be cleaned and disinfected after use prior to testing with a new patient. For cleaning and disinfecting instructions, see page QR-29.



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 amber for charging.



Changing the Battery

NOTE: *Each StatStrip 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 (Battery 4-pack) 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 Lactate 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.



6. Place the drained battery into the Charging Station.

Cleaning and Disinfecting the Meter (USA and Canada)

For Technical Support in the USA dial (800)-545-6682. Outside the USA, contact your local Nova dealer.



All parts of the Nova StatStrip Lactate Hospital Meter system are considered potentially infectious and can potentially transmit 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.

Acceptable Disinfecting Materials

In the USA, Nova Biomedical recommends the use of Clorox® Germicidal Wipes, EPA Registration #67619-12.

In Canada, Nova Biomedical recommends the use of Clorox® Commercial Solutions™ Clorox® Professional Disinfecting Bleach Wipes (DIN 02349272).

The Clorox wipes have been validated for up to 7300 cleaning and disinfection cycles by Nova Biomedical.

Meter Cleaning and Disinfection Procedure

Disinfect after each patient use by following this protocol to help ensure effective cleaning and disinfection and reduction of cross contamination.

Prepare

Make sure the test strip is removed from the meter. Lay the meter on a flat surface prior to disinfecting the meter. Remove a fresh germicidal or professional bleach wipe from the canister.

1. Clean the Meter.

- Wipe the external surface of the meter thoroughly with a fresh germicidal or professional wipe. Discard the used wipe into an appropriate biohazard container.



2. Disinfect the Meter.

- Using a new, fresh germicidal or professional wipe, thoroughly wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times

horizontally followed by 3 times vertically avoiding the bar code scanner and electrical connector.

- Gently wipe the surface area of the test strip port making sure that no fluid enters the port.

3. Observe surface contact time.

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



NOTE: *If the meter surface needs to be re-wiped, use a new, fresh wipe.*

4. Dispose of wipe and gloves.

- Dispose of used wipe and gloves in a standard biohazard container.



5. Wash and sanitize hands.

- Wash your hands thoroughly with soap and water, and put on a fresh set of protective gloves before proceeding to perform testing on the next patient.



Additional information

WARNING: Do not allow liquid to enter the strip port connector or allow pooling of liquid on the touch screen. If liquid does get into the strip port or connector, immediately dry the components with a dry cloth or gauze.

WARNING: *Do not spray the meter directly with solutions as this could cause the solution to enter the case and damage the electronic components.*

WARNING: *Do not immerse the meter or hold the meter under running water.*

Cleaning and Disinfecting the Meter (Outside the USA and Canada)

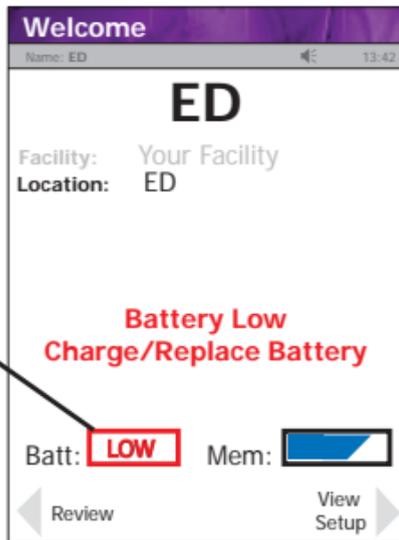
Countries outside of the USA and Canada are advised to utilize commercial surface decontamination products that are approved for use in each country. Apply the decontamination product to a small test area first to ensure surface finish integrity. Avoid harsh solvents such as benzene and strong acids.

Troubleshooting

The Nova StatStrip Lactate Hospital Meter displays screen alerts.

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

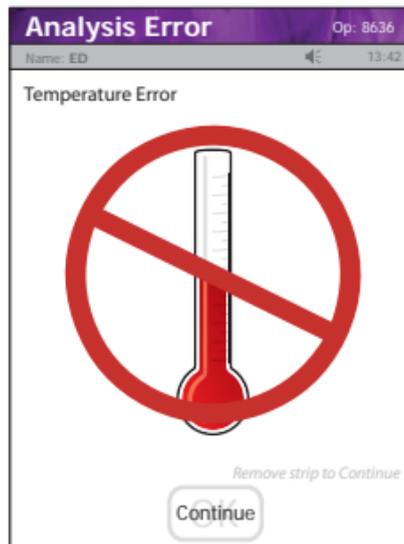
Battery Low Icon



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).



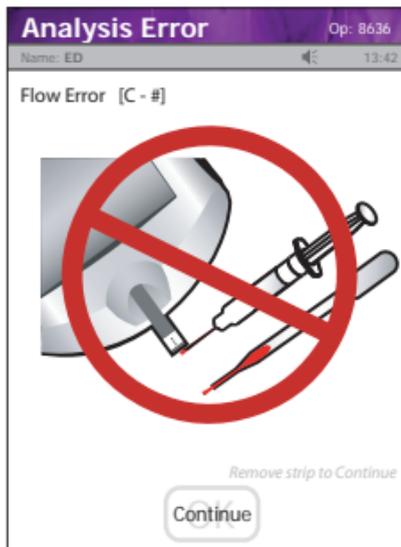
4. **Bad Sample** - Insert a new strip and rerun the test. If the error code persists, perform the test using an alternate test strip vial or alternate method.



5. **Replace 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 a new test strip vial or 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.



For technical assistance outside the United States, call your local Nova subsidiary or authorized distributor.

Nova Biomedical Canada Ltd.

2900 Argentia Road
Mississauga, Ontario L5N 7X9
Canada
Tel: 1 800 263 5999
1 905 567 7700

Nova Biomedical France

Parc Technopolis - Bât. Sigma
3 avenue du Canada 1er étage
Les Ulis courtaboeuf
91940 France
Tel: + 33 1 64 86 11 74

Nova Biomedical Iberia, S.L.

c/Vic 17, Planta 3A
08173 Sant Cugat del Vallès
(Barcelona) Spain
TEL: +34 935531173
es-info@novabio.com or
pt-info@novabio.com

Nova Biomedical Italia Srl

Via Como 19
20045 Lainate Milano, Italia
Tel: +39 02 8707004

Nova Biomedical UK

Innovation House
Aston Lane South, Runcorn
Cheshire, WA7 3FY UK
Tel: + 44 1928 704040

Nova Biomedical GmbH

Hessenring 13A, Geb. G
64546 Mörfelden-Walldorf,
Germany
Tel: + 49 (0) 61054505-0

Nova Biomedical KK

Harumi Island Triton Square
Office Tower X 7F,
1-8-10 Harumi, Chuo-ku,
Tokyo 104-6007, Japan
Tel: +81 3-5144-41441
FAX:03-5144-4177
jp-info@novabio.com

Nova Biomedical Schweiz GmbH

Herostrasse 7
8048 Zürich
TEL: +41-41-521-6655
FAX: +41-41-521-6656
e-mail: ch-info@novabio.com

Nova Biomedical Diagnósticos

Médicos
e Biotecnologia Ltda Nova Biomedical
Brazil
Rua Massena, 107, Jardim Canadá
Nova Lima – MG – Cep: 34007-746
Tel: (55) 31 3360-2500
sac@novabiomedical.com.br

Nova Biomedical Benelux B.V.

Europalaan 4, 5232 BC
Den Bosch, The Netherlands
Tel: + 31(0)733032701
Email: nl-info@novabio.com
be-info@novabio.com



StatStrip® Lactate Hospital Meter

Nova Biomedical Corporation Technical Assistance 1-800-545-6682
200 Prospect Street Web: www.novabiomedical.com
Waltham, MA 02454
U.S.A.

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REF 47643H 2022-10

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