IVD $\quad$ CE

Nova StatStrip Xpress
Lactate Hospital Meter
Instructions for Use Manual

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For Export Only

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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		Electronic Waste
EC REP	Authorized Representative in the European Community	**REF**	Catalog number
$C\epsilon$	Product fulfills the requirements of Directive 98/79 EC (IVDD)		Temperature limitation
⚠	Caution, consult accompanying documents		Upper Limit of Temperature
📖	Consult instructions for use		
☣	Biological risk		Manufactured by

About This Manual

This manual is for the Nova Biomedical StatStrip Xpress Lactate Meter.

Unit of Measure Information

The unit of measure of the StatStrip Xpress Lactate Hospital Meter is factory set to mmol/L.

Throughout this manual:

NOTES provide important or helpful operating information.

CAUTIONS provide information that is important for instrument protection.

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

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Safety

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

1. Read the safety and operating instructions before operating the meter.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the meter and in the operating instructions.
4. Follow all operating and use instructions.
5. The meter should be cleaned only as recommended by the Nova Biomedical.

Electrical Safety

1. Battery powered: 3-volt coin battery

Safety

Chemical and Biological Safety

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

Disposal of Used Batteries for customers in Europe.

- This symbol ☒ on the battery label indicates that the battery provided with the meter should not be treated as household waste. To ensure the used battery is treated properly, remove the used battery from the meter and hand over the used battery to the applicable collection point for the recycling of electrical and electronic equipment."

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Safety

Disposal of Used Meters for customers in Europe.

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

Environmental

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

Dimensions:

Height: 91.4mm (3.6in)
Width: 58.4mm (2.3in)
Depth: 22.9mm (0.9in)
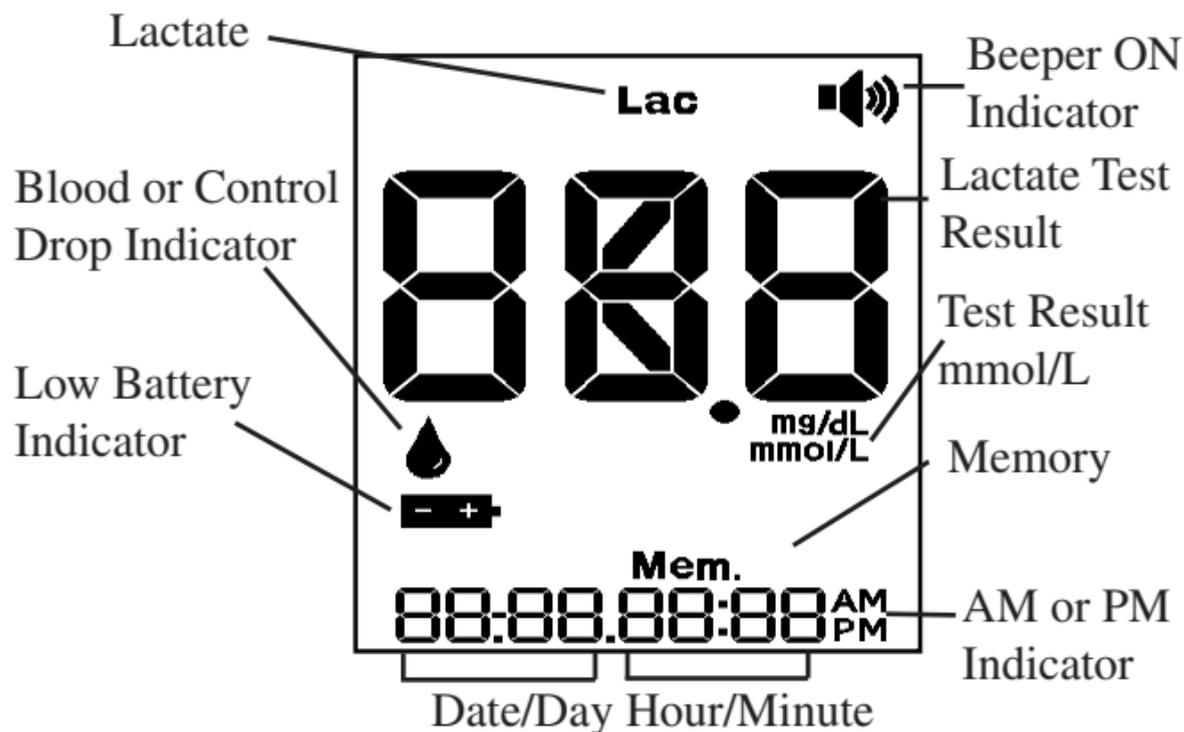
Weight:

75 g (2.65 oz)

Lactate Test Strip

LCD Display

Test Strip Ejector
Push Up to Eject

mmol/L

Left Arrow Button

Right Arrow Button

Mode Button

Result in mmol/L

Nova StatStrip Xpress Lactate Hospital Meter

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Labels on the meter screen diagram:

- Lactate — **Lac**
- Beeper ON Indicator
- Blood or Control Drop Indicator
- Lactate Test Result
- Low Battery Indicator
- Test Result mmol/L
- **mg/dL mmol/L**
- Memory
- **Mem.**
- AM or PM Indicator
- **AM PM**
- Date/Day
- Hour/Minute

Nova StatStrip Xpress Lactate Hospital Meter Screen

Intended Use

The Nova StatStrip Xpress Lactate Meter System is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood. It is intended to provide plasma equivalent results to laboratory methods. The Nova StatStrip Xpress Lactate Hospital Meter System is intended for use in a clinical setting by health care professionals as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis.

Introduction

This manual provides all necessary instructions for the routine operation and maintenance of the Nova StatStrip Xpress Lactate Meter. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Meter.

WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products and strips with care. Gloves and protective clothing are recommended.

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

Introduction

- Prior to use, read the StatStrip Lactate Meter Instructions for Use Manual.
- DO NOT reuse test strips.
- Discard used test strips according to local regulations.
- Use only the Nova StatStrip Lactate Test Strips with the Nova StatStrip Lactate Meter.
- If test result is higher or lower than expected, run a control solution test.
- Remove the test strip from the vial only when ready to test.
- Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
- Do not tamper with the test strip.

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Introduction
Additional Information for Healthcare Professionals

- The Nova StatStrip Lactate Test Strips are calibrated against plasma.
- The Nova StatStrip Lactate Test Strips are used for whole blood testing only.
- Healthcare professionals and others using this system on multiple patients should be aware that all products or objects that come into contact with human blood should be handled as if capable of transmitting viral diseases, even after cleaning.

Introduction

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

Introduction

Clinical Utility

The Measurements of lactic acid (lactate) in whole blood, serum, and plasma are used to evaluate the acid-base status of patients suspected of having lactic acidosis.

Ref. 1. Burtis, Carl A. and Ashwood, Edward R., ed. 1999. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.

The Sample

- Venous and Arterial whole blood
- Plasma calibrated patient test results
- Sample size 0.6 µL
- Anticoagulants: sodium and lithium heparin

Introduction

Interfering Substances

Lactate Interferences:

The Nova StatStrip Xpress Lactate Hospital Meter exhibits **no** interference from the following substances up to the following concentration levels:

Substances	Conc mg/dL(mmol/L)		Substances	Conc mg/dL(mmol/L)	
Acetaminophen	20.0	(0.66)	L-Dopa	5.0	(0,25)
Ascorbic Acid	10.0	(0.57)	Methyl-Dopa	1.0	(0.042)
Bilirubin	15.0	(0.26)	Salicylate	30.0	(1.87)
Cholesterol	500.0	(12.9)	Tetracycline	30.0	(0.62)
Creatinine	6.0	(0.53)	Tolazamide	15.0	(0.48)
Dopamine	10.0	(0.53)	Tolbutamide	45.0	(1.67)
Ephedrine	0.9	(0.055)	Triglycerides	750.0	(8.78)
Glucose	900.0	(49.7)	Uric Acid	20.0	(1.05)
Ibuprofen	48.0	(2.33)			

Introduction

Operation Overview

- To perform a test, the operator inserts a test strip into the test strip port. Touch the end of the strip to a drop of blood, QC solution, or linearity solution. The results are obtained in 13 seconds.
- Prior to analysis, the operator may designate the test sample as a quality control sample (level C1 or C2).
- Test results are automatically stored into non-volatile memory.
- The operator can recall and review all stored test results.
- There are automatic electronic function checks to verify proper meter operation.
- The meter stores up to 400 patient, quality control, linearity, and proficiency test data.

Introduction

- A coin-size battery provides power to operate the meter. The battery provides sufficient power to operate for approximately 600 tests. A low-battery warning on the meter display alerts the operator to change the battery.

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Introduction

Meter Sleep/Wakeup

The LCD display is turned off to conserve battery power (sleep mode) after one minute of no activity.

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

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

Wakeup

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

- Press any button.
- Insert a strip.

Setup

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

### Installing the Battery (Replacing)

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

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

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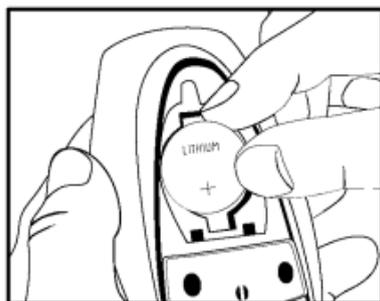
Setup

3. Replace the battery cover. All segments flash 3 times. The software version and the current date and time will appear for 3 seconds then the screen will go blank.

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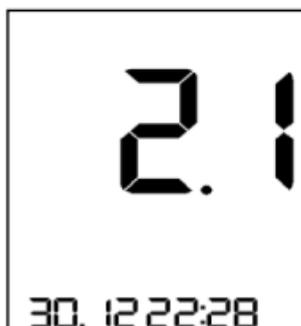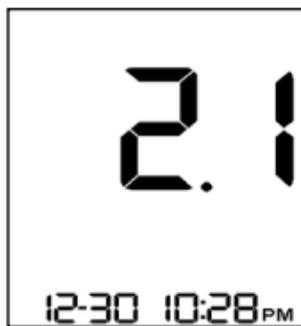
seconds), all setup settings will be saved.
If this is a battery replacement and the battery was not replaced within the time limit (30 seconds), the time and date settings may be lost. The software version and the default date and time will appear for 3 seconds. Go to setup to configure the meter.

Set the Time

1. Press the MODE ⬇ button for longer than 3 seconds. The meter if in Sleep Mode wakes up and enters the SETUP Mode.
2. Select the hour (flashing) format: either 12 Hr or 24 Hr. Press the Right/Left Arrow ◀▶ buttons to toggle between the 2 time format options.

Setup
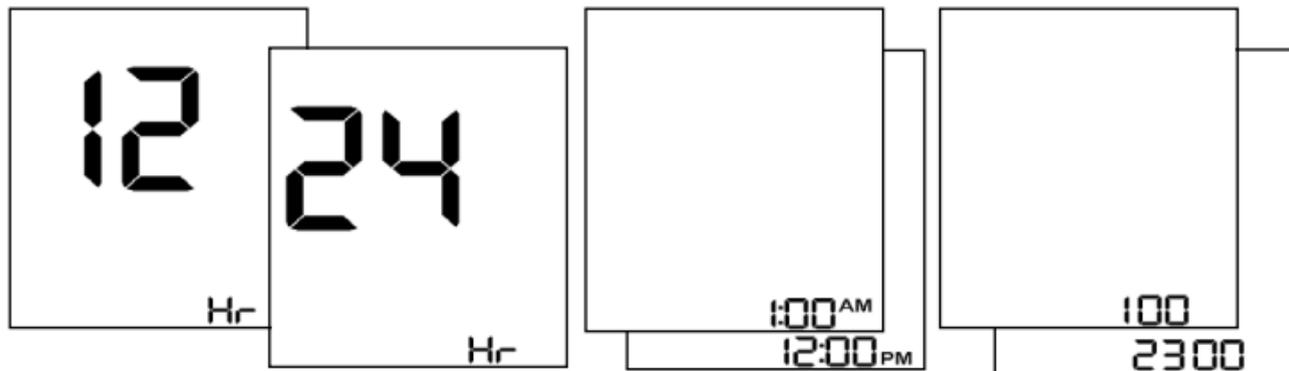
3. Press the MODE ▼ button to accept the Hour Format.
4. The meter displays the current time or the default time with the hour digits flashing.
5. Press the Right/Left Arrow ◀ ▶ buttons to scroll from 1AM to 12PM (for 12 Hr Clock) or 0 to 23 (for 24 Hr Clock).

Setup

6. Press the MODE ⧩ button to accept the displayed Hour choice.

7. Next set the minutes (digits flashing). Press the Right/Left Arrow ◂◂ ▸▸ buttons to scroll from 00 to 59 minutes.

12:00	12:59

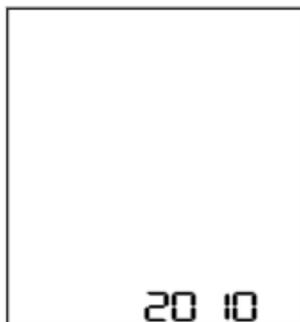8. Press the MODE ⧩ button to accept the displayed Minutes choice.

Set Date Format

1. Next set the date format. The display is 12-31 2010 or 31.12.2010.
2. You can choose to have the date displayed as DD.MM or MM-DD. Press the Right/Left Arrow ⬅️ ➡️ buttons to toggle between DD.MM or MM-DD.

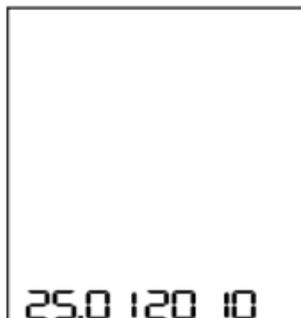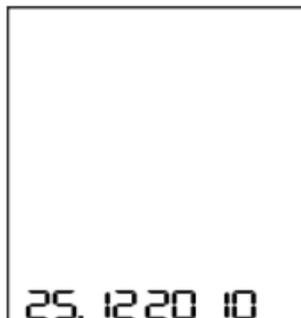3. Press the MODE 🔽 button to accept the displayed Date Format.

Setup

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

```
20 10
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```
2029
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5. Press the MODE Ⓜ▽ button to accept the displayed Year.

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Setup

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

1-25 20 10	12-25 20 10	25. 12 20 10	25.0 1 20 10

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

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

▯ ▯ 20 ▯0	▯3 ▯20 ▯0	0 ▯0 ▯20 ▯0	3 ▯0 ▯20 ▯0
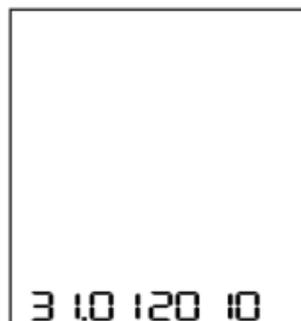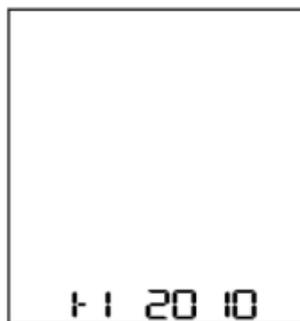
9. Press the MODE ▼ button to scroll the displayed Day.

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Setup

Beeper On or Off

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

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

Setup

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

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Testing: QC/Linearity/Proficiency/Blood Samples
This section describes how to run QC (Quality Control), Linearity Solution, Proficiency Solution, and blood samples.

Testing a Quality Control Solution

Only the Nova StatStrip Lactate Control Solutions are recommended for use with the Nova StatStrip Xpress Lactate Meter and the Nova StatStrip Lactate Test Strips. Run 2 different levels of the StatStrip Lactate Control Solutions during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

- If a patient test has been repeated and the blood lactate results are lower or higher than expected
- If there are other indications that the system is not working properly

Testing a Quality Control Solution

- As required by the institution's quality control policy or local regulatory requirements
- Anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

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Testing a Quality Control Solution

The following section explains how to run a Quality Control Test with one of the 2 StatStrip Lactate Control Solutions.

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

1. Insert a test strip into the meter. All segments of the screen will display for 2 seconds. Then a flashing blood drop will display.
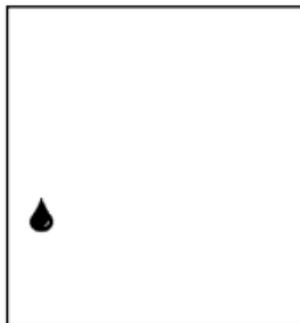
NOTE: *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

Testing a Quality Control Solution

2. Identify the sample as a Control; use the Left or Right button to find the desired control level: C1 and C2.
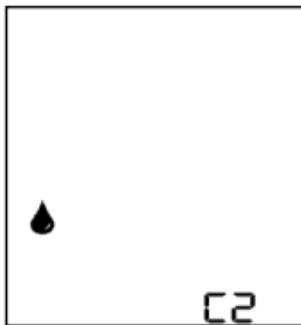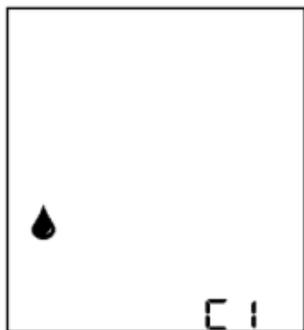
3. Touch the end of the test strip to a drop of control solution until the test strip fills and the meter beeps.

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

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Testing a Quality Control Solution

4. Lactate quality control test results are available on-screen in 13 seconds.

Result
Displayed in
mmol/L

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

Testing a Blood Sample

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

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

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

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Testing a Blood Sample

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

3. Perform a Lactate test immediately after drawing the whole blood sample.

4. Use either a syringe or a pipette to add a blood drop to the Lactate test strip.

5. When the blood drop appears, touch the end of the test strip to the blood drop until the test strip fills and the meter beeps.

6. Lactate test results are available on-screen in 13 seconds.

Testing a Blood Sample

Lac

3.4

mmol/L

10-29 12:37ᴬᴹ

Result in mmol/L

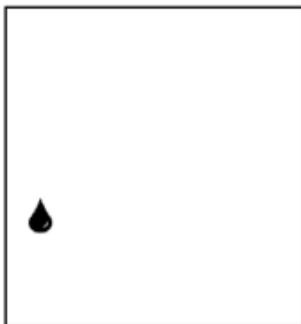7. There is one long beep when the results are ready.
    There are 3 short beeps if test results are outside
    the range of the test strip.

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Testing a Blood Sample

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


| HI Lactate (>20 mmol/L Lac) | LO Lactate (<0.3 mmol/L Lac) |

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

Testing a Linearity/Proficiency Solution

This section describes how to perform Linearity tests with the StatStrip Xpress Lactate Hospital Meter. There are 4 levels in the StatStrip Lactate Linearity kit.

1. Insert a test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.
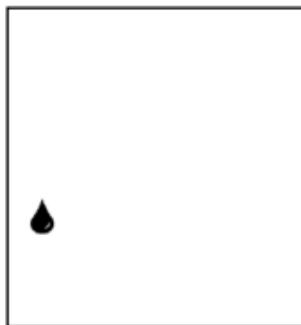
NOTE: If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.

Testing a Linearity/Proficiency Solution

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

NOTE: LinearityIProficiency test results are stored in memory as a blood sample.

NOTE: A quick beep sounds when sufficient linearity/ proficiency solution has been added to the test strip. 🔊

3. Linearity or proficiency test results are available on-screen in 13 seconds.

Testing a Linearity/Proficiency Solution

Result in mmol/L

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

Reviewing Test Results

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

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

Deleting Stored Test Results

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

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

Delete ———

236

Mem.
dELEtE

——— Number of Samples in Memory

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Deleting Stored Test Results

4. When the Screen displays dELEtE (flashing), press the left and right buttons simultaneously for greater than 3 seconds. All results are deleted. The screen will display OK and dELEtEd as shown below.

5. To exit without deleting results. press the MODE button once.

OK

Mem.
dELEtEd

Troubleshooting

This section describes Battery status, Error Codes, and Actions for the Nova StatStrip Xpress Lactate Hospital Meter.

Battery Check

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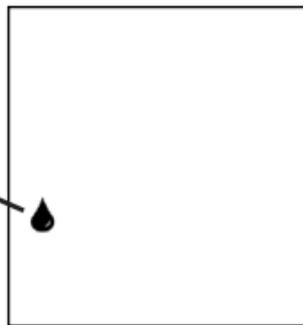
Troubleshooting

How to view the battery status of the meter:

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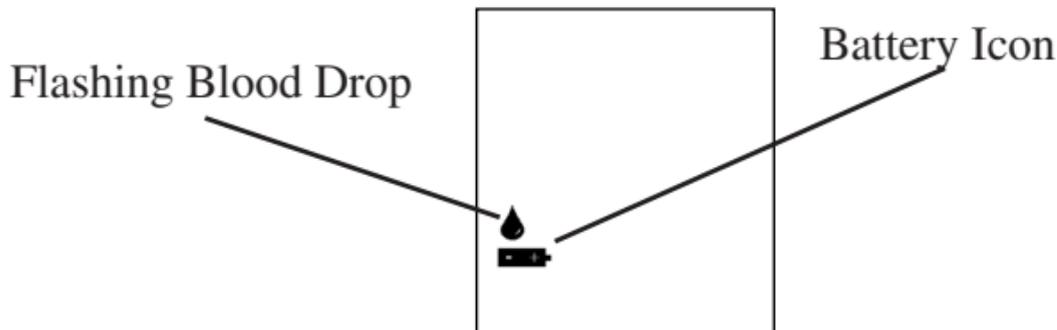 Continue with testing as usual.

Flashing Blood Drop

Troubleshooting

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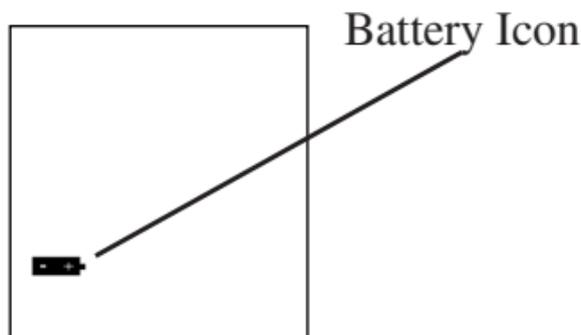
Flashing Blood Drop

Battery Icon

Troubleshooting

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

Battery Icon

Troubleshooting

Error Codes

There are 8 Error Codes to inform you of problems with the meter. This section provides action procedures when these Error Codes are displayed. The error code displays after the test strip is inserted and the all segments screen displays for 2 seconds. If the beeper is enabled, there are also 3 quick beeps. Then the Error Code is displayed on the screen.

E0 Software Error

A software error has been detected.
   Action: Perform the test again. If you get the same error again, remove and reseat the battery. If the error continues, call Nova Technical Support.

$$E-0$$

Troubleshooting

E1 System Hardware Error

A system hardware error has been detected.

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

E - 1
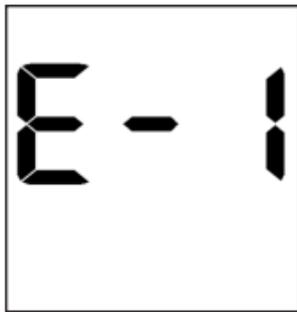
E2 Operating Temperature Error

The Meter temperature is outside of the range for testing.

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

E - 2

Troubleshooting

E3 Used Strip Error

The test strip was previously used.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

$$E-3$$
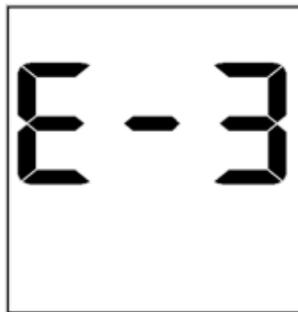
E4 Short Sample Error

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

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

$$E-4$$

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Troubleshooting

E5 Strip Not Recognized Error
The test strip is not recognized.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

$$E - 5$$

E8 Bad Strip Error
The test strip is defective or bad.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

$$E - 8$$

Troubleshooting

E9 Bad Sample Error

A problem was detected with the sample.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

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E-9
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Appendix

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

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Appendix

Specifications

Tests Measured	Blood Lactate (referred to Plasma Values)
Lactate Methodology	Enzyme, Amperometric
Lactate Test Results	mmol/L
Sample Type	Whole blood: Venous & Arterial
Lactate Test Range	0.3 to 20.0 mmol/L
Test Time	13 seconds
Test Strip Volumes	0.6 µL
Memory storage	400 Tests
Battery Life (nominal)	600 Tests
Battery Type	2450 3V coin cell
Data Cable	Serial or USB

Appendix

Operating Ranges:

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

Reference Values

Each laboratory should establish and maintain its own reference value. The value given here should be used only as a guide.
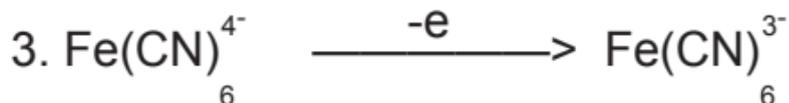
Lactate[1] 0.7 - 2.5 mmol/L

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.

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Appendix

Lactate Methodology

The lactate measurement is based on the following methodology:

$$1.\ \text{L-Lactate} + \text{LOD}_{ox} \longrightarrow \text{Pyruvate} + \text{LOD}_{red}$$

$$2.\ \text{LOD}_{red} + \text{Fe(CN)}_6^{3-} \longrightarrow \text{LOD}_{ox} + \text{Fe(CN)}_6^{4-}$$

$$3.\ \text{Fe(CN)}_6^{4-} \xrightarrow{\ -e\ } \text{Fe(CN)}_6^{3-}$$
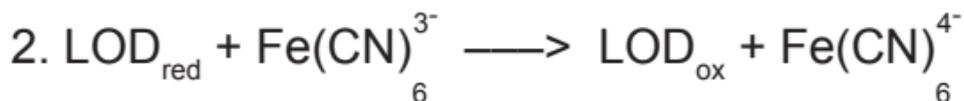
The current generated at the electrode is proportional to the lactate concentration of the sample.

Appendix

Quality Control Solution

QC Solutions	Levels 1, 2
Linearity Solutions	Levels 1, 2, 3, 4

Chemistry Measurement

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

Lactate Levels (mmol/L)	CV%
0.76	9.1
2.16	5.9
10.5	3.4
16.8	1.7

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Appendix

Ordering Information

Supplies and parts for the Nova StatStrip Xpress Lactate Hospital Meter are available from Nova Biomedical.

DESCRIPTION .... **REF**

Instructions for Use Manual 47654
Quick Reference Guide... 47631
StatStrip Lactate Test Strips, 50 test strips per box.. 47486
Lactate Control Solution, Level 1 47553
Lactate Control Solution, Level 2 47554
Linearity Solution, Levels 1-4................................. 47552
Battery (DL2450)... 41221

Appendix

Cleaning and Care

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

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

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Appendix

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

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

Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair of damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor

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Warranty

within thirty (30) days after the component failure. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. Contact Nova for specific information.

The following exceptions apply:

- Consumable items, including the test strips and quality control solutions are warranted to be free of defects until the end of the expiration date or 90 days after the date opened. The item must be placed into service prior to the expiration date printed on the packaging.
- Freight is paid by the customer.

This warranty is invalid under the following conditions:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranty on Nova StatStrip Xpress Lactate Hospital Meter if used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts.

Warranty

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGA-TIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WAR-RANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTAL-LATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHAT-SOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

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