IVD CE

LACTATE PLUS

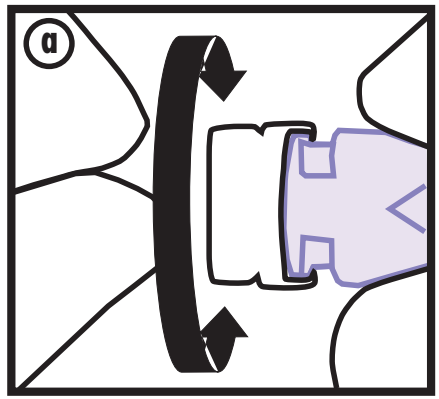
Instructions for Use Manual

nova biomedical

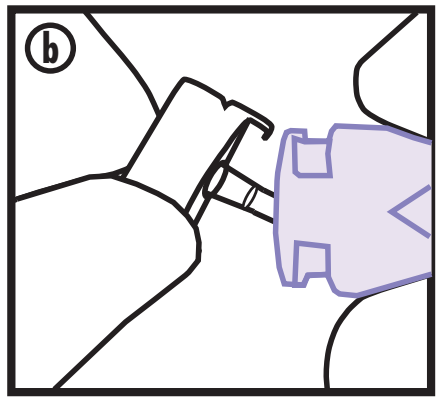
Contents

1. Prepare the lancet.

a. Simply twist off the lancet cap: Hold the lancet body and twist off the lancet cap until you feel it separate from the device.



b. Do not pull, just twist the lancet cap. Dispose of the cap in a suitable container.

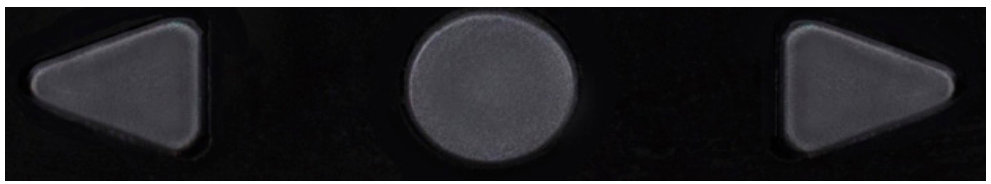


NOTE: *This lancet is for single-use only. The needle retracts immediately after sampling. This leaves the device safe for immediate disposal into a sharps container. To reduce the risk of pre-analytical error, facilities should consider using a 21-gauge lancet when collecting capillary samples.*

2. Insert a Test Strip.

Insert Test Strip: Automatic System Check begins.

User Profile Number displays: use the left ◀ or right ▶ arrow button to select profile.



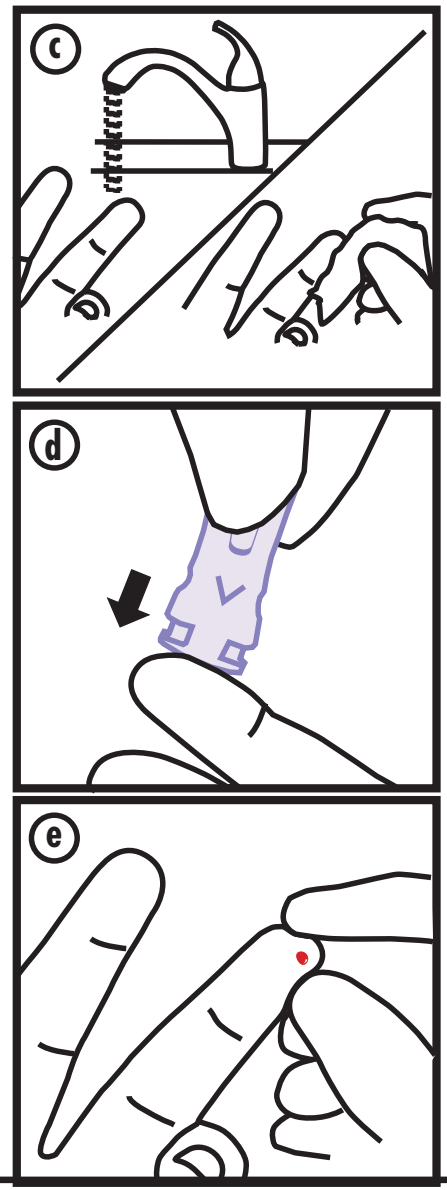
Left Arrow MODE Right Arrow

3. Prepare the Puncture Site.

c. The best puncture sites are on the middle or ring finger. Clean the finger tip **thoroughly** with soap and water. Then dry thoroughly.

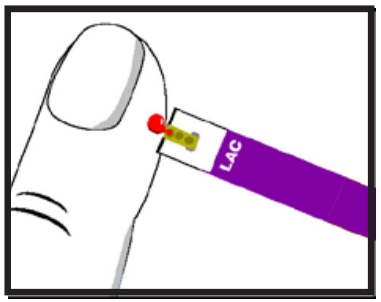
d. Place the single-use, disposable safety lancet against the pad of the finger, press the release button, remove the device from the finger.

e. Wait a few seconds for a blood drop to form. Wipe off the first drop with a clean tissue. Squeeze the finger to form a second drop of blood. **Do not squeeze vigorously.**



4. Add Blood to Test Strip.

When the second blood drop appears, touch the end of the test strip to the blood drop until the well of test strip is full and the meter beeps.



The on-screen Blood Drop flashes on and off repeatedly until sufficient blood has been added to the test strip.

The Lactate result is available on-screen in 13 seconds.

Symbols

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

IVD	*In vitro* diagnostic medical device	SN	Serial Number
EC REP	Authorized Representative in the European Community		Temperature Limitation
			Manufacturer
			Date of Manufacture
	Caution, consult accompanying documents		Contents
		REF	Catalog Number
	Consult instructions for use		Use By Date
	Biological Risk		Electronic Waste
CONTROL	Control		Device for near-patient testing
LOT	Lot Number		

Nova Biomedical recommends that the user of this device read this manual and accompanying product inserts completely before performing blood measurements.

Intended Use

The Lactate Plus Meter System is intended for use by healthcare professionals to quantitatively measure lactate in whole blood to evaluate physical performance and/or to establish a proper intensity of exercise for athletes. The meter system is for *in vitro* diagnostic use only. The Lactate Plus sport meter is NOT intended for use in the diagnosis, treatment, or monitoring of disease or other conditions associated with Lactate values in whole blood.

Limitations

- Do not use the Lactate Plus Meter System in the diagnosis, treatment, or monitoring of disease or other conditions.
- Use only capillary or venous whole blood.
- Do not use serum or plasma.
- There is no effect of altitudes up to 12,000 feet (3,658 meters) above sea level.
- Testing outside of Lactate Plus System environmental specifications may cause inaccurate results.
- Testing of blood sample with Hematocrit outside of 20% - 65% range may cause inaccurate results.

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

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

NOTES *provide important or helpful operating information.*

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. Place the meter away from heat sources.
6. The meter should be cleaned only as recommended by the manufacturer.
7. The meter should be serviced by qualified service personnel.

Safety

Electrical Safety

1. Battery powered: 2 AAA batteries

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.

The Lactate Plus Meter

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 lactate, i.e., test strips, lancets, and alcohol swabs, must be disposed of in accordance to local regulations to avoid risk to anyone.*

WARNING: *Please keep the Lactate Plus Meter and its accessories out of reach of small children to prevent accidents through improper handling and to avoid the risk of small parts being swallowed.*

Introduction

LCD Display

Mode Button

Left Arrow Button

Right Arrow Button

Lactate Plus Test Strip

Eject Button: Bottom-Middle-Back

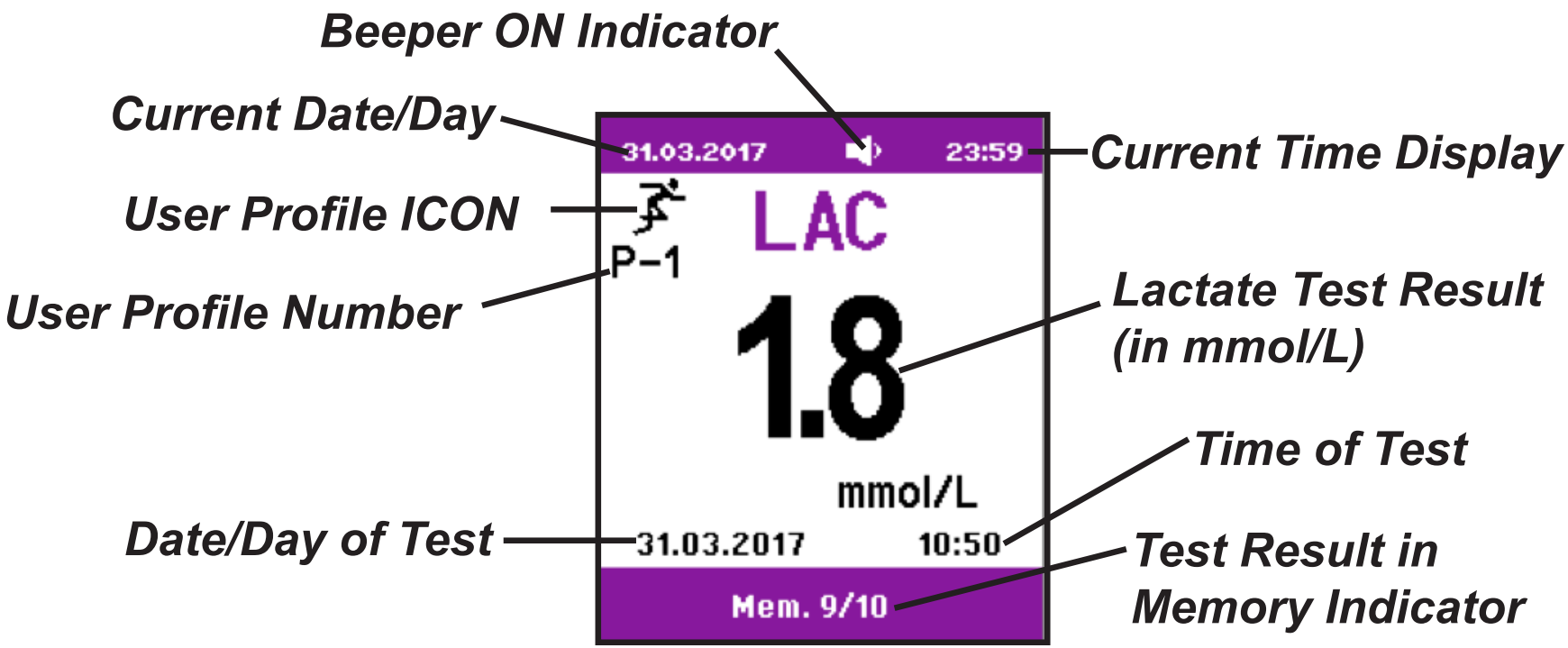
Lactate Plus Meter

Introduction

The Lactate Plus Meter is a hand-held testing device that measures lactate (LAC) in whole blood. The test strip is touched to a drop of blood to initiate the test process.

- A simple one-step process provides a blood lactate result.
- Test result is available in 13 seconds.
- Supports 10 user profiles. P-0 user profile can store up to 20 test results, P-1 to P-9 can store up to 10 test results in each profile;
- Stores up to 10 QC test results each for QC1 and QC2.
- The unit is powered by a battery that can perform for approximately 600 tests.

Introduction



Lactate Plus Meter Screen

Introduction

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 high temperatures.*

Overview

To perform a test, the operator simply inserts a test strip; touches the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps; and obtains a lactate test result in 13 seconds. The test result is automatically stored into the meter's memory. The operator can recall, delete, and review test data resident in the meter, including the average for each control and user profile's results.

Meter, Supplies, Transport Case

The Nova Lactate Plus Meter (62623) comes in a soft carrying case that includes:

1. Lactate Plus Meter with Battery
2. Instructions for Use Manual

See Page 59 for Ordering Information.

Environmental Specifications

- The meter operational temperature range for Lactate: 41°F to 113°F (5°C to 45°C)
- The storage temperature range for the Test Strips and Control Solutions: room temperature 15°-30°C/59-86°F
- The relative humidity range: 10% to 90% non-condensing
- The maximum altitude for meter operation: up to 12,000 feet (3,658 meters)

Disposal of Used Batteries and Meters for Customers in Europe

- This symbol  on the product label indicates that the product should not be treated as household waste.

  Batteries: To ensure the used battery is treated properly, remove the used battery from the product and hand over the used battery to the applicable collection point for the recycling of electrical and electronic equipment.

  Meters: To ensure the product is disposed of properly, decontaminate the product according to the instructions provided in the Appendix of this manual and hand over the product to the applicable collection point for the recycling of electrical and electronic equipment.

Interfering Substances

Seventeen (17) interference compounds were studied to determine if their presence affected the reporting of lactate results in whole blood. None of the compounds interfered with the reporting of the Lactate Results at the tested concentration range.

Compound	Concentration Range Tested
Acetaminophen	0-10 mg/dL
Ascorbic Acid	0-10 mg/dL
Bilirubin	0-15 mg/dL
Cholesterol	0-500 mg/dL
Creatinine	0-6 mg/dL
Dopamine	0-10 mg/dL

Introduction

Compound	Concentration Range Tested
Ephedrine	0-0.8 mg/dL
D-Glucose	0-900 mg/dL
Ibuprofen	0-48 mg/dL
L-Dopa	0-100 mg/dL
Methyl-Dopa	0-1 mg/dL
Salicylate	0-30 mg/dL
Tetracycline	0-30 mg/dL
Tolazamide	0-15 mg/dL
Tolbutamide	0-45 mg/dL
Tryglycerides	0-750 mg/dL
Uric Acid	0-20 mg/dL

Setup

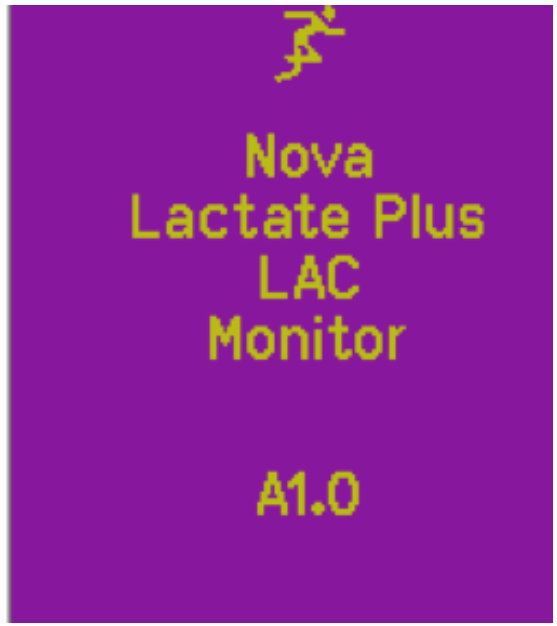
This section describes how to setup the Nova Lactate Plus Meter. The operator can set the meter for local time and date, have the beeper On or Off, enable the sample counter, and set the date display format.

Installing the Battery (Replacing)

The meter is powered by 2 AAA batteries. Install/Replace the battery as follows:

1. Remove the back battery cover on the meter.
2. Install 2 AAA batteries. Make sure the positive and negative ends are facing the correct direction. (If replacing the batteries, remove the used batteries and replace with new batteries.)
3. Replace the battery cover. The software version and the default date and time will appear for 3 seconds.

CAUTION: *Upon installing the battery, the meter software version displays for 3 seconds. Software versions may be numeric (example A1.0); therefore, please exercise caution to ensure the software version is not reported as a test result.*



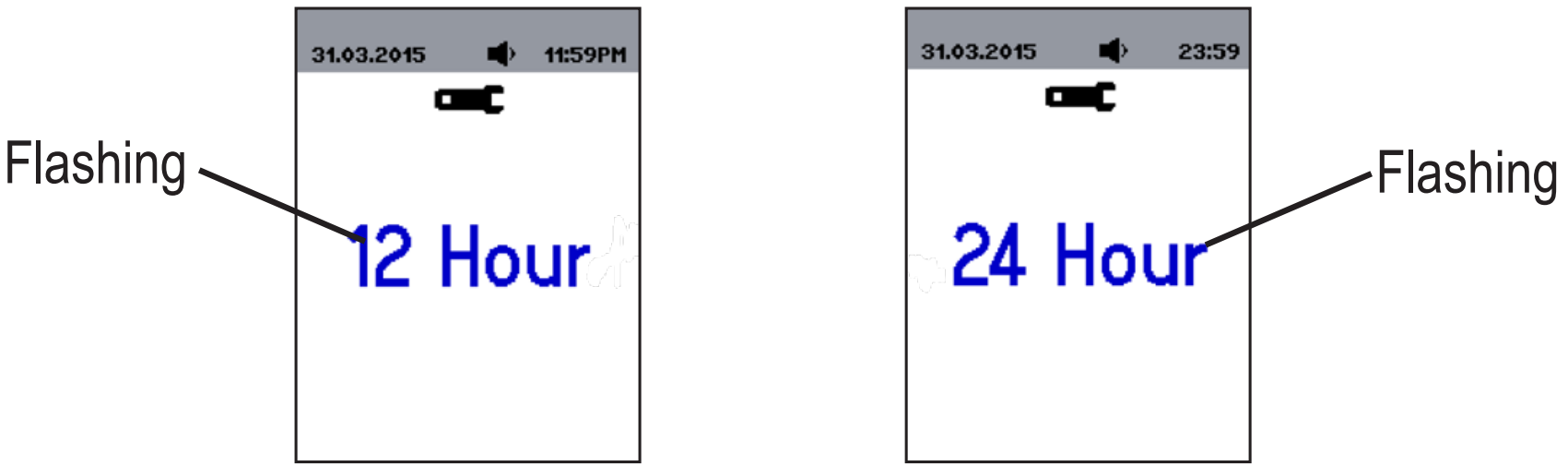
4. After the 3 seconds, the meter immediately goes to setup to configure the meter.

Set the Date and Time

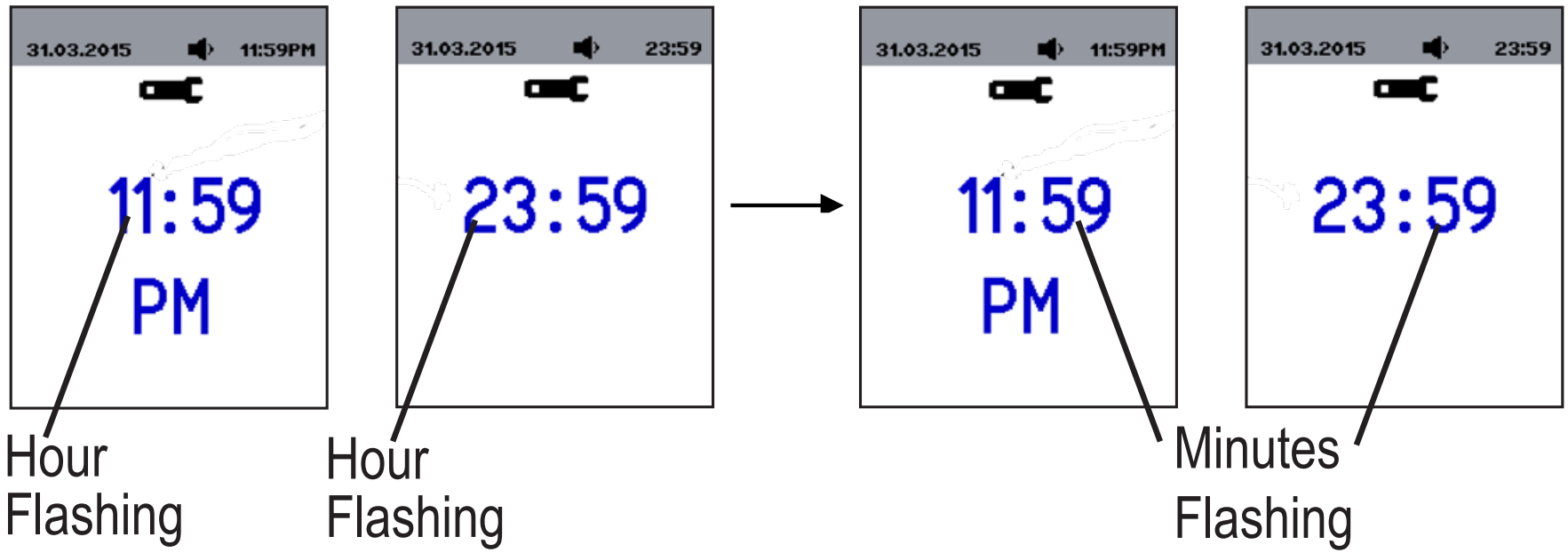
NOTE: *While performing date and time setup, the selected item, hour or minute, day, month or year, will be flashing.*

Set Time Format

1. Press the MODE button for longer than 3 seconds. The meter, if in sleep mode, wakes up and enters the setup mode.
2. Press the left or right arrow button to toggle between the 2 time format options, either 12 Hr or 24 Hr.



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.

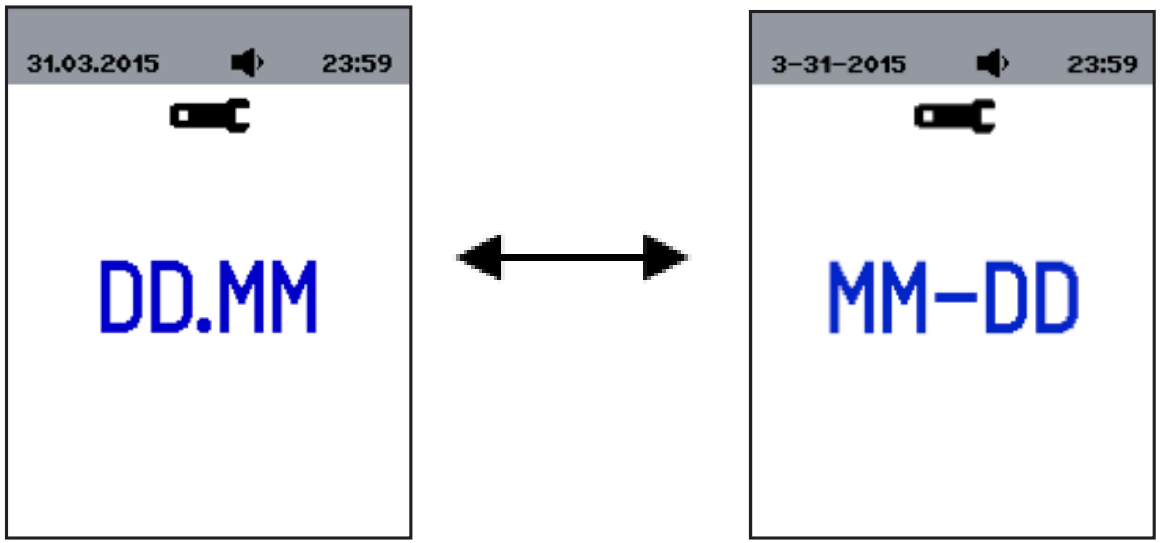


5. Press the left or right arrow button to set the hour. Scroll from 12AM to 12PM for a 12 hour clock, or 0 to 23 (for a 24 Hr Clock).

6. Press the MODE button to accept the displayed hour choice. The hour choice displays with the minute digits flashing.
7. Press the left or right arrow button to set the minutes. Scroll from 00 to 59 minutes.
8. Press the MODE button to accept the displayed minutes choice.

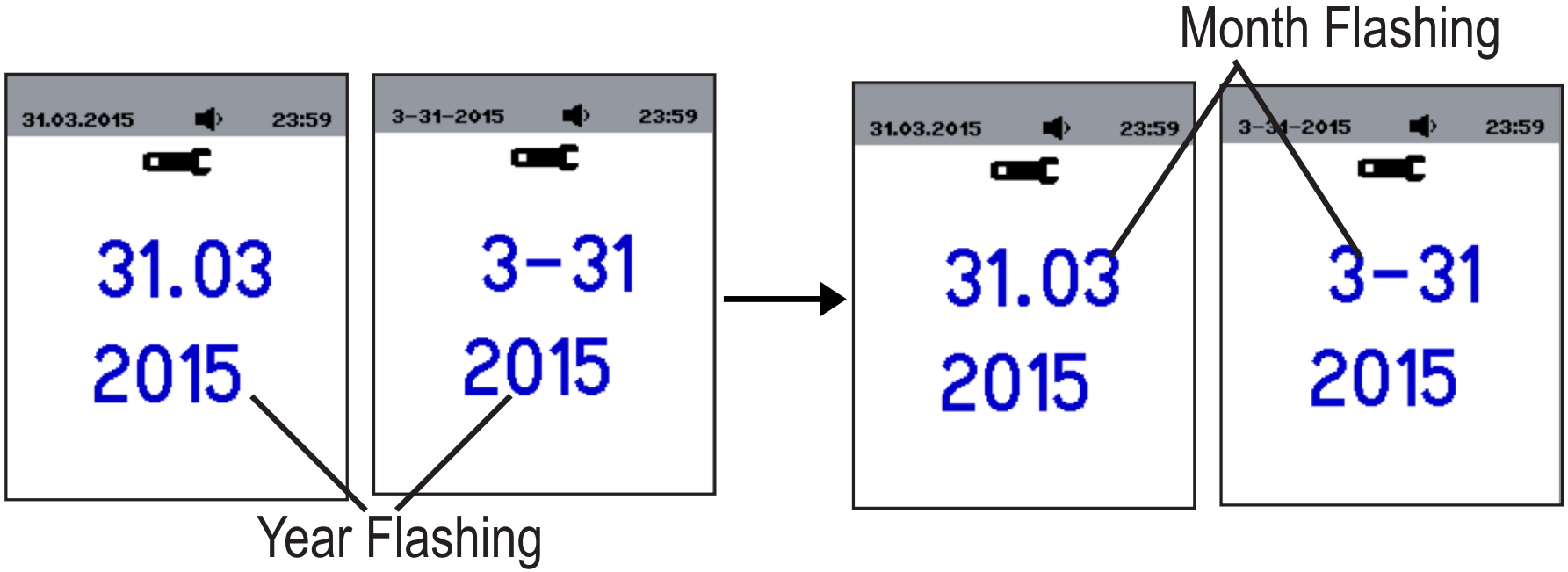
Set Date Format

1. Choose to have the date displayed as DD.MM or MM-DD. Press the left ◀ or right ▶ arrow button to toggle between the two choices.



Setup

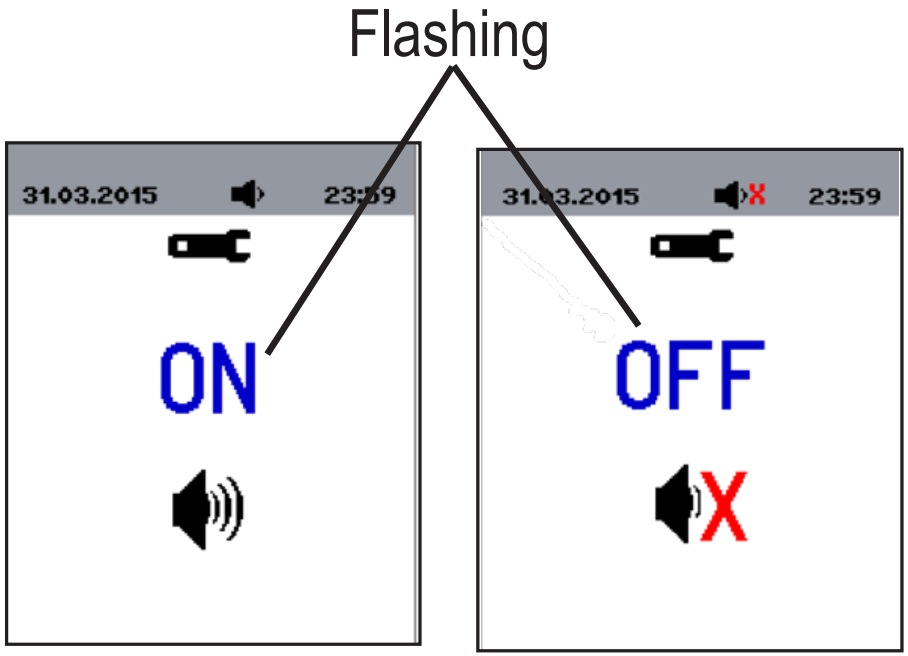
2. Press the MODE ● button to accept the displayed date format. The year should be flashing.
3. Press the left ◀ or right ▶ arrow buttons to select the current year.
4. Press the MODE ● button to accept the displayed Year. The month should be flashing.



5. Press the left ◀ or right ▶ arrow buttons to scroll through the 12 months (1 to 12).
6. Press the MODE ● button to accept the displayed Month. The day should be flashing.
7. Press the left ◀ or right ▶ arrow buttons to scroll through the days of the month.
8. Press the MODE ● button to accept the displayed day.

Beeper On or Off

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



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

End of Setup

End displays 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.

Testing: Blood and Quality Control Solutions

NOTE: *Before running a blood or quality control test, check that the expiration date of the test strips and control solution has not elapsed. (See product insert sheets for details.)*

The control solution test results should fall within the range of results printed on the label of the control solution. You should run a control solution test:

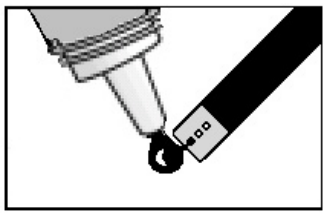
- Before using your Nova Lactate Plus Meter for the first time and at least once a week thereafter
- Each time you open a new box of Nova Lactate Test Strips
- If you leave the Nova Lactate Test Strip vial cap open for an extended period of time
- If you drop your Nova Lactate Plus Meter
- If your results are higher or lower than expected

Only Nova Lactate Plus Lactate Control Solutions are recommended for use with the Lactate Plus Meter and the Lactate Plus Lactate Test Strips. Ranges for the Lactate Plus Meter using other commercially available Lactate controls have not been established.

Testing: Blood and Quality Control Solutions

Testing a Quality Control Solution

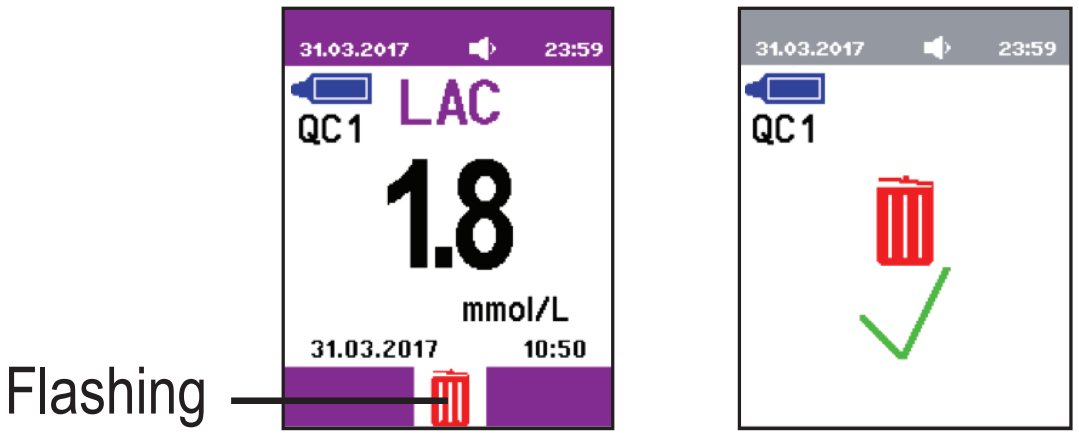
1. Grasp a test strip with logo side up and gold side down. Then insert the gold end into the meter. (See Meter figure.)
2. Identify the sample as a control; Use the left ◀ or right ▶ arrow buttons to find the desired control level: QC1 or QC2 .
3. Shake the control solution well before each use. Discard the first drop.
4. Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip.
5. A Lactate quality control test result is available on-screen in 13 seconds.



6. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.
7. The result is automatically stored into memory.
8. If this result is not needed, hold down the both the left ◀ and right ▶ arrow buttons for 2 seconds to enter

delete single test mode (while the test strip is still in place). The delete icon flashes at the bottom of the screen.

9. Press the mode button to confirm deletion or press the left or right arrow button to stop deletion and exit the delete mode.



Testing: Blood and Quality Control Solutions

Important Safety Instructions

1. Healthcare professionals and others using this system should adhere to Standard Precautions when handling or using the Lactate Plus Meter.
2. Healthcare professionals should be aware that all parts of the Lactate Plus Meter are considered potentially infectious and can potentially transmit bloodborne pathogens between patients and healthcare professionals.
3. The Lactate Plus Meter may only be used for testing on multiple patients when standard precautions are followed and when the system is cleaned and disinfected after use on each patient following the procedure in the Appendix. Healthcare professionals

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

4. Only auto-disabling, single-use lancing devices may be used with this system.
5. For more information, refer to the following references:

"Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," http://www.cdc.gov/hicpac/2007ip/2007isolatio nprecautons.html.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at https://www.cdc.gov/labs/BMBL.html.

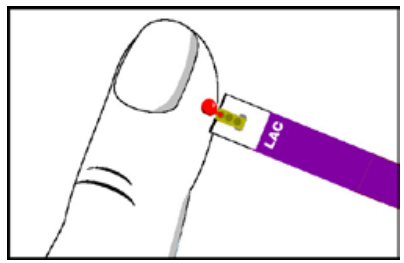
"Protection of Laboratory Workers From Occupationally Acquired Infection ; Approved Guideline - Fourth Edition ," Clinical and Laboratory Standards Institute (CLSI) M29-A4. http://www.fda.gov/Medicaldevices/Safety/ AlertsandNotices/ucm224025.html.

"CDC Clinical Reminder: Use of Fingerstick Devices." https://www.cdc.gov/injection-safety/fingerstick-devicesbgm.html.

Testing a Blood Sample

NOTE: *The hands should be warm and relaxed. Obtain blood sample from a finger.*

1. Check that the expiration date of the test strips has not elapsed.
2. Wash hands thoroughly with soap and water then dry thoroughly. Alternatively, use alcohol pads to clean area 3 times; dry thoroughly after each cleaning.
3. Grasp a test strip. Insert the gold end into the meter.
4. Select a profile number; use the left ◀ or right ▶ arrow buttons to find the Profile Number (P-0 to P-9).



Testing: Blood and Quality Control Solutions

NOTE: *Cleaning of the puncture site is important. Sweat left on the fingers may cause falsely high lactate test results.*

5. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
6. Use a single-use, disposable safety lancet to puncture the finger. To reduce the risk of pre-analytical error, facilities should consider using a 21-gauge lancet when collecting capillary samples.
7. Wipe off the first drop with a clean tissue. The first drop may be contaminated.
8. Squeeze the finger to form a second drop of blood. To avoid collection of interstitial fluid as well as blood, **do not squeeze vigorously**.

9. When the second blood drop appears, touch the end of the test strip to the blood drop until the well of test strip is full and the meter beeps.

NOTE: *The on-screen Blood Drop flashes on and off repeatedly until sufficient blood has been added to the test strip.*

10. If subject has to immediately return to exercise and puncture site is still bleeding, apply light pressure with a cotton pad or tissue until the bleeding stops or cover with a bandage.
11. The Lactate result is available on-screen in 13 seconds. (See pages 42 and 43.)
12. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.

Testing: Blood and Quality Control Solutions

NOTE: *While ejecting a test strip, care should be exercised not to point ejected strips anywhere other than a biohazard container.*

13. The result is automatically stored into memory.
14. If the result is not needed, press both the left ◀ and right ▶ arrow buttons for 2 seconds to go to delete mode (while the test strip is still in place). The delete icon 🗑 flashes at the bottom of the screen.
15. Press the MODE ● button to confirm deletion or press the left ◀ or right ▶ arrow button to stop deletion and exit the delete mode.

Testing: Blood and Quality Control Solutions

WARNING: Once a disposable item, i.e., lancet, test strip, alcohol swab, etc., has been used, it is considered contaminated. Dispose of all contaminated materials in accordance with local regulations. Equipment such as lancets and tissues must be used only once and then disposed of even when repeated measurements are being made on the same subject.

Reference
Graeme Maw, Simon Locke, David Cowley, and Patricia Witt. 2000. Blood Sampling and Sampling Techniques. In *Physiological Tests for Elite Athletes.* ed. Christopher John Gore, PhD. 91-92. Champaign, IL. Human Kinetics.

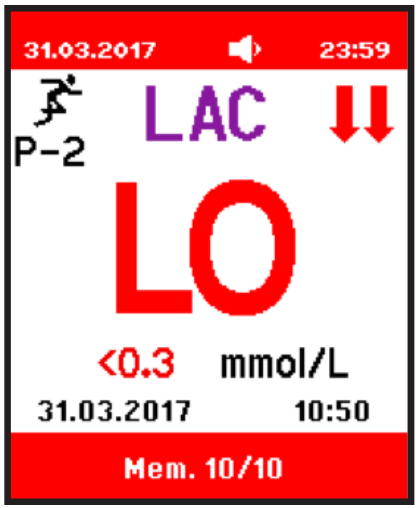
Testing: Blood and Quality Control Solutions

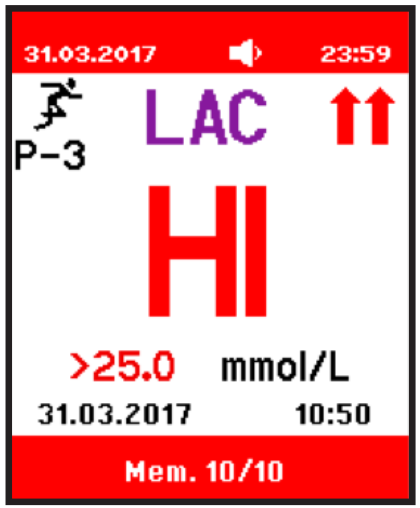
Lactate Plus Meter with Display Results

nova biomedical

Testing: Blood and Quality Control Solutions

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





LO and HI Result Screens

Data Review

NOTE: *If a test strip is inserted while in the Data Review mode, the meter immediately switches to test mode. If you then exit the test mode, the meter screen goes blank- the meter does not return to the Data Review mode.*

Manually Reviewing Stored Test or Control Results

1. With the meter off, press the MODE button for < 1.5 seconds. (To turn the meter off, press the MODE button for 1.5 seconds or longer.)
2. The most recent test result in the last user's profile is displayed.
3. Press the MODE button to advance to the user profile (P-0 to P-9) or control level (QC1 or QC2) that you want to review.

NOTE: *When there are no results in the user profile, the monitor will display three dashes (---).*

4. Press the right ▶ arrow button once to view the average of the test results for the selected user or the control level.
5. Continue pressing the right ▶ arrow button to scroll through additional test results for the selected user or the control level.
6. Press the left ◀ arrow button to scroll through previous test results for the selected user or the control level.
7. If a result is not needed, press both the left ◀ and right ▶ arrow buttons for 2 seconds to go to delete mode. The delete icon flashes at the bottom of the screen.
8. Press the MODE ● button to confirm deletion or press the left ◀ or right ▶ arrow button to stop deletion and exit the delete mode.

Basic Upkeep

Cleaning and Disinfecting the Meter

This section describes two cleaning and disinfecting procedures. Please follow the procedure that adheres to local regulations.

WARNING: Cleaning is not the same as disinfecting. Cleaning means to remove protein or other contaminants from the surface. Disinfecting means to kill or prevent the growth of disease-carrying micro organisms. The Nova Lactate Plus Meter should be cleaned and disinfected after each patient use over the intended 3 year use-life of the Meter.

Procedure 1

The Nova Lactate Plus Meter cleaning and disinfecting procedure was validated a total of 10,950 times by Nova Biomedical to simulate 3 year use-life of the Monitor. The validation testing corresponded to cleaning and disinfecting 10 times a day for 3 years.

Acceptable Cleaning and Disinfecting Materials

Nova Biomedical recommends the use of Clorox Healthcare® Bleach Germicidal Wipes, EPA Registration #67619-12, or any disinfectant product with EPA Registration #67619-12 may be used.

Meter Cleaning and Disinfection

Clean and disinfect after each patient use by following this protocol to help ensure effective cleaning and disinfection. Cleaning is not the same as disinfecting. Cleaning is

intended to remove protein, visible blood, bodily fluids and soils from the external surfaces. Disinfecting means to kill or prevent the growth of disease carrying microorganisms. The Nova Lactate Plus Meter should be cleaned and disinfected after each patient use to minimize the risk of transmission of blood-borne pathogens between patients and healthcare professionals.

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

Basic Upkeep

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

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

2. **Disinfect the Meter.**
   - Remove another fresh Clorox 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.

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

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

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

5. **Wash and sanitize hands.**
   - Wash your hands thoroughly with soap and water.

Alternate Procedure

When cleaning the meter, please follow the guidelines listed below:

- Always apply the cleaning agent to a soft cloth to wipe the meter surface. Once complete, immediately dry thoroughly.
- The meters should never be immersed in any cleaning agent.
- 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.

Basic Upkeep

- Avoid harsh solvents such as benzene and strong acids.
- Care should be used to limit exposing test ports to fluids as it may result in damage to the unit.

General Precautions for Cleaning and Disinfecting the Meter

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! Only Nova Biomedical authorized service personnel can repair the meter. Call Nova Biomedical or an authorized dealer if the meter needs to be repaired or checked.*

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.

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.*

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

Error Messages

Codes

Code	Alerts	Action
E-0	Software error detected	Perform the test again. If you get the same error, call Nova Technical Support.
E-1	Hardware error detected	Perform the test again. If you get the same error, call Nova Technical Support.
E-2	Meter temperature is outside of the range for testing	Move the meter to an area where the temperature is acceptable (41°-113°F), allow meter to adjust to the temperature. Repeat testing.
E-3	Defective or previously used test strip is detected	Repeat test with a new test strip.
E-4	A short sample (control solution or blood) is identified	Repeat test with a new test strip and adequate sample.
LO or HI	If test results are outside of the measuring range of the meter	Repeat test. If you get the same result, consult your physician.
	Battery level is low	Replace the battery

Appendix

Specifications

Tests Measured	Blood Lactate
Lactate Methodology	Lactate oxidase biosensor
Lactate Test Results	mmol/L
Sample Type	Whole blood (capillary or venous)
Lactate Test Range	0.3 to 25.0 mmol/L
Limit of Detection	0.12 mmol/L
Limit of Quantitation	0.12 mmol/L
Test Time	13 seconds
Test Strip Volumes	0.7 µL
Battery Life (nominal)	600 Tests
Data Output Port	Serial
Data Output Cable (optional)	

Appendix

Operating Ranges:

Temperature Range	41° to 113°F (5° to 45°C)
Humidity	10% to 90% relative humidity
Weight	2.77 oz (78.5 g)
Size	3.9x2.4x0.9 in (98.0x61.0x22.9 mm)

On-board data storage files:

User profile P-0 can store up to 20 test results.

P-1 to P-9 each can store up to 10 test results.

QC1 and QC2 can store up to 10 test results each.

Appendix

Ordering Information

Supplies and parts for the Lactate Plus Meter System are available from Nova Biomedical.

DESCRIPTION	REF
Vial of Test Strips (25)	40813
Lactate Plus Control Solution, Level 1	40815
Lactate Plus Control Solution, Level 2	40814
Battery (2 AAA)	57081
Soft Carrying Case	41266

Performance Characteristics

The test measurement range for Nova Lactate Plus Meter is 0.3 to 25.0 mmol/L for Lactate.

Appendix

Accuracy

Accuracy of the Lactate Plus Meter system (Lactate Plus Monochrome) was assayed at clinical sites by comparing lactate results obtained by Lactate Plus Meter vs YSI Reference method from subjects at clinical sites. Blood lactate measurements obtained from Nova Lactate Plus Meter were compared with the same subjects' results from the YSI, a laboratory reference method. The latter results were plasma-derived values from a blood sample measured on a YSI 2300 Stat Plus Analyzer.

- Number of Samples: 210
- Slope: 0.968
- Correlation Coefficient (r): 0.997
- y-intercept: 0.165 mmol/L
- Range tested: 0.5 - 12.4 mmol/L

These results indicate that Nova Lactate Plus Meter compared well with the laboratory reference method.

Appendix

Methodology

The Lactate measurement is based on the following methodology:

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

Equation 1

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

Equation 2

$$\text{Fe(CN)}_6^{4-} \xrightarrow[\text{Electrode}]{-e^-} \text{Fe(CN)}_6^{3-}$$

Equation 3

The current generated at the electrode is proportional to the Lactate concentration of the sample.

Appendix

Precision

Precision of Nova Lactate Plus Meter was measured with both venous blood samples and control solution in laboratory. The results for the blood samples are shown below:

Summary of Lactate Plus Within-Run Precision - Blood Results

		Lactate Blood Level				
		L1 (N=20)	L1 (N=20)	L1 (N=20)	L1 (N=20)	L1 (N=20)
Lot 1	Mean	1.6	6.5	10.8	18.1	22.1
	CV%	3.6	1.9	1.6	2.7	3.2
	SD (mmol/L)	0.06	0.12	0.17	0.49	0.70
Lot 2	Mean	1.2	6.1	10.3	16.9	20.7
	CV%	4.9	2.4	1.6	3.9	4.9
	SD (mmol/L)	0.06	0.15	0.17	0.66	1.01

Summary of Within-Run Precision - Control Solution Results

		Lactate Aqueous Level 1 (N=20)	Lactate Aqueous Level 2 (N=20)	Lactate Aqueous Level 3 (N=20)
Lot 1	Mean	1.3	4.4	14.0
	CV%	4.1	1.9	1.4
	SD (mmol/L)	0.05	0.09	0.20
Lot 2	Mean	1.3	4.6	14.0
	SV%	5.0	2.6	1.0
	SD (mmol/L)	0.06	0.12	0.14

Day to Day Precision - Control Solution Results

		Lactate Aqueous Level 1 (N=20)	Lactate Aqueous Level 2 (N=20)	Lactate Aqueous Level 3 (N=20)
Lot 1	Mean	1.3	4.6	14.1
	CV%	4.74	3.46	1.78
	SD (mmol/L)	0.06	0.16	0.25

Traceability

Analyte is traceable to the Nova L-Lactate Primary Standard (L-Lactate: Sigma CAS 27848-80-2).

Appendix

References

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2. Hirano, K., Yamato, N., Kunimoto, K., and Ohwa, M. 2001. *Novel Electron Transfer mediators Based on Dichloroindophenol Derivatives for Lactate Oxidase: Journal Electroanalytical Chemistry.* Vol. 510 pp 149-152.
3. Shimoje, N., Naka, K., Uenoyama, H., Hamamoto, K., Yoshioka, K., and Kiyoshi, O. 1993. *Electrochemical Assay System with Single-use Electrode Strip for Measuring Lactate in Whole Blood: Clinical Chemistry. Vol.* 39 pp 2312-2314.
4. Sprules, S.D., Hart, J.P., Wring, S.A., and Pittson, R. 1995. *A Reagentless, Disposable, Biosensor for Lactic Acid based on a Screen-printed Carbon Electrode Containing Meldola's Blue and Coated with Lactate Dehydrogenase, NAD+ and Cellulose Acetate: Anal. Chim. Acta.* Vol 304 pp 17-24.

Appendix

Instructional Notes

1. Inserting a test strip overrides all other modes except Upload mode.
2. There is no “All segments Screen” in Upload mode.
3. When in Upload mode, no other meter functions are available, and there is no response by meter to button presses.
4. The meter times out in 5 minutes in Upload mode.
5. If in setup mode when the test strip is inserted, the meter saves all values entered up to that point and immediately switches to test mode. Upon exiting test mode the meter screen goes blank and does not return to setup mode.

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7. If in Data Review mode when the test strip is inserted, the meter immediately switches to test mode. Upon exiting test mode the meter screen goes blank and does not return to Data Review mode.
8. Battery low icon is displayed in every mode except setup.
9. Once battery level goes below the threshold that triggers the “low battery” warning, it continues to give the warning until the meter becomes unusable due to low battery.
10. A failed control solution does NOT lock the user out of the meter.
11. Beeps that are not disabled when ‘BEEP’ is set to OFF: The ‘quick triple beep’ warning for HI or LO errors and Error codes E-0 to E-4.
12. “LO” and “HI” results are omitted from any averages, but are uploaded.

13. The Meter responses to the pressing and the holding of keys:

Left or Right Arrow buttons

- Use the left or right arrow buttons to scroll through the user's test results.
- In cases where the arrow buttons move forward through a series of stored test results or incrementing a value, hold down the left or right arrow button to advance to the next screen.
- While meter is in DATA REVIEW, after user profile is selected, press the right arrow button once to display the result average screen of the selected user.

MODE button

- When the MODE button is pressed < 1.5 seconds to advance to the next user profile, the meter advances to next screen immediately.

- While meter is awake (ON), pressing the MODE button > 1.5 seconds manually turns off the meter (sleep mode).
- While meter is in sleep mode (OFF), pressing the MODE button < 1.5 seconds wakes up the meter and enters data review mode.
- While meter is in sleep mode (OFF), pressing the MODE button > 3.0 seconds wakes up the meter and enters setup mode.

14. With No Activity, Time-out will occur in
    1 Minute for all screens
    2 Minutes during analysis
    1 Minutes after the completion of analysis
    5 Minutes when upload connector inserted

Appendix

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 within one (1) year from date of shipment 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 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 at time of initial use. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing.
- 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:

Appendix

Nova Biomedical will not be responsible for any warranty on Lactate Plus 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. Reagent or quality control solution formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as erratic analytical results or inaccurate meter performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, 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, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

EC REP **Authorized Representative**

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

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

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