



VivaChek

Lactate Analyzer

Dear VivaChek™ Lactate Analyzer User,

Thank you for choosing the VivaChek™ Lactate Analyzer. The VivaChek™ Lactate Analyzer is designed for easy testing of lactate and to access change in physical performance and conditioning in healthy people the field of sport.

Read this User's Manual carefully before you use VivaChek™ Lactate Analyzer. This manual will help you to get using the VivaChek™ Lactate Analyzer reliable test results. Please keep your User's Manual in a safe place, you may want to refer to it in the future.

Thank you again for choosing the VivaChek™ Lactate Analyzer.

Intended Use

The VivaChek™ Lactate Analyzer is intended for use outside the body. It is not designed for taking quantitative lactate measurements to support clinical diagnoses in medical applications. No diagnosis or medical action should be taken on the basis of the values.

Use only VivaChek™ Lactate test strips with your VivaChek™ Lactate Analyzer.

Use only VivaChek™ Lactate control solution with your VivaChek™ Lactate Analyzer.

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Chapter 1: Understanding Your Testing Tools

Your Analyzer Overview

The VivaChek™ Lactate Analyzer and Test Strip

Electrocode end:

this end is inserted into the strip port on the meter, facing upwards, in the direction of the arrows.

Sample tip:

where the blood is drawn in

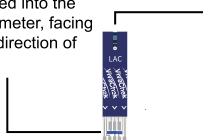
Test strip port

Main button

Type-c data port

Display

Shows test results, and related information



Your Analyzer Display

The picture below shows all the symbols that appear on your analyzer display. To make sure the display is working properly. All of the segments should be clear and exactly like the picture below. If not, contact your local distributor for help.



Icon	What it Means
00:00	The top left area on the screen indicates the time and Code icon.
AM PM	The top middle area on the screen indicates morning or afternoon time.
00-10	The top right area on the screen indicates the date.
M	Indicates test result history.
Bluetooth icon (flashing)	When it is flashing, it indicates an attempt to establish a connection. A solid icon signifies successful Bluetooth communication.
Bluetooth icon (solid)	Indicates unsuccessful Bluetooth communication.
Battery icon (full)	Indicates depleted battery or a battery in need of recharging.
Battery icon (depleted)	Shows test results or error codes.
Test icon and drop icon	Indicates the analyzer is ready to test.
Bottle icon	Control test result.
mmol/L	Test results are displayed as mmol/L.
mg/dL	Test results are displayed as mg/dL.

Analyzer Use and Precautions

- Do not get water or other liquids inside the analyzer.

- Do not drop the analyzer or get it wet.

If you do drop the analyzer or get it wet, check the analyzer by running a quality control test. Refer to **Quality Control Test** for instructions.

- Keep the strip port area clean.

- Keep your analyzer dry and avoid exposing it to extremes in temperature or humidity.

- Do not take the analyzer apart.

Taking the analyzer apart will void the warranty.

- Refer to the **Caring for Your Analyzer** section for details on cleaning the analyzer.

- Keep the analyzer and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the analyzer.

Important Safety Information

- **Always keep the test strips in the original vial.** Tightly close the vial immediately after you have removed the test strip.
- Do **not** use the **analyzer** if it is **wet**.
- **Wash and dry your hands** well before and after testing.
- **Test strips and lancets are for single use only.**
- Do not drop blood directly on to the flat surface of the test strip.
- **Check the expiry dates and discard dates** on your **test strips** vial label and **control solution** bottle label.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.



Potential Biohazard

Persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects, which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

Chapter 2: Pairing your analyzer with the Smartphone

The VivaChek™ Lactate Analyzer can establish seamless communication with the Smartphone after pairing. Ensure the analyzer is within 5 meters of the Smartphone for pairing and synchronization. Download the VivaGuard™ app before initiating the pairing process between your analyzer and Smartphone.



WARNING

DO NOT pair another person's analyzer with your Smartphone.

During the initial synchronization, the Smartphone will establish the time on the analyzer. Subsequent synchronizations involve the Smartphone verifying and updating the date and time on your analyzer. Regularly check the date and time on your Smartphone to ensure accuracy. If you discover any inaccuracies, refer to the "Setting up your analyzer" section to reset the time and date.

NOTE: Ensuring accurate test results, it is crucial to synchronize the analyzer and app before conducting the first test. This synchronization guarantees that the correct date and time are associated with your test results. Results from any lactate tests conducted before the initial sync will not be transmitted to the app.

1. When you turn on your analyzer, the (📶) symbol will appear to indicate Bluetooth is on.
2. To turn on Bluetooth on your Smartphone.
3. Open the VivaGuard™ app on your Smartphone.
4. Navigate to "Profile" or "More Page"
5. Then enter "My Device"
6. Click Add button, then the analyzer will appear add page

list.

7. Enter the last 5 digitals of the device SN number(In the meter back label).
8. The analyzer will appear on the app to notify you that the analyzer is communicating with the app.

After the Syncing, the app will display a list of any lactate results sent from the analyzer.

Using your analyzer without the app

The analyzer can be used without a Smartphone or the app. You can still test your lactate and review your results on the analyzer screen.

Automatically, the analyzer stores up to 500 results along with their respective time and date stamps. Results are stored chronologically, from the most recent to the oldest. When the memory reaches its capacity of 500 records, the oldest record will be overwritten to accommodate a new one.

Chapter 3 Taking a Test

Set up your analyzer correctly and have all the materials you will need ready before you begin testing. This includes your VivaChek™ Lactate Analyzer, the VivaChek™ Lactate test strips, VivaChek™ Lactate Code Strip (contained within the Test strip box) and suitable lancet.

Coding the Meter

Every time you opening a new box of test strips, it is necessary to replace the used code strip with the new code strip from the test strip box.

Take the code strip out of the test strip box to compare the code number on the code strip with the code number printed on the test strip canister label. Results may be inaccurate if the two numbers are not identical. If the code number on the code strip does not match the number on the test strip canister with which it was packaged, please contact your local distributor immediately. You will need a new package of test strips to perform a test.

With the meter powered off, insert the new code strip into the test strip port of the meter. The code number will be displayed on the initial screen. Remove the code strip before conducting a test.

Turn the meter on by inserting a test strip. The code number will appear on the initial screen. If the code number on the test strip vial label does not match the number displayed on the screen, please contact your local distributor immediately.



Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the analyzer in the direction of the arrows. The analyzer turns on after a beep.



4. A symbol of a test strip with a flashing blood drop will appear to let you know the analyzer is ready to do a test.



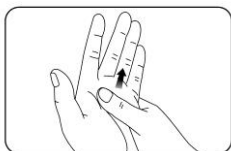
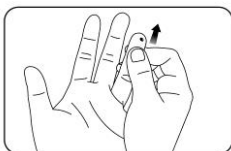
Note:

Check the expiry and discard dates on the test strip vial. All expiry dates are printed in Year-Month format. 2023-01 indicates January, 2023. Your VivaChek™ Lactate test strips have 4 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or wash with soapy water. Use warm water to wash your hands to help increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Sample collection and testing

The blood **collection sites** are **fingertip** and **earlobe**, and the testing steps take fingertip blood collection as an example.

1. Wash and dry your hands well before testing. Dry the puncture site. Puncture the washed finger using a suitable lancet.
2. Wipe away the first droplet of blood. Apply gentle pressure to the puncture site. The second droplet must be large enough to fill the measurement chamber of the test strip in one go. Gently massage from the base to the tip of the finger to achieve the necessary blood volume. Take care to prevent smearing the blood drop. If feasible, consider lancing on the sides of the fingertips to minimize discomfort. Conduct the test promptly once a sufficient blood drop has formed.



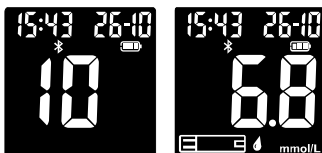
3. Immediately touch the tip of the test strip to the drop of blood. The blood is drawn into the test strip through the tip. Make sure that the blood sample has fully filled the check window on the test strip. Hold the tip of the test strip in the blood drop until the analyzer beeps.



Note:

If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

- The analyzer counts down 10 seconds and your result appears on the display after a beep. The test result will automatically be stored in the analyzer memory. Please do not touch the test strip during the countdown as this may result in an error.



Caution: *In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.*

**Potential Biohazard**

Dispose of the used test strips as medical waste. Always dispose of the used lancet properly to prevent injury or contamination to others.

Discard the Used Test Strip

Dispose of the used test strip manually. The Analyzer will automatically power off after emitting a beep.

Chapter 4 Using the Analyzer Memory

Your analyzer automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest.

Notes:

- When the memory reaches its capacity of 500 records, the oldest record will be overwritten to accommodate a new one.
- *It is very important to set the correct time and date in the analyzer, please make sure the time and date are correct.*

Viewing Your Test Results

When your analyzer is off, press  to turn the analyzer on. After a beep, a symbol of a test strip flashes on the display. Continue to press  to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken. When END appears on the display, it indicates that you have reviewed all the results stored in the memory.



Chapter 5 Setting up your analyzer

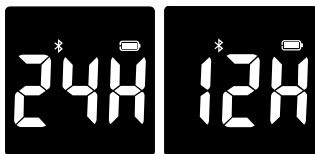
Before you first time use your analyzer system for testing, you should check and update your meter settings

Set the Date and Time

1. Enter the setting mode and set the clock

With the analyzer turned off, press and hold the  button for more than 3 seconds. The analyzer will beep, and all display segments will momentarily appear and disappear. The flashing of 24h (or 12h) on the screen signifies that you have entered Set-up mode.

Clock format: you have two options for time format – 12h or 24h. Press the  button once to adjust and set the clock for 12 or 24 hour mode. Press and hold  until the analyzer beeps to set. The analyzer will prompt you to set the date.



2. Set the date

The year will now flash. Press  to adjust it then press and hold  until the analyzer beeps to set, then it will shift to the next digit for setting. Repeat the above action until the year setting is completed.



The month will now flash. Press  to adjust the month, press

and hold  until the analyzer beeps to set.



The date will now flash. Press  to adjust the date, press and hold  until the analyzer beeps to set, then it will shift to the next digit for setting. Repeat the above action until the date setting is completed.



Note:

Before you first time use your analyzer system for testing, please adjust the analyzer settings to set the date and time, ensuring that results stored in the memory are shown with the correct date and time.

3. Set the Time

Clock format: you have two options for time format – 12h or 24h (If you choose the 24h format, you do not need to select AM or PM).

If you need set AM or PM, you can follow the steps below. the AM or PM icon will flash. Press  to adjust the current time period. press and hold  until the analyzer beeps to set. Then you can set the Time.

The hour now is flashing. Press  to adjust the current hour, press and hold  until the analyzer beeps to set the hour, then it will shift to the next digit for setting. Repeat the above action until the hour setting is completed.

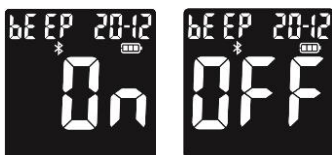


The minute now is flashing. Press  to adjust the minute, press and hold  to set.



Set the audio feature

After setting the time, the word bEEP will now be flashing. Press  to select "On" or "OFF". Press and hold  to set.



Now you have completed your analyzer set up. A symbol of a test strip appears letting you know the analyzer is ready to test.



Chapter 6 Testing with Control Solution

Why Perform Control Tests

Performing a control test confirms you know that your analyzer and test strips are working properly and will give reliable test results. You should perform a control test when:

- You want to check the analyzer and test strips
- If you leave the VivaChek™ Lactate Test Strip vial cap open for an extended period or store it in extreme temperature or humidity
- If you drop your VivaChek™ Lactate Analyzer
- If your results are higher or lower than expected

About the Control Solutions

- Only use VivaChek™ Lactate Control Solutions (Low, Normal or High) to practice on the system.
- Your analyzer automatically recognizes the control solution.
- The expiration dates are printed in Year-Month format on the bottle label. 2024-01 indicates January, 2024.
- Avoid using a control solution that has exceeded its expiry date or discard date (the control solution expires 4 months after the bottle is initially opened).
- Shake the bottle well before use.
- Close the bottle tightly after use.

Performing a Control Test

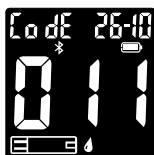
1. Take out a test strip from the test strip vial. Promptly secure the vial cap tightly after removing the test strip.

Note: Check the expiry and discard dates of the test strips. Do not use the expired test strips.

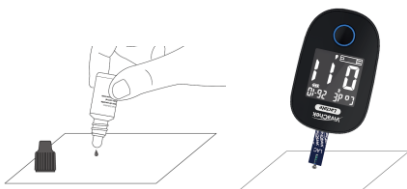
2. Insert the test strip into the analyzer in the direction of the arrows.



3. The analyzer turns on after a beep. An image of a test strip, accompanied by a flashing blood drop, indicates that the analyzer is ready for testing.



4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out another drop on a clean nonabsorbent surface.



Note: Do not apply control solution to the test strip directly from the bottle.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is drawn into the test

strip through the strip tip.

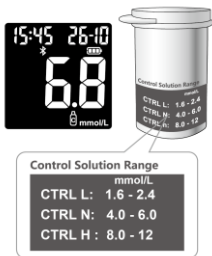
Note: If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

6. Hold the test strip in the drop of control solution until the analyzer beeps, the screen will display a countdown, and your control test result will be shown after another beep.



Understand Your Control Test Result

Compare your control test result with the ranges printed on the test strip vial label.



Notes:

If your control test result is out of range:

- Check the expiry dates and discard dates of the test strip and control solution. Make sure that the test strip vial has not been opened for more than 4 months and the control

solution bottle has not been opened for more than 4 months. Discard any expired test strips or control solution.

- Confirm the temperature in which you are testing is between 15 and 40°C (59-104°F).*
- Make sure that the test strip vial and the control solution bottle are tightly capped.*
- Make sure the test strip was used immediately after taking out from the test strip vial.*
- Make sure the control solution was mixed well.*
- Confirm that you are using VivaChek™ Lactate brand control solution.*
- Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your analyzer or test strips may not be working properly. **DO NOT** use the system to test blood. Contact your distributor for help. To turn your analyzer off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically stored in the analyzer memory.

Charter 7: Recharging the Battery and Caring for Your Analyzer

Recharging the Battery

When the analyzer requires recharging, the Empty Battery symbol () will be displayed. If the Empty Battery symbol () appears on its own, the analyzer cannot be used, and it must be recharged before further use.

The analyzer battery can be charged using one of the following options:

- USB cable
- USB cable with the AC adapter

If you need the USB cable or AC adapter which are not included in your kit, please contact your local distributor.



Caution:

- Do Not charge the analyzer outdoors or in a wet environment.
- Do not use the USB cable, AC adapter, or analyzer if they are damaged, discolored, abnormally hot, or have an unusual odor. Contact your local distributor for assistance.
- Do Not plug the AC adapter into a wall socket and leave it unattended.
- Verify that the wall socket voltage matches the AC adapter voltage.
- Do Not allow unsupervised children to charge the analyzer battery.



Caution:

Do Not insert a test strip when the analyzer is connected to a power source.

NOTE:

- *Using the USB cable or AC adapter charges the battery in about 2 hours.*
- *When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the analyzer does not charge, try using another USB port on your computer.*
- *To optimise battery life, it is recommended to recharge the battery when the Low Battery symbol () appears.*



Caution:

- *If you use the AC adapter which not provided by VivaChek, be ensure it meets the standard EN 60950-1;*
- *If you use the USB-C port on your computer to charge the battery, be ensure it meets the standard IEC60950.*

Caring for Your System

Proper maintenance is recommended for best results.

Lactate Analyzer

Your VivaChek™ Lactate Measuring Analyzer does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the analyzer. Take care to avoid getting liquids, dirt, blood or control solution into the analyzer through the strip or data ports. It is recommended that you store the analyzer in the carrying case after each use.

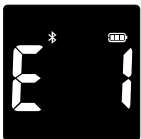
The VivaChek™ Lactate Measuring Analyzer is a precision electronic instrument. Please handle it with care.

Chapter 8: Questionable or Inconsistent Results

If your lactate result are higher or lower than expected please:

- Check the expiry date and the discard date of the test strip. Make sure that the **test strip** vial has **not** been **opened** for **more than 4 months**.
- Confirm the **temperature** in which you are **testing** is **between 10 and 45°C (50-113°F)**.
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored in a cool, dry place.
- Make sure the test strip was used immediately after taking out from the test strip vial.
- Make sure that you have followed the test procedure accurately.
- Perform a control solution test (See **Testing with Control Solution** for instructions).
- After verifying all the conditions mentioned above, retry the test using a new test strip. If you remain uncertain about the issue, please contact your local distributor for assistance.

Charter 9: Troubleshooting Guide

	What It Means
	Blood or control solution was applied to the test strip before the blood drop icon started flashing on the display.
	What You Should Do Discard the current test strip and perform the test again using a new one. Ensure that you wait until the blood drop icon starts flashing on the display before initiating the test.
	What It Means
	The analyzer is sensing a used or contaminated test strip.
	What You Should Do Discard the test strip and repeat the test with a new test strip. Wait until the blood drop icon starts flashing on the display before initiating the test.
	What It Means
	Incorrect test strip.
	What You Should Do Discard the test strip and repeat the test with a new test strip. Make sure that you are using a VivaChek™ Lactate test

	strip from VivaChek Biotech (Hangzhou) Co., Ltd.
	What It Means
	Incorrect sample.
	What You Should Do
	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and VivaChek™ Lactate control solution are used for the test.
	What It Means
	Temperature out of range.
	What You Should Do
	Move to an area that is within the operating temperature range for the analyzer. Allow the analyzer to acclimate to this temperature for 20 minutes before conducting a test.
	What It Means
	Potential software or hardware issue.
	What You Should Do
	Restart the analyzer. If the problem continues, contact your local distributor for assistance

	What It Means
	A test strip was inserted the analyzer is currently connected to the power source.
	What You Should Do After charging is completed (approximately 2 hours for an empty battery), disconnect the USB cable from the analyzer, and proceed to perform a test.
	What It Means
	Insufficient sample.
	What You Should Do Repeat the test and apply enough sample to fill the test strip check window.
	What It Means
	The synchronization between the analyzer and the smartphone was unsuccessful.
	What You Should Do Activate the analyzer, enable Bluetooth on your Smartphone, and open the app. Attempt to pair again. If the issue persists, please contact your local distributor for assistance.

	<i>What It Means</i>
	The test result is below 0.5 mmol/L.
	<i>What You Should Do</i>
	Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.
	<i>What It Means</i>
	The test result is above 25.0 mmol/L.
	<i>What You Should Do</i>
	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.

Chapter 10: Technical Information

System Specifications:

Feature	Specification
Measurement range	0.5 - 25.0 mmol/L
Result calibration	whole blood -equivalent
Sample	Fresh whole blood
Sample volume	About 0.5 μ L
Test time	About 10 seconds
Power source	Rechargeable 3.7 Volt Lithium Ion battery
Charging current	100mAh,  Direct current
Battery type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
units of measure	millimoles per liter (mmol/L)
Memory	Up to 500 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	83 mm x 52 mm x 18.7 mm
Display size	32mm x 32 mm
Weight	53g
Operating temperature	10 - 45°C (50-113°F)
Operating relative humidity	10 - 90% (non-condensing)
Hematocrit range	20 - 70%
Data port	USB-C Port
Bluetooth	Version 4.2

Limitations

The VivaChek™ lactate Analyzer, test strips and control solution have been designed, tested and proven to work together effectively to provide accurate lactate measurements. Do not use components from other brands.

- Use only with whole blood. Do not use with serum or plasma samples.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- The VivaChek™ lactate analyzer has been tested and shown to work properly up to 10,000ft (3,048 analyzers).
- Severely ill persons should not run the lactate test with the VivaChek™ lactate analyzer.

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.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the VivaChek™ Lactate analyzer.

Symbols	Explanation
	Consult instructions for use
	Manufacturer
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
	Lot Number
	Sterilised using irradiation
	Control range
	Catalogue number
	Model number
	Do not re-use
	Caution, consult accompanying documents
	Dispose of items according to local relevant laws regarding disposal and recycling
	Use by 4 months from the opening
	Series number
	Keep away from sunlight and heat

Warranty

Please complete the warranty card that came with this product and mail it to your dealer to register your purchase.

If the analyzer fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new analyzer free of charge. For your records, also write the purchase date of your product here.

Date of purchase:

Note:

This warranty applies only to the analyzer in the original purchase.



This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

Radiation Exposure Statement

The device has been evaluated to meet general RF exposure requirement in portable exposure condition without restriction.