Mira Analyzer User Manual

Please read entire manual before any use

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1. INTRODUCTION

Thank you for choosing the Mira Analyzer. This user manual provides important information to help you use the Mira Analyzer properly. Mira Analyzer offers accurate and convenient testing results of human biomarker levels when used with various types of Mira test wands. Before using this Mira Analyzer, please read the user manual thoroughly. If you have questions regarding this Analyzer, please visit www.miracare.com or contact Mira customer service at: support@miracare.com.

2. INTENDED USE

The Mira Analyzer is a device with data output for self-testing outside the body (*in-vitro* diagnostic use) used by people at home. Together with Mira test wands, it is intended to be used for monitoring level of a variety of human biomarkers.

Caution:

- Make sure to use the appropriate Mira test wand.
- Misuse of the Mira test wand may lead to misunderstanding of your test results.
- The Mira Analyzer is intended for tracking your biomarkers levels at home.
- Do not conduct a Mira test when USB cable is connected to the Mira Analyzer. Misuse of the Analyzer can cause device damage, electric shock, burns, fires, or other damages.
- Use the Mira Analyzer only in the manner described in this manual. If the Analyzer is used in a manner not specified by the manufacturer, the warranty provided for the Analyzer may be impaired.
- Do not place the Mira Analyzer in or near any liquid.

3. PACKAGE CONTENTS

Your Mira Analyzer system contains several items as shown below. Please identify each item and learn how to use them.

- Mira Analyzer
- Micro-USB charging cable
- Pouch
- User manual
- Quick start guide

The Mira Analyzer:
The screen of Mira Analyzer displays information such as testing status, battery level, test results, etc.

Screen

Button

Test Wand Slot

Micro-USB Port

3
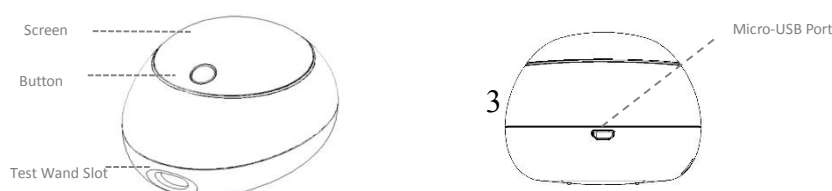
4. IMPORTANT INFORMATION BEFORE USE

4.1   Charging the Analyzer

Your Mira Analyzer is powered by a built-in and rechargeable battery. Plug one end of the charging cable into the micro-USB port of the Analyzer and the other end into a computer USB port or an adapter that is compliant with 5V DC. Charge for two to four hours before the first use. A fully charged battery can typically last up to 20 tests depending on your daily usage.

Caution:
- When using your computer USB port or an adapter to charge the Analyzer, the USB port or the adaptor should be a standard port with 5V±10% DC output voltage.
- Please charge the Analyzer regularly and no less than once every three months. If your Analyzer has not been used for a long time, charge the Analyzer before use.
- Please charge the Analyzer at an ambient temperature between 5 ° to 40 °C (41 ° to 104 °F).

4.2   Turning On / Off the Analyzer

Press the button or insert a Mira test wand to turn on the Analyzer.

Press and hold the button for 3 seconds to power off the Analyzer.

The Analyzer will power off automatically after 1 minute of no operation.

4.3   Pairing with smartphone

When you pair the smartphone with the Mira Analyzer for the first time, the Analyzer will automatically display a QR code. By scanning the QR code with your smartphone camera, you will be directed to download the Mira App, which will guide you through the process of conducting a Mira test.

5. TESTING PROCEDURE

5.1 Please refer to the user manual of each Mira test wand line for instruction on how to conduct a test.

Caution:
- A test may take 5 to 20 minutes to process depending on the selected Mira test wand. Please refer to the user manual of each respective Mira test wand line you are using. When the test is processing, the Mira Analyzer will show you the count down time.
- If you pull out the test wand before finishing the test, you may re-insert the test wand back into the Analyzer immediately. The Mira Analyzer will decide whether the test is valid or not.
- When the test is completed, the screen will show the result directly and sync the data to your smartphone if they are paired.
- Mira Analyzer will automatically turn off if there is no operation for 1 minute. You can also hold button for about 3 seconds to turn off the Mira Analyzer manually.
- Click and hold button for about 2 seconds to activate Mira Analyzer if the Analyzer screen is off.
- When Mira Analyzer is active, you may click button to switch between the standby screen and the latest test result, if applicable.

5.2 Test Memory

The Mira Analyzer is able to automatically store up to 200 test results with testing time and dates. If your Mira Analyzer has stored 200 results, the newest test result will replace the oldest one. The historical test results can be viewed from the Mira App, if the App is paired with the Analyzer.

For further information or other methods to obtain historical test results, please contact Mira customer service at: support@miracare.com.

6. PRODUCT CARE

6.1   Maintenance

Keep your Mira Analyzer free of dust, water or any other liquid. If the Mira Analyzer is dropped or damaged, please turn on the Mira Analyzer to check for any error messages before conducting a test.

Clean the outside of the Mira Analyzer with a damp cloth, ensuring that the test wand slot does not get wet.

If your test wand slot is stained with body fluids, please use a dry tissue or alcohol swab to clean it immediately. Do not use anything wet to contact the Mira

Analyzer Test Wand Slot.

Caution:
- Do not attempt to open Mira Analyzer or try to repair by yourself.
- Do not keep the Mira Analyzer in the high humidity and dusty environment.
- Store your Mira Analyzer inside the pouch when not being used daily.

6.2 Error Messages and Troubleshooting

- Low Battery

If you see the "Low Battery" message on the screen, the Mira Analyzer will not function as the battery power is too low. Please charge the battery as soon as possible.

- Troubleshooting

  Mira Analyzer errors could be caused by the following reasons:

  - Reading failed - Please try again with a new wand. Do not use the test wand that is expired. The expiration date is printed on the foil wrapper of test wand. Otherwise, you may get incorrect test results.
  - Invalid wand - Please use a Mira test wand. Incompatible or off-brand test wands may damage the Analyzer.
  - Used wand - The inserted test wand has been used or damaged. Please use a new Mira test wand.
  - Test warning - Please re-insert the Mira test wand to continue the test.
  - Update available - Please update Analyzer software via the Mira App to have the accurate reading.
  - Heat error - The temperature is too high. Please stop the test by removing the inserted test wand, turn off the Mira Analyzer, and move Analyzer to a cooler place before conducting a new test.
  - Sample error - The test wand is dry or insufficient body fluid was sampled. Please use a new test wand and conduct a test.
  - Device error - The Mira Analyzer may have an internal error. Please press button for 3 seconds and restart it. If the error message appears again, please contact Mira customer service at: support@miracare.com.

- Reset
  - At the bottom side of the Analyzer, you will find a small pinhole.
  - Insert a paperclip into the hole and press for 2 seconds to reset

the Analyzer.

7. LIMITATIONS

- Mira Analyzer is only compatible with Mira test wand series.
- Never use non-Mira product in Mira Analyzer.
- Store and transport in a dry environment between -20 ° to 55 °C (-4 ° to 131 °F), and relative humidity <90%.
- Operating temperature is between 5 ° to 40 °C (41 ° to 104 °F), and relative humidity is <80%. Do not freeze.
- Never use the Analyzer in an intense magnetic or electromagnetic field.
- Do not expose the Mira Analyzer to strong shocks, vibrations, or direct sunlight.
- Keep out of reach of children.
- For *in-vitro* diagnostic use only.

8. SPECIFICATIONS

Dimension (W*H*D)	72mm*90mm*56mm
Weight	Approx. 200g
Battery	DC 3.7V output, Li-ion 600mAh
Data input/output	Bluetooth 4.0
USB	Micro-USB (recharging only); 5V±10% power adapter (available separately)
Display	1.54 inches IPS
Support Language	English
Operation Temperature	5 ° to 40°C (41 ° to 104 °F)
Operating Humidity	< 80% (no condensation)

9. WARRANTY

Quanovate Tech Inc. (Mira) warrants that this product will be free from defects in materials and workmanship for a period of one-year (1) from the date of purchase, except that if you reside in the European Economic Area (EEA) and you purchased your Mira Analyzer in the EEA, the warranty period is two-years (2) from the date of purchase (the "Warranty").

This warranty does not apply to the performance of a Mira Analyzer that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the originally manufactured Mira Analyzer. Different Analyzer models have different specifications.

Mira does not warrant that the operation of the product will be uninterrupted or

error-free. Mira is not responsible for damage arising from failure to follow instructions relating to the product's use. This warranty only applies to the Mira Analyzer.

Other models are not covered by this warranty policy.

10. CONTACT INFORMATION

We sincerely would like to provide complete and considerate services to our customers. Please review all the instructions to make sure you are operating the product properly. If you have any questions or encounter problems with the products, please contact Mira customer service at: support@miracare.com. Please include the product series number which appears on the device label when you email Mira customer service.

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Suite 230, 4367 Chabot Dr., Pleasanton CA, 94588, USA

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Made in China.

Manufactured at:
Area C, Floor 2, Building 1, 550 Yinhai Road, Hangzhou, 310018, China

11. LIMITATION OF THE TEST

Please refer to the user manual of each Mira test wand line for limitation of the test.

This Analyzer 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 Analyzer must accept any interference received, including interference that may cause undesired operation.

WARNING: Changes or modifications not approved by the party responsible for compliance could void the user's authority to operate this device.

This Analyzer complies with EN 61326-1:2013 and EN 61326-2-6:2013 standard for electromagnetic compatibility, and IEC 61010-1 and IEC 61010-2-101 standard for safety requirement.

12. TERMS & CONDITIONS AND PRIVACY POLICY

Please visit www.miracare.com for the latest Terms & Conditions and Privacy Policy.

13. SYMBOLS USED IN LABEL

Manufacturer name and address

EC | REP   Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Tel:+49-40-2513175

IVD *in-vitro* diagnostic
For self-test

Keep away from sunlight

Keep dry

Temperature limitation

Electric component disposable information

⚠ Attention. See Instructions for use

Consult Instructions for use

RoHS

CE 0123   Corresponds to the requirements of EU guidelines for *in-vitro* diagnostic devices and bears the CE marking (conformance label) CE 0123

SN   Series number

FCC STATEMENT :

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.
Warning: Changes or modifications 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.

RF warning statement:
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.