

USER'S MANUAL

Project or System Name
Immunofluorescence Analyzer

May, 2017

Revision Sheet

Release No.	Date	Revision Description
V1	5/30/2016	User's Manual (the first draft)
V1	1/10/2017	User's Manual(Iterative review draft)
A	5/10/2017	User's Manual (Review draft)

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1 INTRODUCTION

Thank you for choosing the EVA3000 Immunofluorescence Analyzer. This User's Manual provides important information to help you use the Analyzer properly. EVA3000 offers convenient and accurate testing results when used with Fluorescent Immunoassay Test strips manufactured by Hangzhou Careomedic Tech Co., Ltd. Before using this Analyzer, please read the User's Manual thoroughly. This Analyzer is designed to monitor your hormone levels in the most convenient way. If you have questions regarding this Analyzer, please visit www.guanovate.com or call Careomedic Customer Service at +86-571-86899229.

2 INTENDED USE

The EVA3000 Immunofluorescence Analyzer is a device with qualitative data output for Self-testing outside the body (in vitro diagnostic use) used by people at home. It is used to analyze the human hormone with Careomedic Fluorescent Immunoassay Test strips.

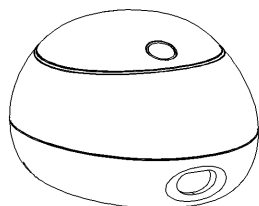
Caution:

- Choose the proper Careomedic Fluorescent Immunoassay Test strips. Misuse of the Fluorescent Immunoassay Test strips may lead to misunderstanding of your test results.
- The EVA3000 Immunofluorescence Analyzer is intended for medical use at home.
- Do not conduct a Fluorescent Immunoassay Test when USB cable is connected to the Analyzer.
- Misuse of the Analyzer can cause device damage, electric shock, burn, fire, or other damages.
- Use the Analyzer only in the manner described in this manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- Do not place the Analyzer in or near liquid.

3 CONTENTS OF EVA3000 IMMUNOFLUORESCENCE ANALYZER SYSTEM

Contents:

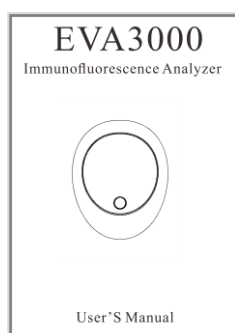
Your EVA3000 Immunofluorescence Analyzer system contains several items as shown below. Please identify each item and learn how to use them.



• EVA3000 Immunofluorescence Analyzer



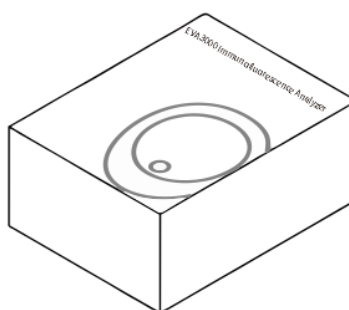
• Micro-USB Charging Cable



• User's Manual



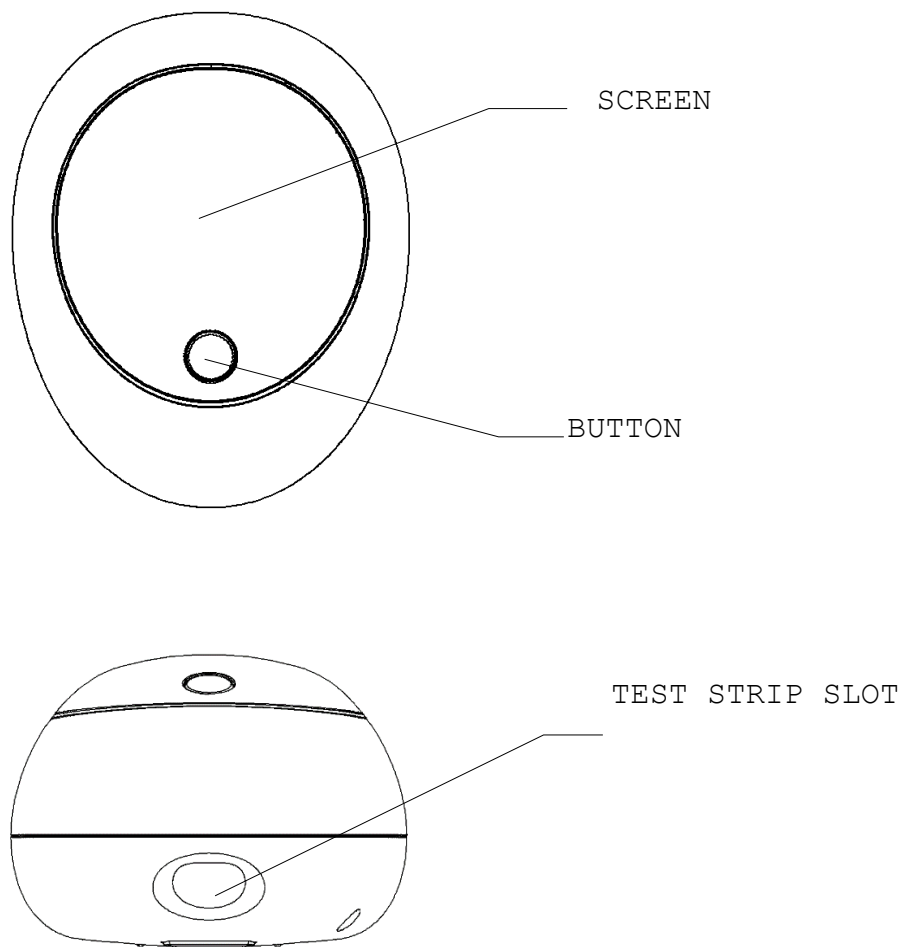
• Certificate of Product Quality

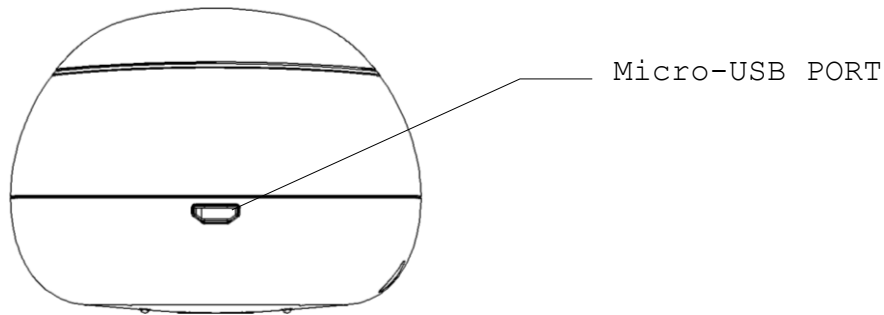


• Package

Caution:

If any items above are missing from your package or the package appears to be opened prior to your use, please call Careomedic Customer Service at +86-571-86899229.

The Analyzer:



When you turn on the analyzer, the screen will show information such as embedded Software version, device status, current time, battery level, test results, etc.

4 IMPORTANT INFORMATION BEFORE USE

4.1 Charging the Analyzer

Your Analyzer is powered by a built-in and rechargeable battery. Plug one end of the charging cable into the Micro-USB port of the device and the other end into a Computer USB port or an adaptor that is compliant with $5V \pm 10\%$ DC. Charge for two to four hours before the first use. A fully charged battery can typically take up to 20 tests depending your daily usage.

Caution:

- when use your computer USB port or an adaptor to charge the analyzer, the USB port should be a standard port with $5V \pm 10\%$ DC output voltage and 500mA output current, and also the computer and the adaptor must comply with the current edition of IEC/ EN 60950-1 or IEC/EN 60601-1.
- Please charge the analyzer regularly if your analyzer is not used for a long time, the recommended cycle of charge the analyzer should not exceed 3 months.
- Please charge the analyzer at an ambient temperature between $10 \sim 35^{\circ}\text{C}$

4.2 Turning On/Off the Analyzer

- 1) Press the button or insert a Careomedic Fluorescent Immunoassay Test strip to turn on the Analyzer.
- 2) Press and hold the button for 3 seconds to power off the Analyzer.
- 3) The Analyzer will power off automatically after 5 minutes of no operation.

4.3 Quick Start Guides

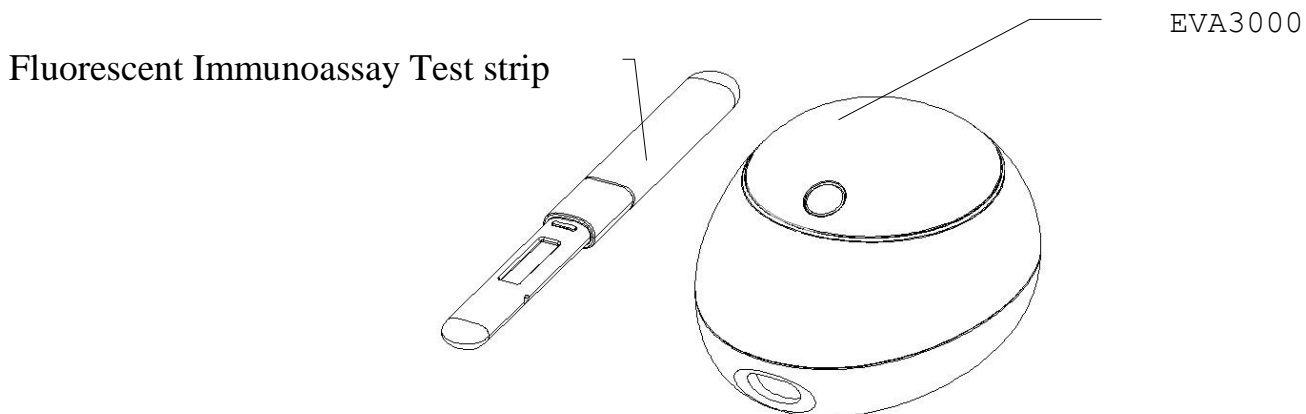
When pressing button to turn on the Analyzer, the Analyzer will automatically display quick start guides on how to conduct a Fluorescent Immunoassay Test.

5 TESTING PROCEDURE

5.1 Getting ready to test

Before conducting a Fluorescent Immunoassay Test, please prepare the following items:

- EVA3000 Immunofluorescence Analyzer
- Careomedic Fluorescent Immunoassay Test strip
- A cup to collect body fluids if choosing the dipping method



5.2 Conducting a Fluorescent Immunoassay Test

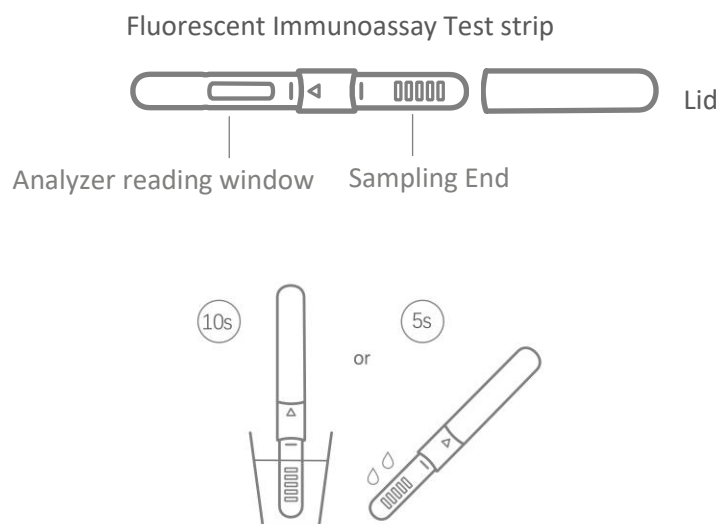
1. Choose one of the following methods to test. We recommend the dipping method.

- ◆ **Dipping:** Collect body fluid in a clean and dry container. Remove the Fluorescent Immunoassay Test strip from its protective foil wrapper and use immediately. Make sure that at least 3 grids of the sample collecting

window are immersed in the body fluids. Put the Sampling End only into the body fluids for 10 seconds.

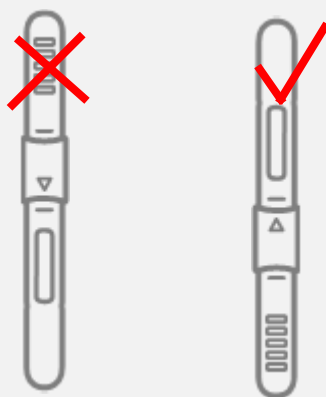
OR

- ◆ **In stream:** Hold the Sampling End of the Fluorescent Immunoassay Test strip pointing downwards in your body fluid stream for 5 seconds. This is long enough to ensure the Sampling End is sufficiently immersed.



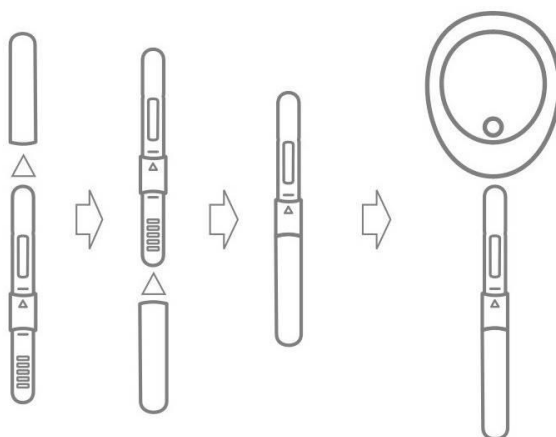
Caution:

- Make sure the Fluorescent Immunoassay Test strip is within shelf life.
- Do not hold the Test strip with the Sampling End pointing upwards after sampling the body fluid. The test results may be affected.



2 .While keeping the test strip pointing downwards, remove the cap and use it to cover the Sampling End until hearing the "click" to avoid contamination. Wipe off

any excessive body fluid from the test strip. Insert the test strip into the Analyzer immediately, which will automatically begin to process the test.

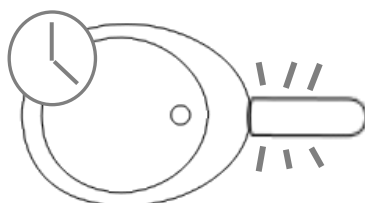


Caution:

The test strip is inserted into the test strip slot of Analyzer along with the direction of the orange triangular mark facing up.



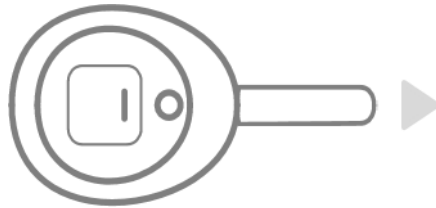
3. A test may take 15 to 20 minutes to process depending on the selected Fluorescent Immunoassay Test. Please refer to the User's Manual of Fluorescent Immunoassay Test strip. When the test is processing, the following sign will show on the Analyzer screen.



4. If you pull out the test strip before finishing the test, you may re-insert the test strip back into the Analyzer immediately. The Analyzer will decide whether the

test is valid or not.

5. When the test is completed, screen will show the following sign and remind you remove the test strip and discard. This sign will disappear after 16 seconds. Once the sign disappears, the test result will show on the screen.



6. EVA3000 Immunofluorescence Analyzer will automatically turn off if there is no operation for 5 minutes. You can also hold button for about 2 seconds to turn off the Analyzer manually.

7. Click and hold button for about 2 seconds to activate EVA3000 Immunofluorescence Analyzer if the Analyzer screen is off.

8. When EVA3000 Immunofluorescence Analyzer is active, you may click button to switch between the quick start guides and the latest test result, if applicable.

5.3 Understanding the Test Results

Your test results will display on EVA3000 Immunofluorescence Analyzer screen after the test. Hormone levels of body fluid are shown as None (N), Low (L), Medium (M), or High (H).

Caution:

Please read the instruction manual of your specific **Fluorescent Immunoassay Test** product to understand the test results.

5.4 Test Memory

The EVA3000 Immunofluorescence Analyzer is able to automatically store up to 200 test results with testing time and dates. If your Analyzer has stored 200 results, the newest test result will replace the oldest one.

Caution:

Careomedic offers a Stored Data Reading Service. This service extracts your historical measurement data stored in your Analyzer and sends to you. For further information or other methods to obtain historical measurement data, please visit www.quanovate.com or call Careomedic Customer Service at +86-571-86899229.

6 CARING FOR YOUR DEVICE

6.1 Maintenance


- Keep your EVA3000 Immunofluorescence Analyzer free of dust, water or any other liquid. If the Analyzer is dropped or damaged, please turn on the Analyzer to check if it reports error messages before doing a test.
- Clean the outside of the Analyzer with a damp wipe. Do not get the test strip slot wet.
- If your test strip 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 test strip slot.

Caution:


DO NOT decompose EVA3000 Immunofluorescence Analyzer or try to repair by yourself. Please contact Careomedic Customer Service for repair service at +86-571-86899229.

6.2 Error Messages and Troubleshooting

- Battery Error

If the “  ” symbol appears, the Analyzer will not function as the battery power is too low. Please charge the battery as soon as possible.

- Sampling Error

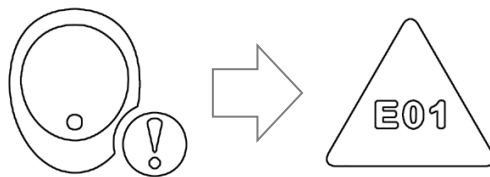
Please remove the inserted test strip when the “  ” symbol appears. This error could be caused by the following reasons:

- ◆ The inserted test strip has been used or damaged. Please use a new test strip.
- ◆ Do not use the test strips out of expiration date, the date is printed on the foil wrapper. Otherwise, you may get incorrect test results.
- ◆ The test strip is dry or insufficient body fluid was sampled. Please use a new test strip and conduct a new test.
- ◆ The test strip is not Careomedic Fluorescent Immunoassay Test strip.
Incompatible test strips may damage the Analyzer.

- Temperature Error

In order to get an accurate test result, please conduct tests between 5~40 °C (35~104 °F) .

When the ambient temperature is too high or too low, the screen of the Analyzer will display the symbol blow. Error message “E01” will show on the screen when you press the button. Please move the Analyzer to an operating ambient temperature.



When moving from a temperature that is outside the operating temperature range to an operating temperature, please wait for 10 minutes before conducting a test.

- Motor Error

If “” symbol appears, the Analyzer may have a motor error. Error message “E02” will show on the screen when you press the button. Please restart the Analyzer by pointing into the tiny hole at the bottom of the device. If the symbol appears again, please contact Careomedic Customer Service at +86-571-86899229.

7 LIMITATIONS

- ◆ EVA3000 Immunofluorescence Analyzer is only compatible with Careomedic Fluorescent Immunoassay Test Strip series.
- ◆ Never use non-Careomedic product in EVA3000 Immunofluorescence Analyzer.
- ◆ Store and transport in a dry place between -20 to 55 °C (-4 to 131 °F) , and relative humidity <93%.
- ◆ Operating temperature is between 5 to 40 °C (35 to 104 °F), and relative humidity <80%. Do not freeze.
- ◆ Never use the analyzer in an intense magnetic or electromagnetic fields and strong vibration environment.
- ◆ Do not expose the analyzer to strong shocks or vibrations or strong sunlight.
- ◆ Keep out of reach of children.
- ◆ For *in-vitro* diagnostic use only.
- ◆ EVA3000 Immunofluorescence Analyzer is designed for handheld use.

8 SPECIFICATIONS

Dimension (W*H*D)	72mm*90mm*56mm
Weight	Approx. 200 g
Battery	DC 3.7 V, Li-ion 600mAh, Maximum charging current 240mA, Maximum discharge current 300mA
Data input/output	Bluetooth 4.0
USB	Micro-USB (recharging only); 5V±10% power adapter (available separately)
Display	1.54 inches IPS
Supported Language	English, Chinese

Operating Temperature	5 to 40°C (35 to 104 °F)
Operating Humidity	80% or less (no condensation)
Life span	3 years

Note: the analyzer complies with EN 61326-1:2013 and EN 61326-2-6:2013 standard for electromagnetic compatibility. Enquire at the analyzer for details on this measurement data.

9 WARRANTY

Careomedic warrants that this product will be free from defects in materials and workmanship for a period of three years (3) from the date of shipment.

This warranty does not apply to the performance of a EVA3000 Immunofluorescence Analyzer that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the originally manufactured EVA3000 Immunofluorescence Analyzers.

Please complete and return the enclosed warranty card.

Different Analyzer models have different specifications. This warranty only applies to the EVA3000 Immunofluorescence Analyzer. Other models are not covered by this warranty card.

10 CUSTOMER SERVICE

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 us at:

Email: customservice@quanovate.com



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11 SYMBOLS USED IN LABEL



Manufacturer



In vitro diagnostic medical device for self-test



the Immunofluorescence Analyzer corresponds to the requirements of EU guidelines 98/79 for in vitro diagnostic devices and bears the CE marking (conformance label) CE 0123



Consult Instructions for use



Attention, See Instructions for use



Authorised representative in the European Community



Environmental Protection – Electrical products waste should not be disposed within household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling information.



Dispose of used Test Strip with your household waste, Consult your local authority or your supplier for information about disposal



Keep away from sunlight



Keep dry



Serial number



Temperature limitation

12 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 not accept any interference received, including interference that may cause undesired operation.

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications 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.

FCC Caution:

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

The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.