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POCT Analyzer

Dear VivaDiag POCT Analyzer VIM3000 User,

Thank you for choosing the VivaDiag Point-of-Care-Testing Analyzer VIM3000! The analyzer has the advantages of easy operation, strong stability, reliable results and simple maintenance. It can be used widely in many areas, such as hospital, medical center, clinic, pharmacy, laboratory, etc.
This User's Manual applies to VivaDiag POCT Analyzer VIM3000. It provides detailed descriptions of the analyzer's characteristics, graphical operation steps and other relevant information for your convenience. Please read this User's Manual carefully before you use your analyzer and keep your User's Manual in a safe place, you may want to refer it in the future.

Thank you again for choosing the VivaDiag POCT Analyzer VIM3000.

Principle and Intended Use

The VivaDiag POCT Analyzer (Model: VIM3000) works with VivaDiag FIA Test Kit as a system to measure multiple parameters. The analyzer is an immunofluorescence detection device that is based on photoelectric detection principle. With the fluorescence immunochromatography technology and tiny sample, the analyzer gives reliable results in just few minutes, which is ideally suitable for professionals to make quick and correct decision at the point of care. It is intended for professional use outside the body (*in vitro* diagnostic use).

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CHAPTER 1: UNDERSTANDING YOUR ANALYZER

Introduction to Analyzer

1. Model: VIM3000
2. Basic size: 192 mm (Length) x 209 mm (Width) x 169 mm (Height)
3. Total weight: 1.8 kg

Analyzer Use and Precautions

- Keep your analyzer dry and avoid exposure it to extreme temperatures or humidity.
- Do not drop the analyzer or let it get 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.
- Do not take the analyzer apart. Taking the analyzer apart will void the warranty.
- Refer to the **Maintenance and Troubleshooting** for details on cleaning the analyzer.
- Keep the analyzer and accessories out of the reach of children.

Important Safety Information

- It is for *in vitro* diagnostic use by professionals.
- Use only VivaDiag FIA Test Kits with your Analyzer. Do not use other brands.
- Use the accessories provided by VivaChek with your VivaDiag POCT Analyzer. Do not use other accessories.
- Please read this User's Manual carefully before use your analyzer and keep your User's Manual in a safe place for referring it in the future.
- If the analyzer emits peculiar smell, smoke or the liquid flows into the analyzer, please cut off the power immediately and contact your local distributor. Continuous use of the analyzer may cause fire, electric shocks or personnel injury.
- Please comply with all the national standards for health and safety. This includes (but is not limited to) protective cover, gloves, and suitable experimental installation when operating and maintaining the analyzer.
- If the analyzer is used in a manner not specified by the manufacturer, the protection provided by the analyzer will be impaired.

Caution

All products or objects, which come in contact with blood/urine/ respiratory secretions, even after cleaning, should be handled as if capable of transmitting infectious disease.

CHAPTER 2: COMPONENTS AND STRUCTURE

Please check whether any component is missing or damaged and refer to the list below after opening the package.

***Note**: If some parts are missing or damaged, please contact your local distributor or manufacturer immediately.*

Components List

Number	Component	Quantity
1	VivaDiag POCT analyzer VIM3000	1
2	Power adapter	1
3	Power line	1
4	Print paper roll	1
5	User's manual	1
6	Quality control test device 1	1
7	Quality control ID card 1	1

Structure

The actual appearance of analyzer and accessories may vary with the specific model.

Analyzer

(1) Front Side Structure (Figure 1, 2)

(Figure 1)

(Figure 2)

(2) Back Side Structure (Figure 3)

(Figure 3)

Power Adapter (Figure 4)

(Figure 4)

Quality Control Test Device 1 (Figure 5)

(Figure 5)

Quality Control ID Card 1 (Figure 6)

The quality control ID card is a specific USB flash drive with calibration curve, and can be only used with the quality control test device.

(Figure 6)

Test Device (Figure 7)

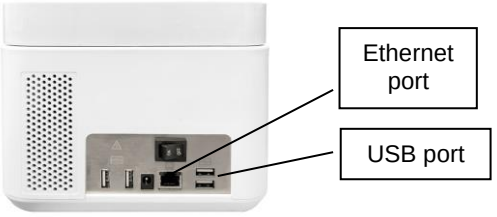
The test device below is only supplied in VivaDiag FIA Test Kit.

(Figure 7)

CHAPTER 3: INSTALLATION AND USE CONDITIONS

Analyzer Installation

Please use the analyzer under the proper conditions.
Step 1: Place the analyzer on a stable and level surface.
Step 2: Connect the structure according to your needs (Figure 8).

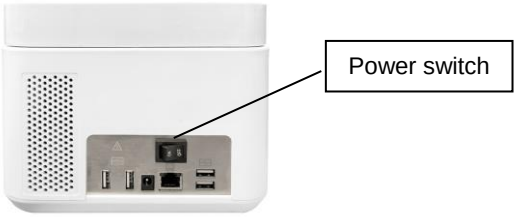


(Figure 8)

Step 3: Connect the power adapter with the power adapter port of the analyzer (Figure 9).

(Figure 9)

Step 4: Turn on the power switch and start the analyzer (Figure 10).



(Figure 10)

Use Conditions

Basic Parameters

- Excitation light source: LED
- Excitation spectrum: 365 nm & 610 nm

- Connector: Ethernet port RJ-45, USB
- Printer: Built-in thermal printer

Positioning and Placement Requirements

1. The analyzer should be placed on a stable and level surface, and in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of at least 1.8 kg.
2. The analyzer should be placed in a well-ventilated place (without strong vibration source and electromagnetic fields around). There should be at least 10 cm space around the analyzer to ensure the necessary space for operation and maintenance.

Storage and Transport Conditions

1. Storage Conditions
Storage temperature: -10 to 55°C
Relative humidity: 20 to 80%
Atmospheric pressure: 86.0 to 106.0 kPa
2. Transport Conditions
Avoid moisture, impact and severe vibration.

Power Supply Voltage Requirements

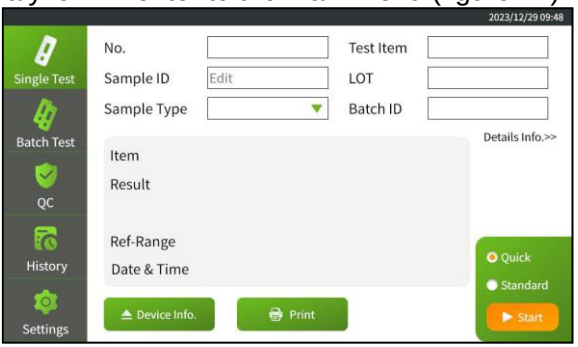
Caution

The AC-DC power adapter of the analyzer has an input voltage of 100-240V, which varies in the range of 50/60Hz and can be used in different countries. The output voltage is 12V DC and the maximum power is 48W. Please avoid short circuits and electric shock during the use of the analyzer.

CHAPTER 4: OPERATION INSTRUCTIONS

Starting

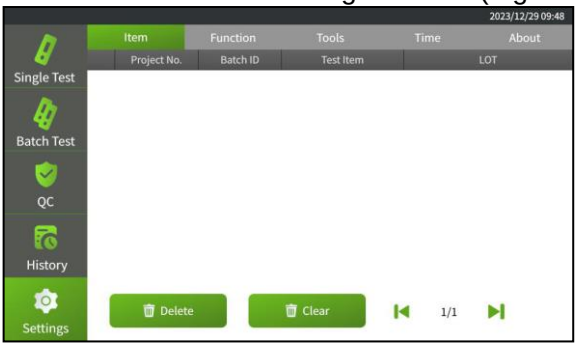
Tum on the analyzer, the analyzer will initialize and run to self-test. After the self-test, the analyzer will enter to the main menu (figure 11).



(Figure 11)

Settings

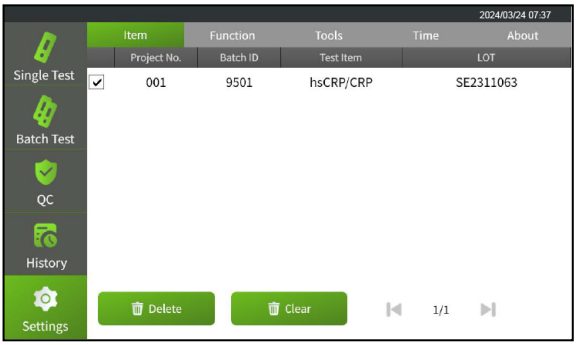
Please set up the analyzer according to your requirements before using. Click “Settings” button to enter the following interface (Figure 12).



(Figure 12)

Item

Click “Item” button to enter the test item interface (Figure 13). You can browse the saved test items in this interface.

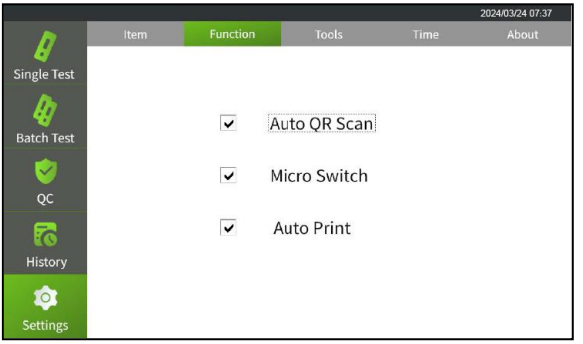


(Figure 13)

(1) Click “Delete” to delete the item you selected.
(2) Click “Clear” to delete all the items.
(3) Click “ ” or “ ” to browse the saved item records.

Function

Click “Function” button to enter the following interface (Figure 14).

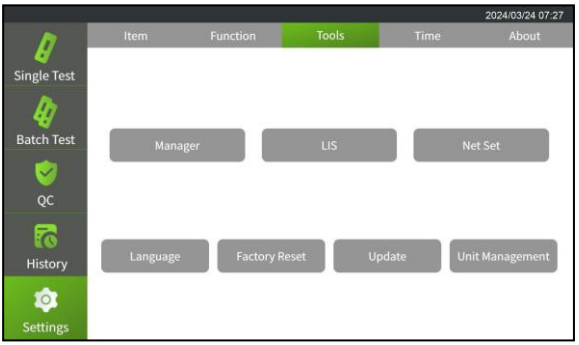


(Figure 14)

1. Auto QR Scan
☐ Start the test directly without scanning the barcode on test device.
☑ Scan the barcode on test device and then start the test.
2. Micro Switch
☐ Start the test manually after inserting the test device.
☑ Start the test automatically after inserting the test device.
3. Auto Print
☐ Print the test result manually after completing each test.
☑ Print the test result automatically after completing each test.

Tools

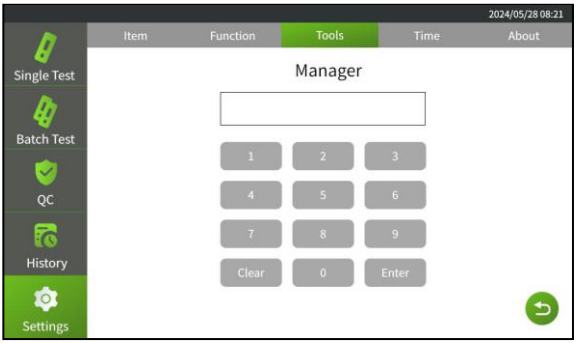
Click “Tools” button to enter the following interface (Figure 15).



(Figure 15)

1. Manager

The manager function is only for professional technicians to manage the analyzer (Figure 16).

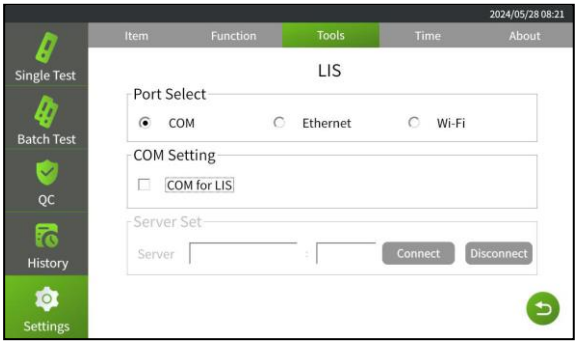


(Figure 16)

Note: please contact with your local distributor or manufacturer to get the correct password.

2. LIS

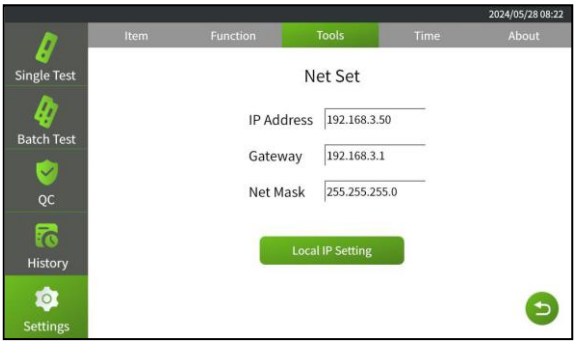
Click “LIS” to enter the following interface (Figure 17). You can set the analyzer’s port of LIS connection.



(Figure 17)

3. Net Set

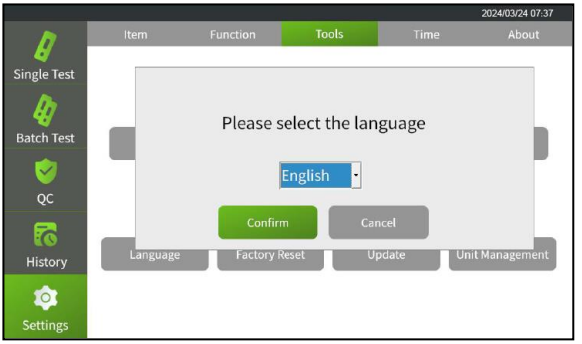
Click “Net Set” to enter the following interface (Figure18). You can input the analyzer's IP address, gateway and net mask.



(Figure 18)

4. Language

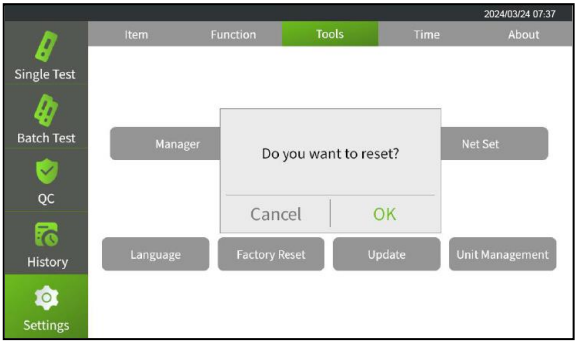
You can set the analyzer’s language by clicking the drop-down arrow (Figure 19).



(Figure 19)

5. Factory Reset

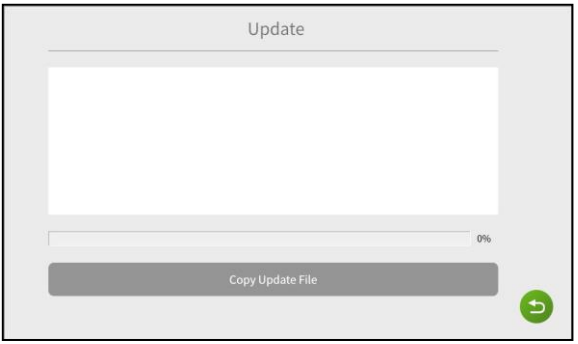
Click “Factory Reset” to restore to the factory settings (Figure 20).



(Figure 20)

6. Update

Click “Update” to enter the following interface (Figure 21).

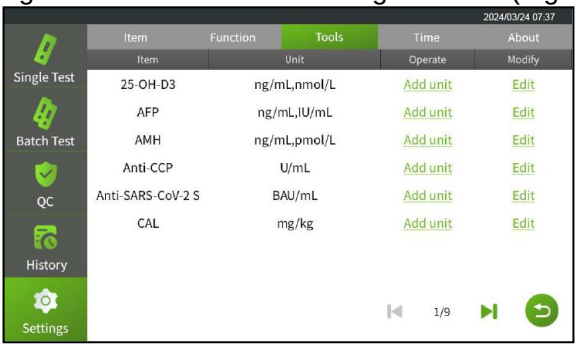


(Figure 21)

Get new version of software from your local distributor or the manufacturer. Put the software file in a USB flash drive. Insert it into a USB port, and click “Copy Update File” to copy the update file. When the progress bar reaches to 80%, click “Restart Application” to update the software.

7. Unit Management

Click “Unit Management” to enter the following interface (Figure 22).

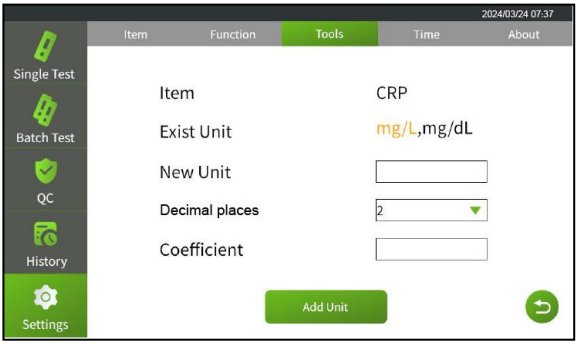


(Figure 22)

(1) Click “ ” or “ ” to browse the existing display items and units.

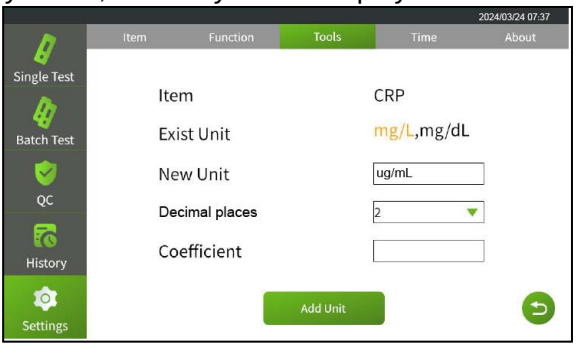
(2) Click “ ” to return to the previous interface.

Identify the items that need units added. Click “Add unit” to enter the following interface (Figure 23).

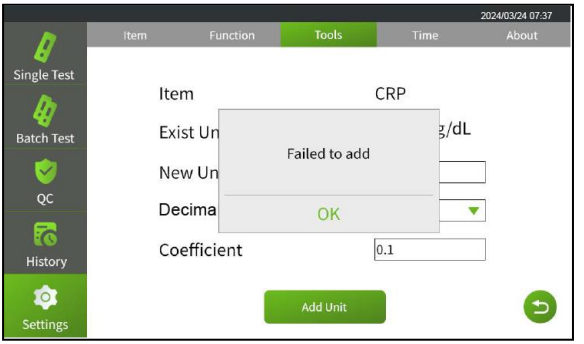


(Figure 23)

Input new units that do not exist in the analyzer in New Unit (Figure 24). If the new unit already exists, the analyzer will display "Failed to add" (Figure 25).

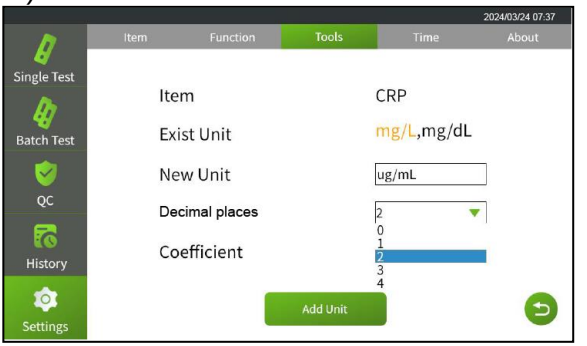


(Figure 24)



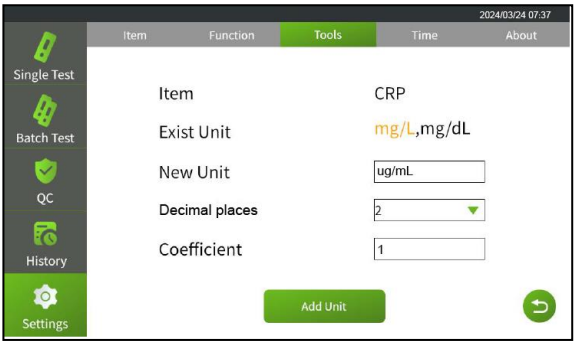
(Figure 25)

Click the drop-down arrow of “Decimal places” to set the number of decimal points (Figure 26).



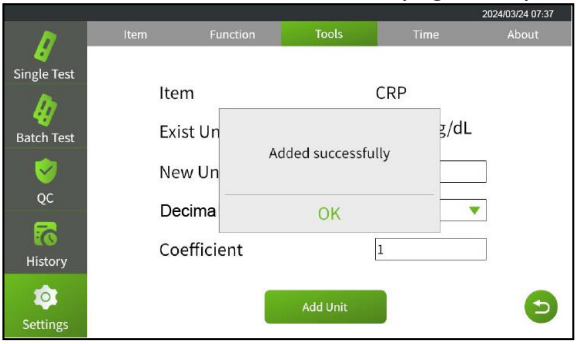
(Figure 26)

Input the corresponding value in Coefficient (Figure 27).



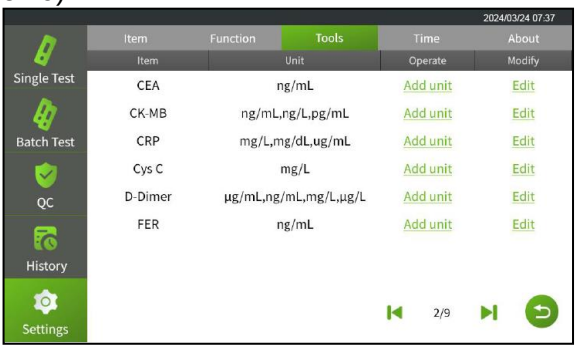
(Figure 27)

Click “Add Unit” and "OK" to save the new unit (Figure 28).



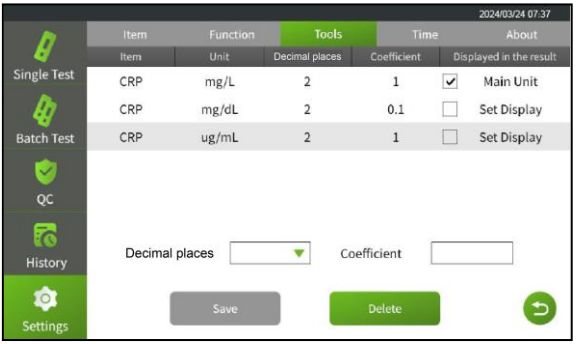
(Figure 28)

After setting successfully, the analyzer will automatically return to the main interface of unit management. The analyzer will display the new unit in this interface (Figure 29).



(Figure 29)

Click “Edit” to enter the following interface (Figure 30). You can edit the new unit as you’re needed.



(Figure 30)

(1) Click “☐” to choose the second unit which need to be displayed in the result.

(2) Click “ ▼ ” to choose the decimal places.

(3) Input the correct coefficient in “Coefficient”.

(4) Click “Save” to save the settings.

(5) Click “Delete” to delete the selected unit.

(6) Click “ ↩ ” to return to the previous interface.

Note：

1) The “Main Unit” is displayed by default and cannot be edited or deleted.

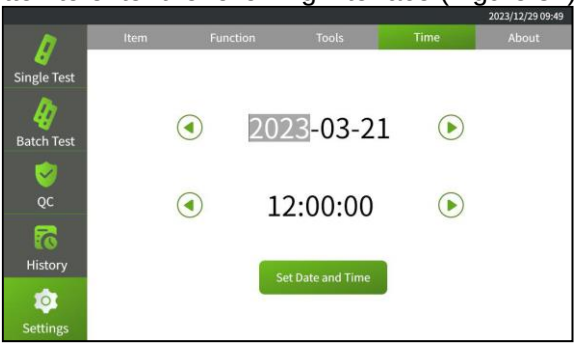
2) Except for the main unit, other analyzer default units can be selected to display or not, and the decimal point can be edited, but the coefficient cannot be modified. It can't be deleted either.

3) This function only supports displaying one additional unit simultaneously, besides the main unit.

4) The new units for the combo test need to be added individually for each test item, such as hsCRP/CRP.

Time

Click “Time” button to enter the following interface (Figure 31).



(Figure 31)

Click the field which needs to be modified by press “◀” or “▶”, then, click “Set Date and Time” button to save the date and time.

About

Click “About” button to enter the following interface (Figure 32).

(Figure 32)

Model, software version, serial number will be displayed on the screen.

Testing

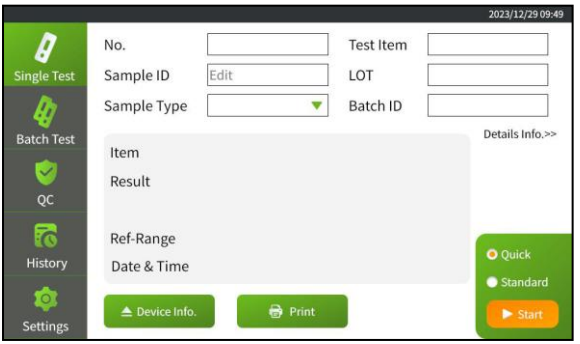
Before you perform the single test, you need to prepare the VivaDiag POCT Analyzer and VivaDiag FIA Test Kit.

Operation Steps for Quick Test

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 5 minutes.

Note: *5 minutes is the preheating time for analyzer.*

Step 2: Click “Single Test” and “Quick” to choose quick test mode (Figure 33).

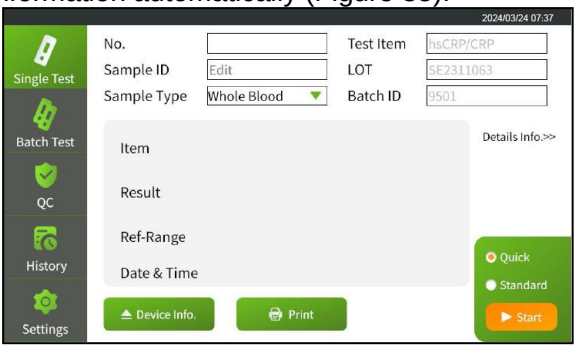


(Figure 33)

You can click “Details info.” to input the name, weight, age and gender (Figure 34).

(Figure 34)

Step 3: Take the ID card from VivaDiag FIA Test Kit of the item you need to test, and insert it into the ID card slot until you hear a beep, the analyzer will get the item’s information automatically (Figure 35).

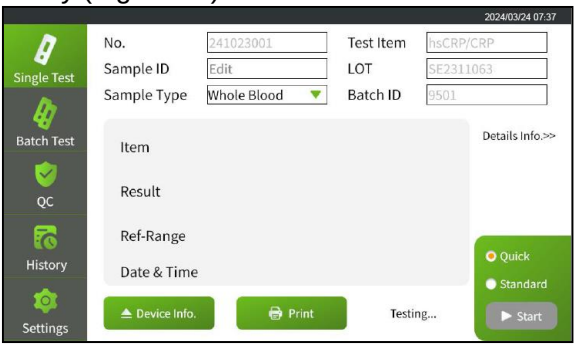


(Figure 35)

Step 4: Remove the test device from foil pouch in VivaDiag FIA Test Kit of

the item you need to test, refer to the package insert to add the sample and wait for the corresponding reaction time.

Step 5: Insert the test device into the test device slot after the reaction time completed, the analyzer will scan the barcode on test device first and start the test automatically (Figure 36).



(Figure 36)

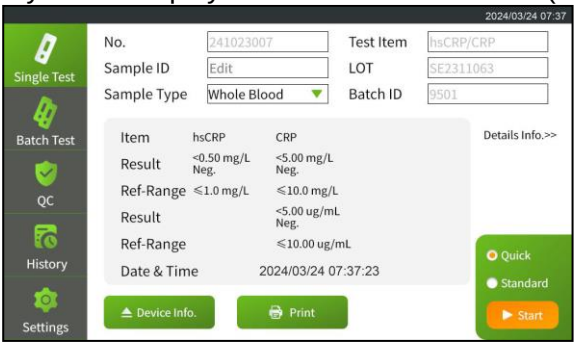
Note:

1) If you turn off "Micro Switch" function, you need to click "Start" button manually to start the test.

2) If you turn off "Auto QR Scan" function, the analyzer will start the test directly without scanning the barcode on test device.

3) If you turn off "Auto Print" function, you need to click "Print" button manually to print the test result

Step 6: The analyzer will display the test result in seconds (Figure 37).



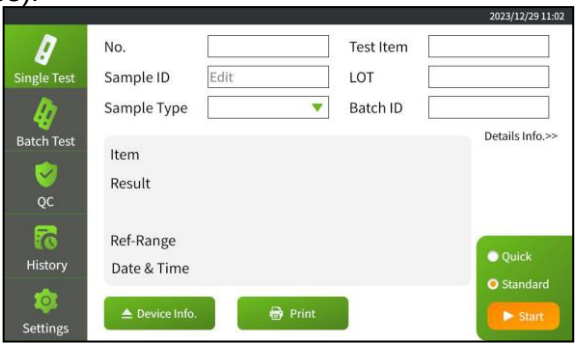
(Figure 37)

Operation Steps for Standard Test

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 5 minutes.

Note*: 5 minutes is the preheating time for analyzer.*

Step 2: Click “Single Test” and click “Standard” to choose standard test mode (Figure 38).

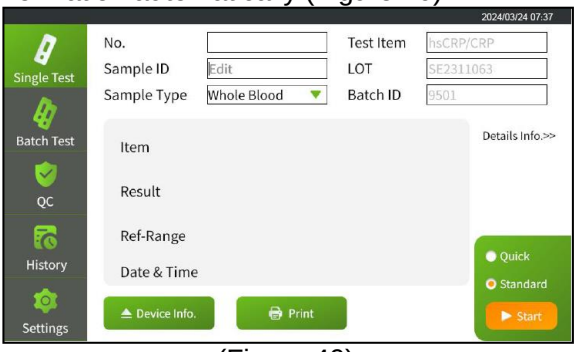


(Figure 38)

Step 3: You can click “Details info.” to input the name, weight, age and gender (Figure 39).

(Figure 39)

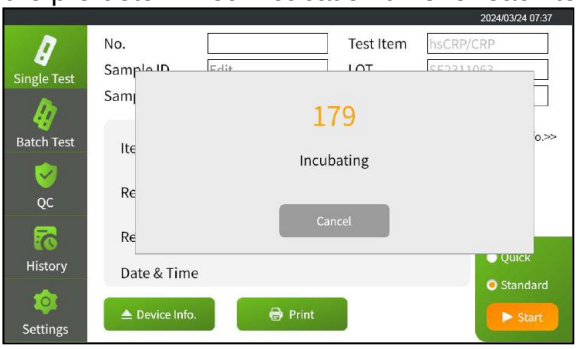
Step 4: Take the ID card from VivaDiag FIA Test Kit of the item you need to test, and insert it into the ID card slot until you hear a beep, the analyzer will get the item’s information automatically (Figure 40).



(Figure 40)

Step 5: Remove the test device from foil pouch in VivaDiag FIA Test Kit of the item you need to test, refer to the package insert to add the sample.

Step 6: Insert the test device into the test device slot, then the analyzer will start incubating. The incubating time is the reaction time of the item you test. Please wait for the pre-determined incubation time for each test (Figure 41).



(Figure 41)

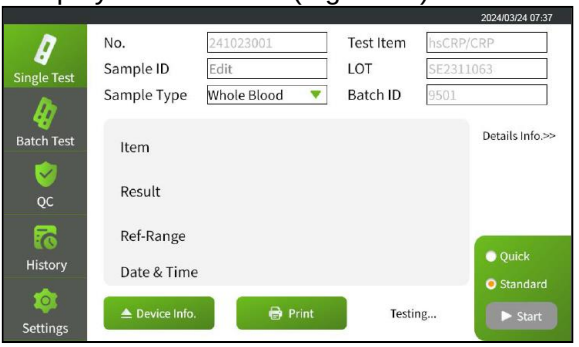
Note:

1) If you turn off "Micro Switch" function, you need to click "Start" button manually to start the test.

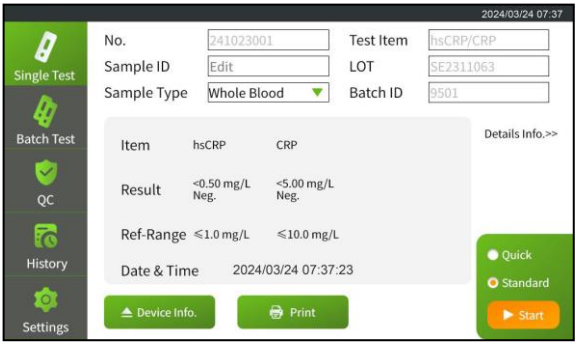
2) If you turn off "Auto QR Scan" function, the analyzer will start incubating without scanning the barcode on test device.

3) If you turn off "Auto Print" function, you need to click "Print" button manually to print the test result.

Step 7: The analyzer will start testing after the incubating time is ending (Figure 42), and display the test result (Figure 43).



(Figure 42)



(Figure 43)

Batch Test

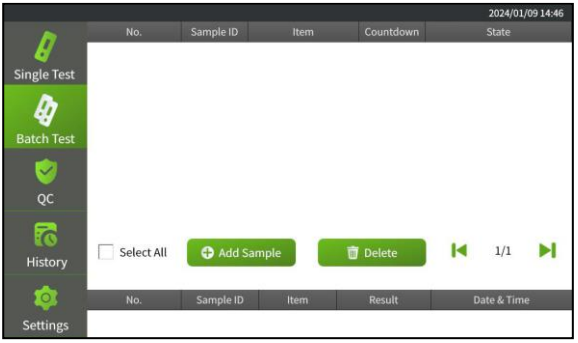
Before you perform the batch test, you need to prepare the VivaDiag POCT Analyzer and VivaDiag FIA Test Kit.

Operation Steps

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 5 minutes.

***Note**: 5 minutes is the preheating time for analyzer.*

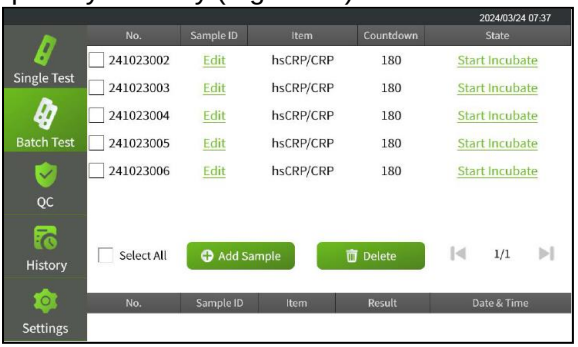
Step 2: Click “Batch Test” to enter the following interface (Figure 44).



(Figure 44)

Step 3: Take the ID card from VivaDiag FIA Test Kit of the item you need to test, and insert it into the ID card slot until you hear a beep, the analyzer will get the item’s information automatically.

Step 4: Click “Add Sample”, the analyzer will display the sample information (including No., sample ID, item, countdown and state) automatically. You can add all samples by this way (Figure 45).

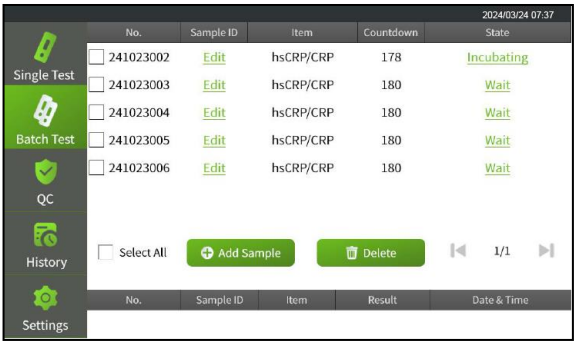


(Figure 45)

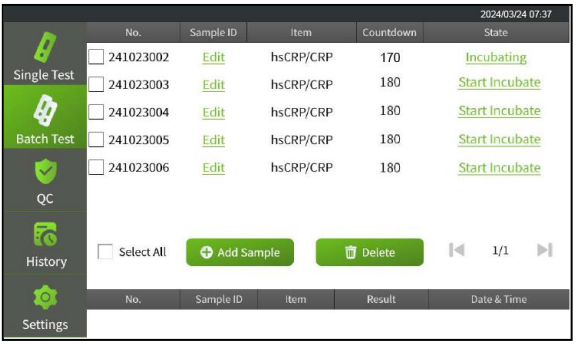
Note: *You can also delete the item you selected by clicking “Delete” button.*

Step 5: Remove the test device from foil bag in VivaDiag FIA Test Kit of the item you need to test, refer to the package insert to add the sample.

Step 6: Click “Start Incubate” to incubate the sampled test device and the analyzer enter to incubating (Figure 46). You have 10 seconds to add the sample for the next test device and click “Start Incubate” to incubate the next test device. You can complete all samples’ sampling and incubation by this way (Figure 47).

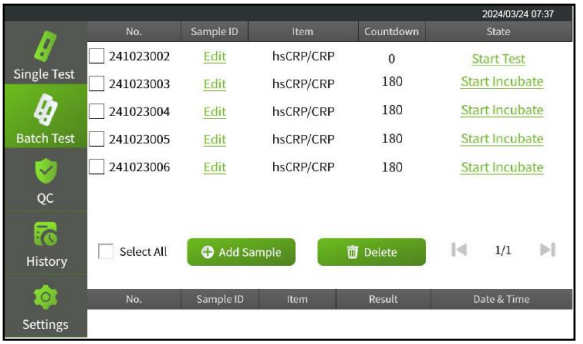


(Figure 46)



(Figure 47)

Step 7: The analyzer will display “Start Test” after incubating completed. Insert the test device and click “Start Test”, and the analyzer will start to test (Figure 48).



(Figure 48)

Step 8: The result is displayed on the screen after testing, and the test item will be removed from the waiting list (Figure 49).

(Figure 49)

Step 9: Repeat Step 6 to 8 to complete the test of all samples.

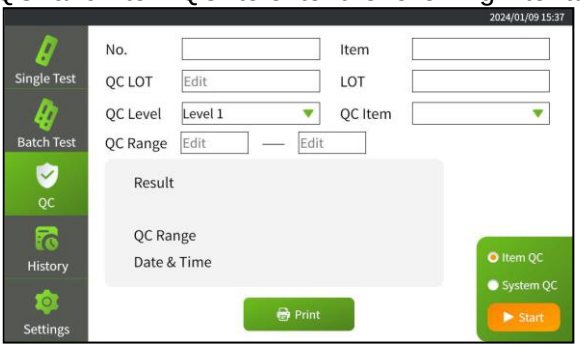
Quality Control Test

Before you perform the quality control test, you need to prepare the materials of item QC and system QC

Operation Steps for Item QC

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 5 minutes.

Step 2: Click “QC” and “Item QC” to enter the following interface (Figure 50).



(Figure 50)

Step 3: Take the ID card from test kit, insert the ID card into ID card port, then the analyzer will read the test item information automatically (Figure 51, Figure 52). Input the QC LOT, QC level, QC range according to the label of control solution.

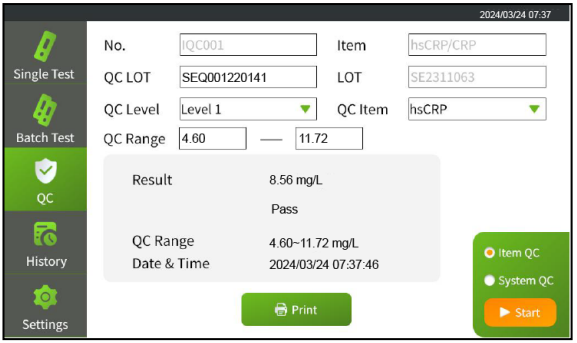
(Figure 51)

(Figure 52)

Step 4: Remove the test device from foil pouch in VivaDiag FIA Test Kit of the item you need to test. Refer to the control solution package insert to add control solution and wait for the corresponding reaction time.

Step 5: Insert the test device into the test device slot after the reaction time completed.

Step 6: Click “Start”, the analyzer will start testing and display the test result (Figure 53).

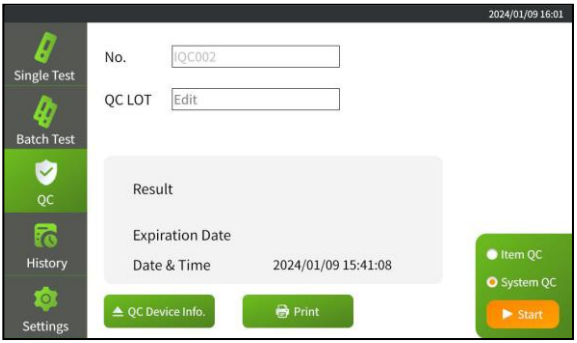


(Figure 53)

Operation Steps for System QC

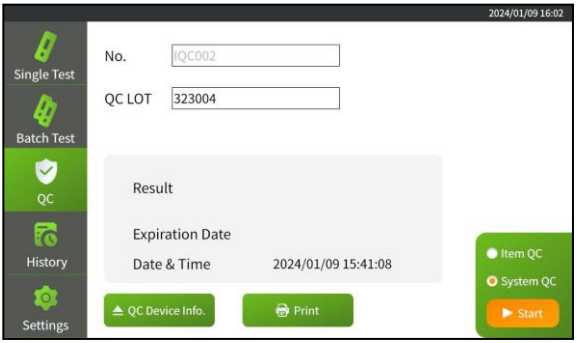
Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 5 minutes.

Step 2: Click “QC” and “System QC” to enter the following interface (Figure 54).



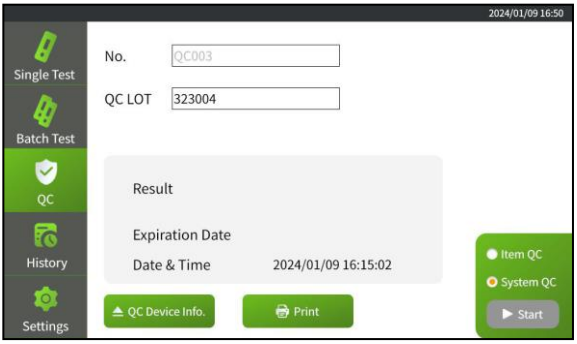
(Figure 54)

Step 3: Insert the QC ID card into ID card port, and the analyzer will read the information automatically (Figure 55).



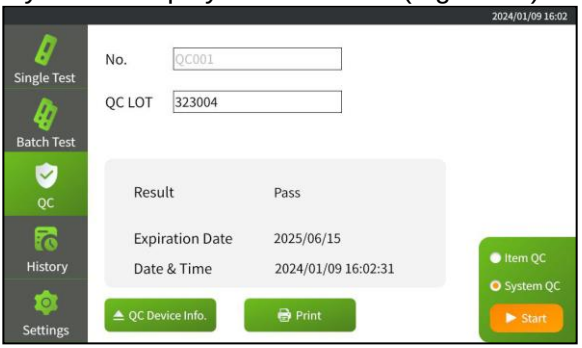
(Figure 55)

Step 4: Remove the QC test device from the foil bag, and insert the QC test device into the test device slot, click “Start”, the analyzer will start test (Figure 56).



(Figure 56)

Step 5: The analyzer will display the test result (Figure 57).



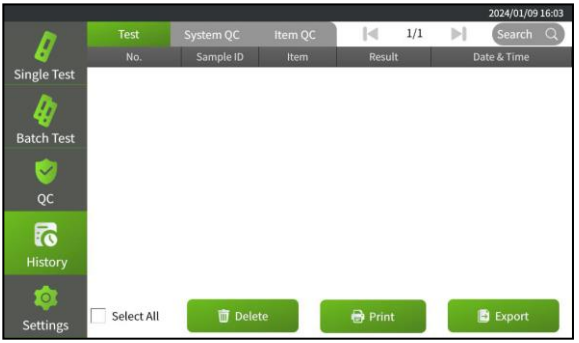
(Figure 57)

Note:

1) *The quality control device is reusable.*
2) *Please replace the quality control test device in the self-sealing foil pouch after the testing.*
3) *Keep the quality control ID card and test device in in a cool, dry place between 2 ~ 30°C.*
4) *Keep away from light.*

History

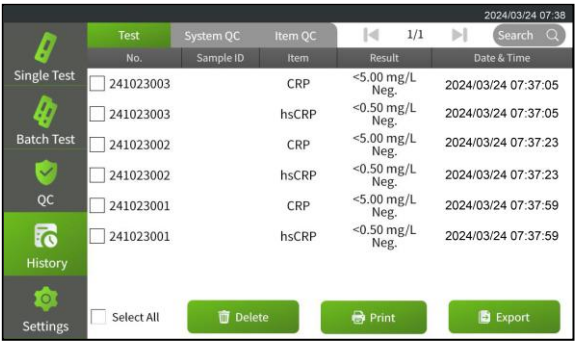
Click “History” to enter the following interface (Figure 58).



(Figure 58)

Test Record

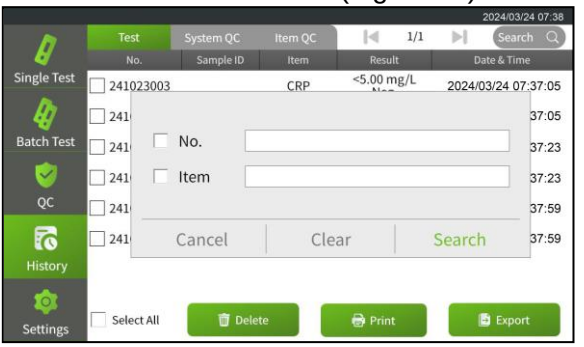
Click “Test” to enter the following interface (Figure 59).



(Figure 59)

(1) Click "◀" or "▶" to browse the saved records.

(2) Click "🔍" to search the saved records (Figure 60).



(Figure 60)

(3) Click "Select All" to select all the saved records.

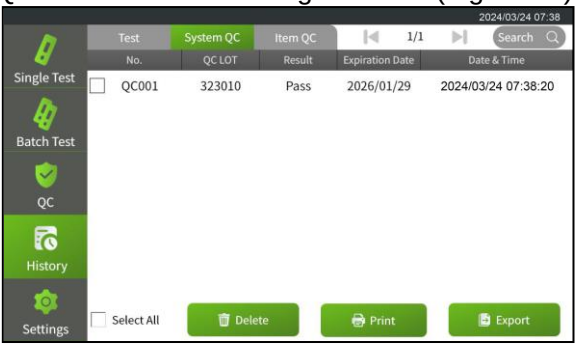
(4) Click "Delete" to delete the record you selected.

(5) Click "Print" to print the record you selected.

(6) Click "Export" to export all the saved records.

System QC Record

Click "System QC" to enter the following interface (Figure 61).

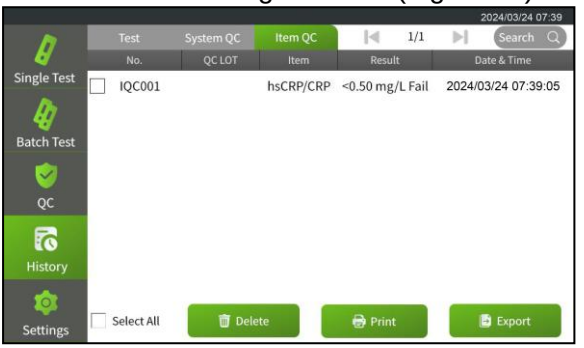


(Figure 61)

(1) Click “ ” or “ ” to browse the saved system QC records.
(2) Click “ ” to search the saved records.
(3) Click “Select All” to select all the saved records.
(4) Click “Delete” to delete the record you selected.
(5) Click “Print” to print the record you selected.
(6) Click “Export” to export all the saved records.

Item QC Record

Click “Item QC” to enter the following interface (Figure 62).



(Figure 62)

(1) Click “ ” or “ ” to browse the saved test item QC records.
(2) Click “ ” to search the saved records.
(3) Click “Select All” to select all the saved records.
(4) Click “Delete” to delete the record you selected.
(5) Click “Print” to print the record you selected.
(6) Click “Export” to export all the saved records.

CHAPTER 5: MAINTENANCE AND TROUBLESHOOTING

Maintenance

- Your VivaDiag POCT Analyzer VIM3000 does not require special maintenance or cleaning. Basic maintenance is to keep the external clean of the analyzer.

External cleaning and maintenance method: A cloth dampened with 70% alcohol can be used to wipe the outside of the analyzer. Do not use strong bleach (≥0.5% bleach solution), because oxidizing substances and solvents may damage the analyzer's parts and touch screen. Take care to avoid getting liquids, dirt, blood or buffer into the analyzer through the slot or data port.

- Except for external cleaning, your VivaDiag POCT Analyzer VIM3000 also requires thermal printing paper replacement when needed.

> ⚠ **Caution**
> Turn off the power switch before cleaning! Ensure the power line is disconnected to avoid the risk of short circuit and electric shock!

Replacing printing paper method: VivaDiag POCT Analyzer VIM3000 uses the built-in thermal printer, it does not require changes the cartridge, just require replace the thermal printing paper when needed. After the thermal printing paper is run out, open the built-in thermal printer's cover of the analyzer, and replace the thermal printing paper with a new one (Figure 63), then close the cover.

(Figure 63)

Note: *Recommended paper size：57/30/12 mm*

Troubleshooting

Appearance	Description	Actions
Power failure	Power switch is unopened	Turn on the power switch.
	Power plug or power adapter is damaged	Contact your local dealer or manufacturer.
	Bad wire contact between the analyzer and power adapter	Pull off the power line and reconnect, If the problem continues, contact your local dealer or manufacturer.
No response	The analyzer is crashed	Turn off the power switch, replug the power line, and then turn on the power switch again, if the problem continues, contact your local dealer or manufacturer.
Abnormal display	Electrostatic effect	Ground and release the static electricity or reopen the analyzer.
	Circuit fault	Contact your local dealer or manufacturer.
Unable to test	Internal structure, technical or software is damaged	Contact your local dealer or manufacturer.
	Interface error	Contact your local dealer or manufacturer.
	The ID card does not match the analyzer or the ID card is damaged	Repeat the test with a new one. Make sure that it is not damaged and you are using a ID card from VivaChek Biotech (Hangzhou) Co., Ltd.

	The test device does not match the analyzer or the test device is over the expiration date	Discard the test device and repeat the test with a new one. Make sure that it is not over the expiration date and you are using a test device from VivaChek Biotech (Hangzhou) Co., Ltd.
	The ID card and test device are not match	Make sure that the ID card and test device you are using is match and gain from VivaChek Biotech (Hangzhou) Co., Ltd.

CHAPTER 6: TECHNICAL INFORMATION

System Specifications

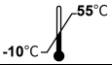
Feature	Specification
Wavelength	Single
Principle	Fluorescence Immunochromatography
Dimensions	192 mm (Length) x 209 mm (Width) x 169 mm (Height)
Weight	1.8 kg
Display size	7'' LCD
Sample type	Whole blood/Serum/Plasma/Urine/Hair /Nasal swab
Test items	40+
Barcode identification	2D
Operating temperature	5-40°C
Storage temperature	-10-55°C
Relative humidity	20-80%
Atmospheric pressure	86.0-106.0 kPa
Connectivity	Ethernet port RJ-45, USB
Battery	AC/DC adapter
Printer	Built-in thermal printer
Memory	10000 test results

Limitations

- Do not place the analyzer in a position that is difficult to operate or inconvenient to disconnect.
- Please use the analyzer strictly according to the User's Manual provided by the manufacturer.
- Do not insert anything into the test device slot except for the test device provided by or purchased from the manufacturer.
- If the tested samples are potentially contagious, please take protective measures such as wear protective gloves to avoid skin contacting with sample.
- Please dispose the analyzer that no longer use according to the procedures and rules of destruction for Class A electric devices.
- Please dispose the used test device according to "Medical Waste Management Regulations" to avoid biohazards.
- Dispose the tested samples and materials carefully. Treat them as if they are infectious materials. Follow proper precautions and obey all local regulations when dispose them.

Index of Symbols

These symbols may appear on the package and in the instructions for the VivaDiag POCT system.

Symbols	Explanation
	Consult instructions for use
	Manufacturer
	Date of manufacture
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
LOT	Lot Number
EC REP	Authorized representative
REF	Catalog number
#	Model number
SN	Serial Number
	Do not re-use
	Caution, consult accompanying documents
⎓	Direct current
~	Alternating current
IVD	*In vitro* diagnose
	Dispose items according to local relevant laws regarding disposal and recycle
	Keep away from sunlight and heat

Warranty

Please complete the warranty card that came with the product and mail it to your distributor 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 repair or replace it with a new one 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, and does not apply to the battery supplied with the analyzer.

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to the local distributor address labeled on the product.

If the analyzer does not work for any reason other than obvious abuse in the first 5 years after purchase, we will repair or replace it with a new or equivalent analyzer free of charge.

Date of purchase _____/_____/_____

Analyzer serial number (e.g.701B0000001) _____

Where purchased _____

Telephone number _____

Email address _____

Suggestion/Comments _____

VivaChek Biotech (Hangzhou) Co., Ltd.

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