



**U-Card Dx™ Automated Rapid Molecular
Diagnostic Instrument**

Model No.: MDx-301

REF: W992

Operation Manual

GUANGZHOU WONDFO BIOTECH CO., LTD.

IVD

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Chapter 1: Terms and Conditions

Thank you for choosing Wondfo U-Card Dx™ Automatic Rapid Molecular Diagnostic Instrument (referred to as the U-Card Dx Instrument). This instrument is developed, designed, manufactured, and sold by Guangzhou Wondfo Biotech Co., Ltd. This Operation Manual contains the details about the instrument's specifications and the graphical output on the user interface(screen) during operation.

In this manual, you will find information on the U-Card Dx Instrument installation, system settings, testing procedures, data management options, instrument maintenance, warranty, customer services, etc. To optimize the U-Card Dx Instrument performance, the user must follow these guidelines for operation and maintenance.

The manual also includes safety precautions and operation guidelines. Please operate in strict accordance with the manual to ensure the safe use of the U-Card Dx Instrument.



Troubleshooting: For unexpected failures during operation of the U-Card Dx instrument, refer to "**Chapter 8: Troubleshooting Guide**", or refer to "**Chapter 10: Contact Information**" to contact technical support.

Chapter 2: Warnings, Precautions, and Symbol

Before you start to use the U-Card Dx Instrument, make sure you read this operation manual carefully and are familiar with the safety information. Ensure this document is kept handy in case the operator has any doubts/questions or concerns.

2.1 Warnings and Precautions

2.1.1 Warnings and Precautions for Operation Environment

- The U-Card Dx Instrument is for in vitro diagnostic use only, not for home use.
- The ambient temperature for normal use of the U-Card Dx Instrument is +10 °C to +30 °C. Ambient temperatures outside this range may affect the accuracy of the U-Card Dx Instrument and cause damage to the internal components or circuits.
- Do not use the U-Card Dx Instrument in an environment with flammable gas or liquid to avoid the risk of fire or explosion.
- The U-Card Dx Instrument does not have a waterproof design. Do not use the instrument in an environment where water may enter the U-Card Dx Instrument.
- Keep the U-Card Dx Instrument dry and avoid exposing the instrument to rapid changes in temperature. If the instrument is moved indoors from an environment below 10 °C, it may take more than 30 minutes to equilibrate to room temperature before proper use, otherwise, condensation or water droplets may occur, causing a short circuit.
- Ensure that the U-Card Dx Instrument is not operated close to any strong electromagnetic sources such as large CT machines, nuclear magnetic oscillation equipment, wireless transmitters, etc.

2.1.2 Warnings and Precautions for Installation

- Before installation of the U-Card Dx Instrument, the user must inspect the instrument and the accessories package. If any damage is present, please contact

Wondfo according to **Chapter 10: Contact Information**.

- Place the U-Card Dx Instrument on a firm and stable platform to avoid instrument toppling and vibrating during the test. U-Card Dx is a highly sensitive optical instrument.
- For adequate ventilation, maintain at least a 50 mm clearance between the rear and the sides of the U-Card Dx Instrument.
- To avoid electric shock hazards, make sure that the power outlet is well-grounded. Ensure that power outlets have a ground prong. Do not plug or unplug the power cord with wet hands.
- Make sure it is easy to disconnect the U-Card Dx Instrument power cord from the power outlet.
- Please use the product accessories provided by Wondfo, such as test cartridges and printing paper. Unauthorized replacement of product accessories may provide inaccurate results and cause damage to the U-Card Dx Instrument.

2.1.3 Warnings and Precautions for Operation of the Instrument

- The U-Card Dx Instrument is for professional use only. It should be used by a trained, qualified healthcare professional.
- If the U-Card Dx Instrument is not used in a manner specified by the manufacturer, the protection provided by the Instrument may become invalid.
- Ensure that the cartridges and other accessories used during the operation are within their respective expiration date.
- The U-Card Dx Instrument operates at a 61 dB noise level and is only produced by the fans. In case an abnormal sound is coming from the U-Card Dx Instrument, please contact Wondfo according to **Chapter 10: Contact Information**.
- Before using the U-Card Dx Instrument, the user must inspect the instrument and its accessories as **Chapter 3, Section 3.5: Packaging list**. If the user finds any discrepancy or damage, do not use the instrument and contact Wondfo according to **Chapter 10: Contact Information**.

- DO NOT disassemble the U-Card Dx Instrument or accessories without authorization by Wondfo.
- When using the U-Card Dx Instrument, always ensure that the correct date and time are set in the system. These system settings are used for recording the test results.
- NEVER modify the U-Card Dx Instrument. Any modifications to the instrument will VIOLATE the instrument warranty and may compromise user safety.
- The U-Card Dx Instrument must be used ONLY with U-Card Dx Cartridges.
- Do not move the instrument while a test is in progress.
- Do not place any objects on the U-Card Dx Instrument. This may result in compromised performance or mechanical damage.
- Do not drop or knock the U-Card Dx Instrument.
- Avoid touching the instrument's screen with gloves that have been in contact with biohazardous material.
- Do not open the front-loading door during an on-going/in-progress test to avoid errors in the test results caused by ambient light interference.
- Turn the instrument's Power OFF before cleaning.
- At any instant, if the instrument is contaminated by the sample or any hazardous chemicals, please follow the cleaning instructions listed in this manual as well as the local safety guidance for cleaning and disinfecting.

2.1.4 Warnings and Precautions for Test Cartridges and Waste Disposal

- Test cartridges should be removed from the U-Card Dx Instrument as soon as possible once the test has finished.
- Please ensure that the test cartridge used for running a test are within its expiration date to avoid an invalid test.
- Once a cartridge has been used for a test, the same cartridge CANNOT be re-used.
- The user should treat the used cartridge as biological waste and should adhere to the local biosafety/hazardous substance disposal procedures and guidelines.

- The user should follow all local procedures and regulations for the use of gloves, safety glasses/eyewear, or other personal protective measures when handling potentially infectious materials.






2.1.5 Warnings and Precautions for Electromagnetic Compatibility (EMC)


















- It is the manufacturer's responsibility to provide U-Card Dx Instrument electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment can be maintained so that the instrument will perform as intended. The electromagnetic environment should be evaluated before operating the U-Card Dx Instrument.
- This instrument has been designed and tested to CISPR 11.
- Do not use this instrument in proximity to sources of strong electromagnetic radiation, as these can interfere with the proper operation.
- The instrument complies with the immunity requirements and emission requirements described in EN 61326-1 and EN 61326-2-6.

2.2 Symbols

The U-Card Dx Instrument, related components and accessories, labels, and this Operation Manual use the following symbols.

Table 2.1 Symbols

Symbol	Description
	Cautionary Information
	Consult Operation Manual
	Biological risks
	CE Marking
	For <i>in vitro</i> Diagnostic Use only

	European Authorized Representative
	Manufacturer
	Date of manufacture
	Temperature limitation
	Humidity limitation
	Catalogue number
	Serial number
	Alternating current
	Power On
	Power Off
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	This side up
	6 identical packages can be stacked at maximum
	WEEE (Waste Electrical and Electronic Equipment)
	Trade mark

Chapter 3: U-Card Dx™ Instrument

The pictures and interfaces in this manual are for reference only, please refer to this manual while initializing the actual instrument.

3.1 Intended Use

- The U-Card Dx Instrument is part of the Wondfo U-Card Dx in-vitro diagnostic system. The U-Card Dx Instrument is required to process U-Card Dx test cartridges. Please refer to the U-Card Dx test cartridge instruction for specific information on each test type.
- The U-Card Dx Instrument is for in-vitro diagnostic use, for professional use only.
- The U-Card Dx instrument is based on polymerase chain reaction (PCR) technology. It is used together with a U-Card Dx test cartridge to perform qualitative detection during clinical practice.

After a cartridge containing a patient sample is loaded into the instrument, the U-Card Dx Instrument processes the sample through the following steps:

- Sample preparation
- Nucleic acid amplification
- Optical detection

Once the instrument completes these steps, the internal software will automatically determine if the test target is detected in the sample, and will report the qualitative result.

3.2 U-Card Dx Instrument

The following figures show the U-Card Dx Instrument:

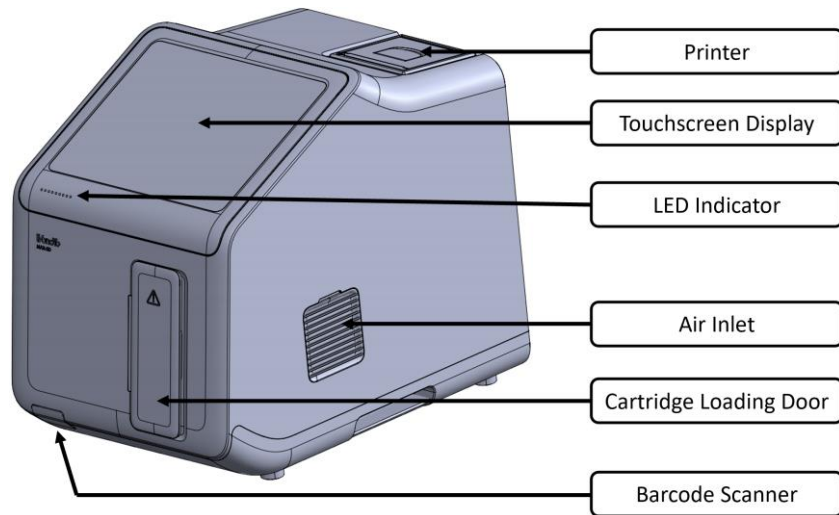


Fig. 3.1 U-Card Dx Instrument – Front View

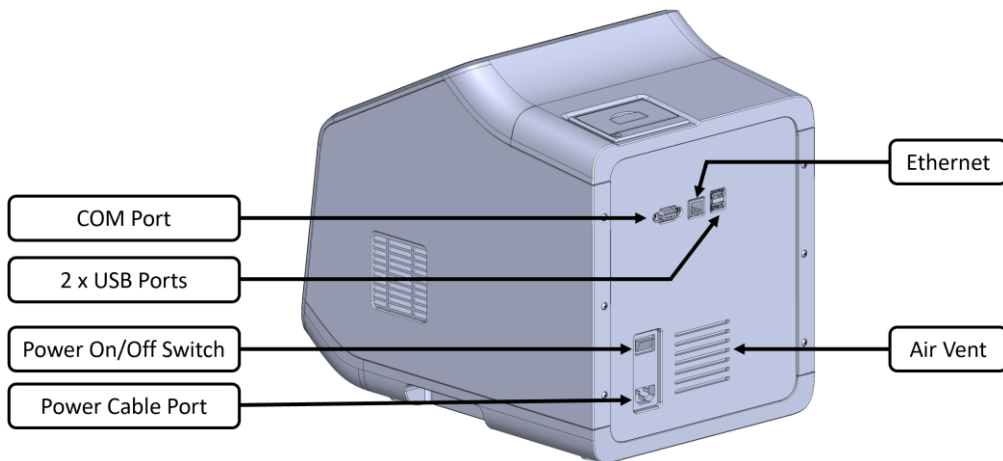


Fig. 3.2 U-Card Dx Instrument – Back View



Ethernet port is used to establish an internet connection. USB ports are used to connect external keyboard, mouse, and USB drive. COM port is used for system debugging.

3.3 Cartridge Holder

The cartridge holder is included in the instrument package. It provides convenience for the sample preparation. See the figure below:

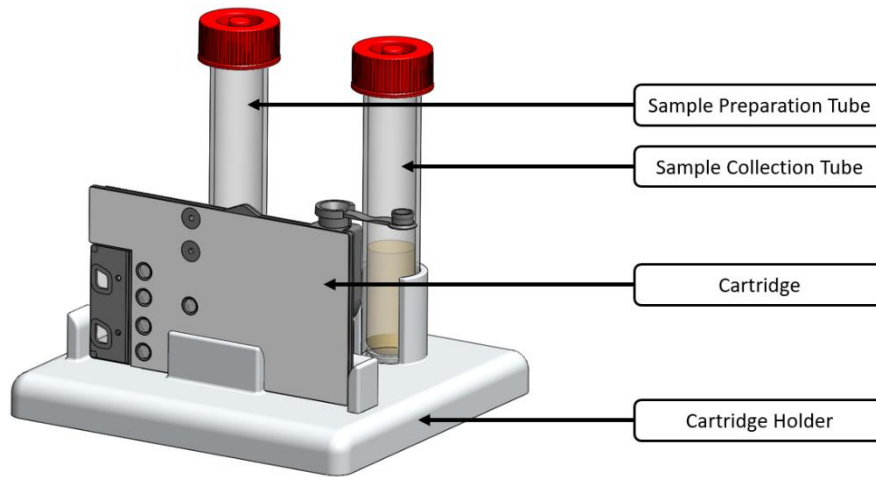


Fig. 3.3 Cartridge Holder

3.4 Specifications and Operation Conditions

3.4.1 Basic Technical Specifications

Table 3.1 Instrument Basic Technical Specifications

Dimensions	315 mm x 245 mm x 355 mm (H x W x D)
Weight	11 kg
Electrical Rating	Power input: 100-240±10% V \sim , 50/60 Hz, 300W Max
Operating Environment	<ul style="list-style-type: none"> • Indoor use • Ambient temperature: 15 °C to 30 °C • Relative Humidity (RH): 10% to 80% • Atmospheric pressure: 85.0 to 106.0 kPa • Altitude: up to 2000m • Pollution degree: 2
Ports	<ul style="list-style-type: none"> • 1 x Ethernet • 1 x COM Port • 2 x USB Ports
Fuse	<ul style="list-style-type: none"> • F6.3AL250V, Φ5*20mm
Shipping & Storage	<ul style="list-style-type: none"> • For shipping use the original cardboard/foam packaging provided • -5 °C to 40 °C • Relative Humidity (RH): 10% to 80%
Result Export	<ul style="list-style-type: none"> • Build-in printer • External USB storage • Support LIS system
Throughput	<ul style="list-style-type: none"> • One cartridge loading dock

3.4.2 Thermal Technical Specifications

Table 3.2 Instrument Thermal Technical Specifications

Average ramp-up rates	From 50 °C to 90 °C, ≥ 8 °C/sec
Average ramp-down rates	From 90 °C to 50 °C, ≥ 6 °C/sec
Temperature uniformity	± 0.5 °C
Temperature accuracy	± 1 °C

3.4.3 Optical Technical Specifications

Table 3.3 Instrument Optical Excitation and Emission Ranges

Optical Channel	Excitation(nm)	Emission(nm)
1	455nm ~ 485nm	510nm ~ 530nm
2	520nm ~ 540nm	554nm ~ 576nm
3	560nm ~ 580nm	595nm ~ 635nm
4	620nm ~ 640nm	655nm ~ 675nm

3.5 Packaging List

After opening the package, please check the components in the Packaging List. If any item is missing or damaged, please contact the sales distributor or Wondfo according to **Chapter 10: Contact Information**.

Table 3.4 Packaging List

#	Item	Quantity
1	U-Card Dx™ Automated Rapid Molecular Diagnostic Instrument	1
2	Cartridge Holder	1
3	Main Power Cable	1
4	Ethernet Cable	1
5	Fuse	2
6	Print Paper	1
7	Operation Manual	1

8	Warranty Card	2
9	Packaging list	1
10	Product Certification	1

Materials needed but not provided

Table 3.5 Materials needed but not provided

Material Name	Required/Optional
U-Card Dx cartridges	Required (Provided as part of the Test Kit)
Nasopharyngeal Swab	
Sample Collection Buffer	
Sample Preparation Buffer	
Transfer Pipette	
Disposable, powder-free gloves	Optional
10% sodium hypochlorite solution (or equivalent)	Optional
70% ethanol or isopropanol	Optional

The U-Card Dx Instrument must be unpacked and installed according to the steps outlined in this guide.

1. Check the package to ensure there are no visible signs of damage caused during shipping.
2. With the instrument box in the upright position, remove the packaging list, cartridge holder, and the main power cable from the box. Remove the top foam insert and lift the instrument completely out of the instrument box, remove the attached foam.
3. Place the instrument upright on a flat, stable surface, that will be free of vibrations and contains sufficient space to ensure there is a minimum clearance of 50 mm at the sides and rear of the instrument for ventilation.
4. Save the instrument box and foam inserts for future transportation.



If there is a need to relocate or transport the instrument, use the saved box and foam

inserts to re-package the instrument. Please contact the sales distributor or Wondfo according to **Chapter 10: Contact Information** for any questions.

3.6 Installation of the U-Card Dx Instrument

3.6.1 Installing Printing Paper

Procedure:

1. Open the printer paper compartment cover (insert thumb/finger and pull the latch).
2. Put the new printing paper roll into the printing compartment of the printer. The front of the print paper should face the thermal print head.
3. Pull out the print paper about 2 cm and close the printer paper compartment cover; ensure the printing paper roll's position does not shift while pulling it out.



- Always use the printing paper rolls only recommended by Wondfo. Otherwise, it may cause damage to the built-in thermal printer and will not be covered under warranty.
- Do not directly touch the thermal print head and paper detector to avoid damage caused by static electricity.
- The printing paper compartment cover should always remain closed except for maintenance or replacing the printing paper roll.

3.6.2 Connecting the Cables

1. Connect the power cable to the wall power outlet.
2. Plug the power cable into the instrument power port.
3. Connect other ports if necessary

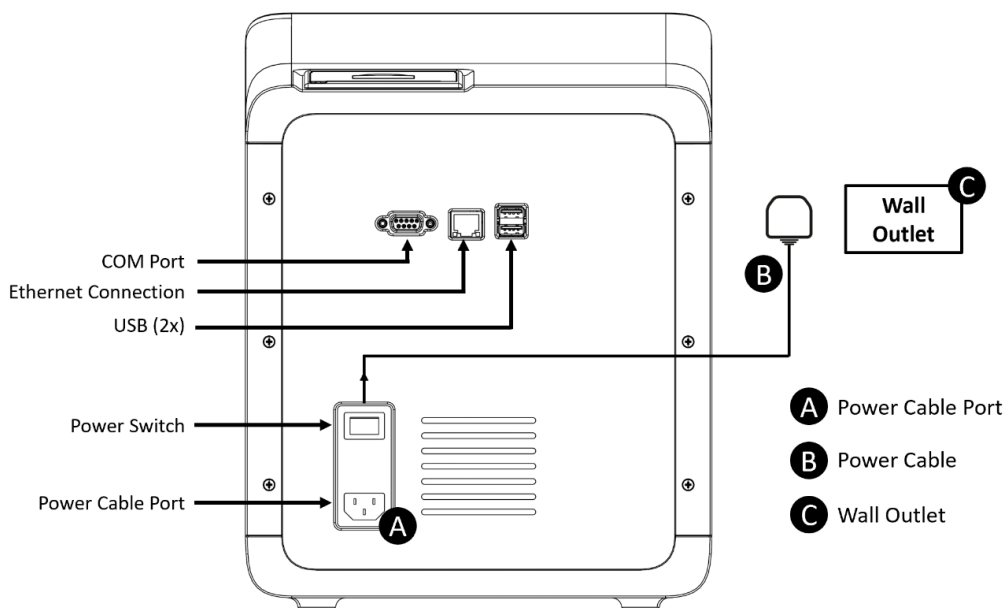


Fig. 3.4 Connecting the Power

4. Press the **Power Switch on the back panel** to turn the instrument on. The light on the front panel will turn green and the following screen will appear to show that the instrument is initializing.



Fig. 3.5 Initializing the U-Card Dx system

5. Once initialized, the Login Screen will appear. If the instrument fails to initialize and the Login screen never appears, turn off the power switch and repeat steps 1-3. If the instrument continues to fail to initialize after several attempts, please contact the sales distributor or Wondfo according to **Chapter 10: Contact Information**.

3.7 User Log In/Out

The instrument includes two login accounts: (i) default Administrator login, and (ii) User login. The Administrator login is recommended to be used for setting up the instrument and managing the individual User accounts. The User login is recommended to be used by operators who will run the test cartridges. The two login options are described in detail below.

The default Administrator User ID is **Admin**. The default **Admin** password is attached to the warranty card. The user could press the Login button to access the main menu. The Admin login has full access to all customer-accessible features of the instrument. The Admin also has the authority to create new user accounts and passwords.

Note: The Admin account can neither be deleted nor the Admin password can be changed.

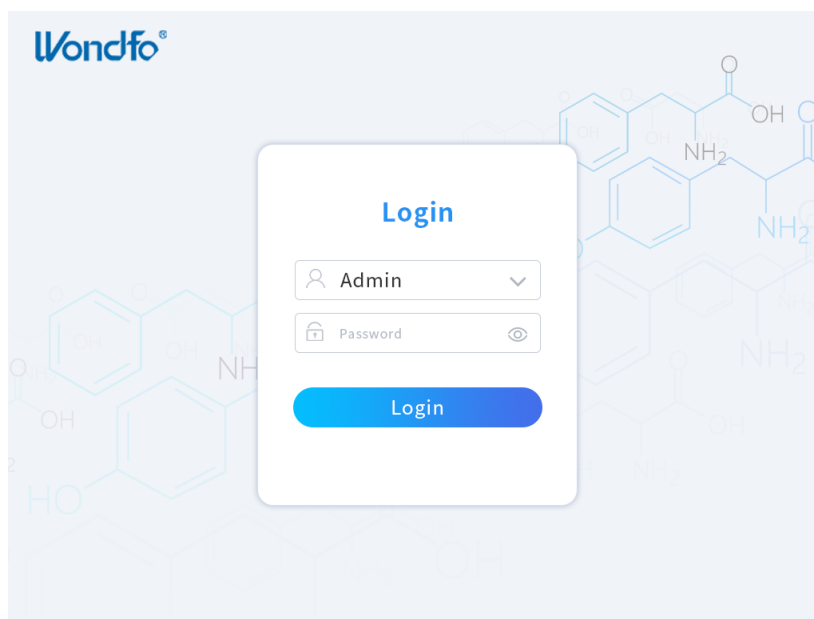


Fig. 3.6 Login Page

After logging in, the Home page for the Admin account is shown below. The Admin can set up User accounts under the User Management option as well as modify/remove User accounts.

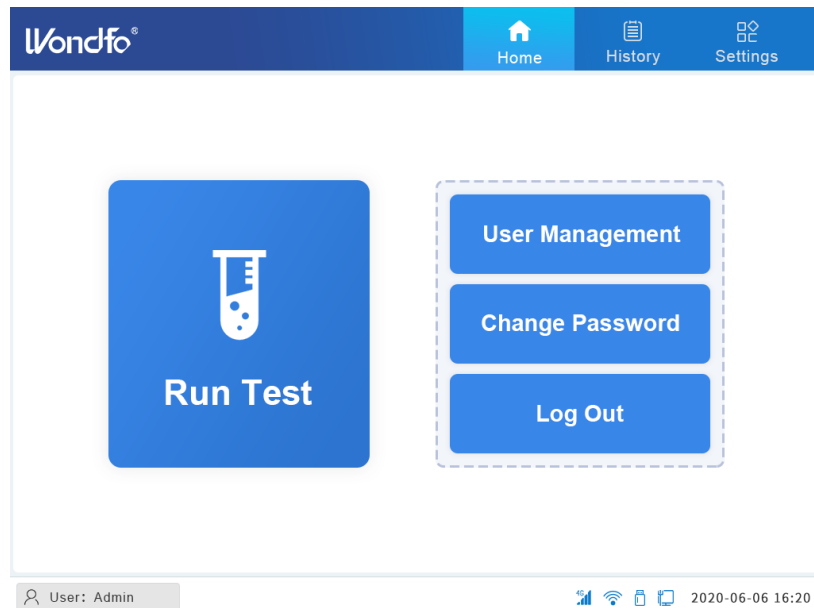


Fig. 3.7 Home Page for Admin

The Home page for the user login will be different, as shown in Figure 3.8.

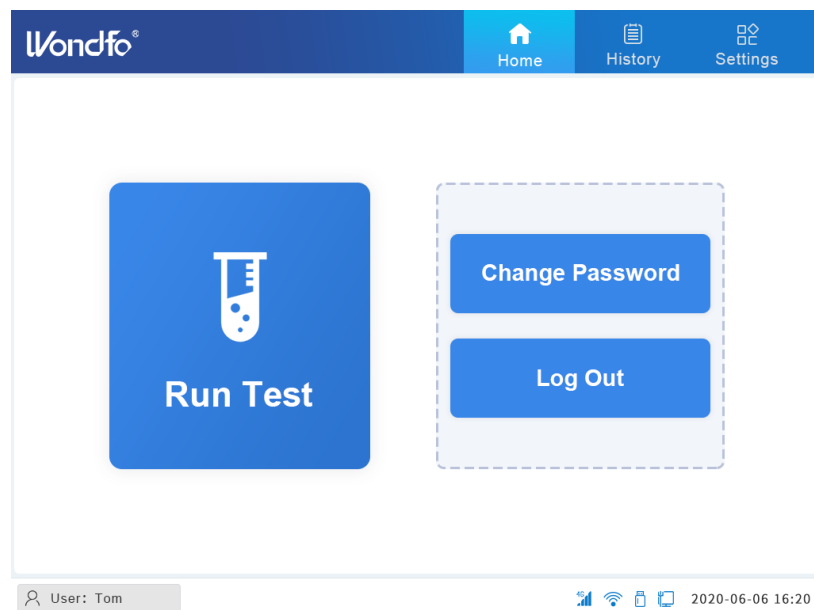


Fig. 3.8 Home Page for the User

Only one user account is permitted for login at a time. To log in to a different account, click **Log Out** from the current User account, this will return the instrument to the Login page.

3.8 System Configuration

Click **Settings** on the home page to go to the System configuration page.

Note: This function is only accessible by the Administrator login; For the user logins, **Settings** is greyed out and there will be no access to the System configuration page.

The screenshot shows the Wondfo System Settings page. The header includes the Wondfo logo and navigation links for Home, History, and System. The System page is active, showing a sub-menu with 'System' selected. The main content area contains three input fields: 'Health Care Facility' with a placeholder 'Please enter the Facility name', 'Language' with 'English' selected and a 'Select' button, and 'Date' with '2000-01-01 00:00:00' selected and a 'Select' button. At the bottom are three buttons: 'About', 'Restore', and 'Save'. The footer shows 'User: Admin' and the date '2020-06-06 16:20'.

Fig. 3.9 Settings: System Page

3.8.1 System

On the **System** page, the Administrator can enter the Health Care Facility information, choose the system language, set the system date and time, and view the system information.

To change the system language, click **Select** after Language input field and choose the language of choice.

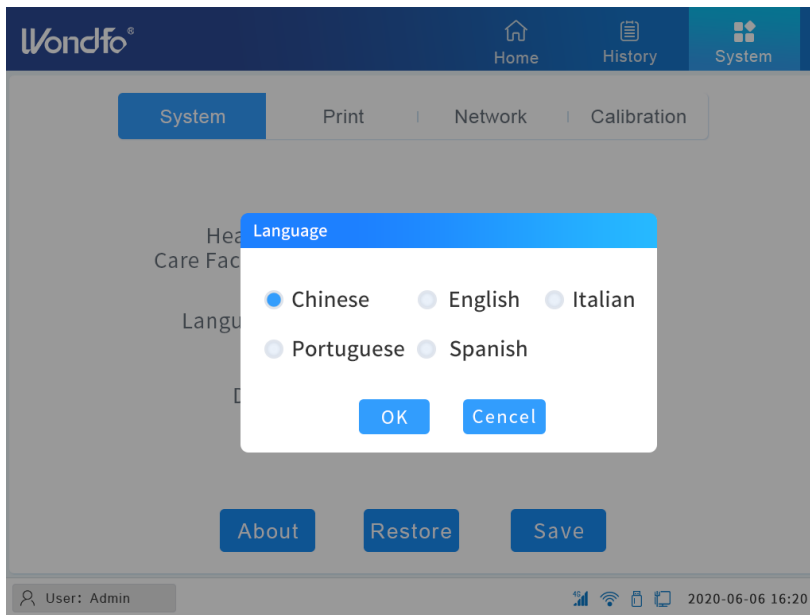


Fig. 3.10 System Language Options

To change the system date and time, click the **Select** tab right next to the Date input field and set the appropriate date and time.

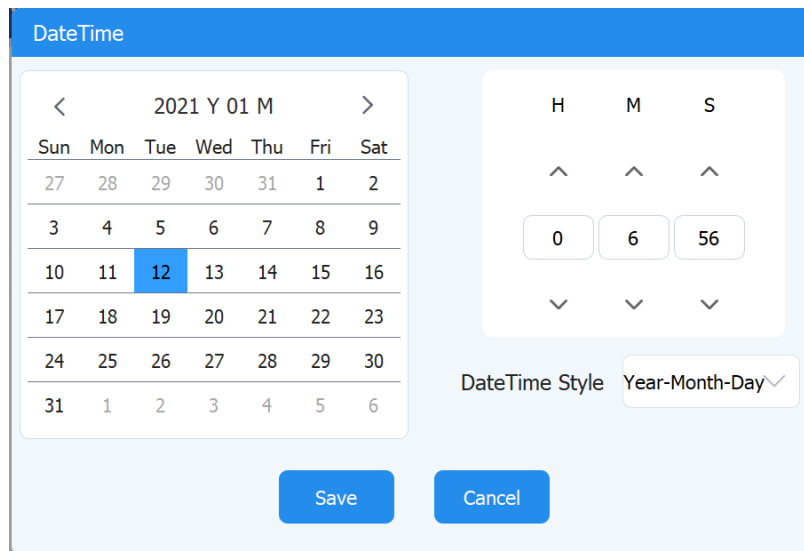


Fig. 3.11 System Date setting

Clicking **About** on the system page will display the system information:

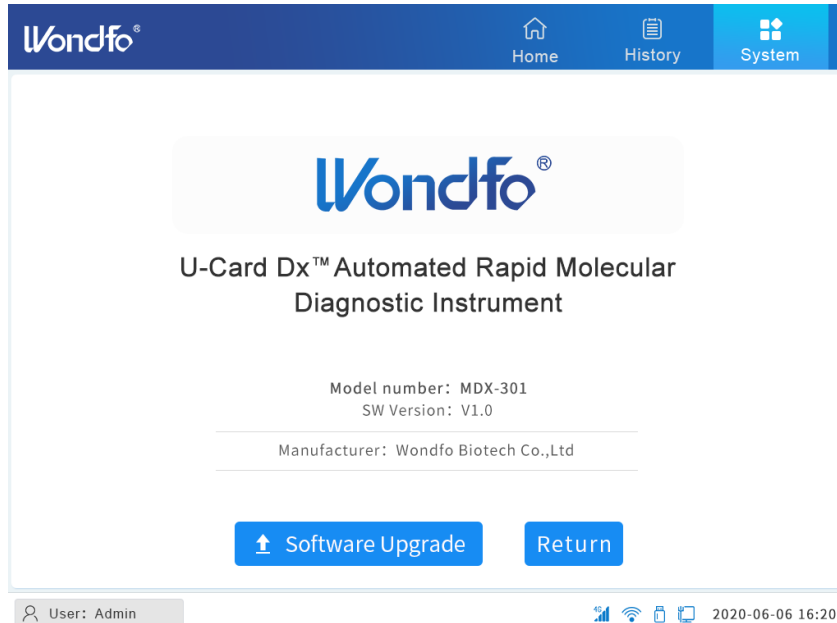


Fig. 3.12 System Information Page

On the System Information page, the Administrator can execute a system upgrade by clicking **Software Upgrade**. The latest software can be stored in the external USB driver provided by Wondfo or can be downloaded through the internet. In either case, after clicking **the Software Upgrade** button, the system will check for the latest software version and will begin upgrading if it is available.

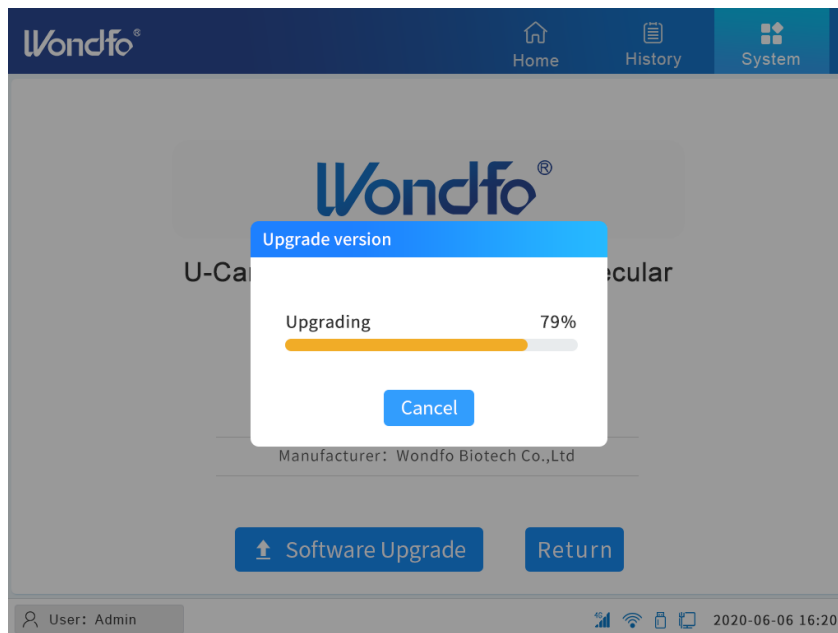


Fig. 3.13 Software Updating Page

3.8.2 Print



Fig. 3.14 Print Setting Page

Custom Printed Report Content: Content for the customizable report includes the name of Health Care Facility, Sample ID, Patient Name, User, Test Result, Age, Test Date, Gender, Sample Collection Date, and Telephone. The Admin can create combinations by selecting the checkbox. Only selected items will be included in the test report.

By default, the test report only includes User, Sample ID, Test result, Test date, and Sample Collection Date.

3.8.3 Network

Press the **Network** button on the System Menu. The U-Card Dx Instrument provides three options: WiFi, LIS Server, and Local Ethernet.

3.8.3.1 WiFi Setting

Click **WiFi** and go to the WiFi page. The Administrator can turn the WiFi function ON/OFF by clicking the sliding bar.

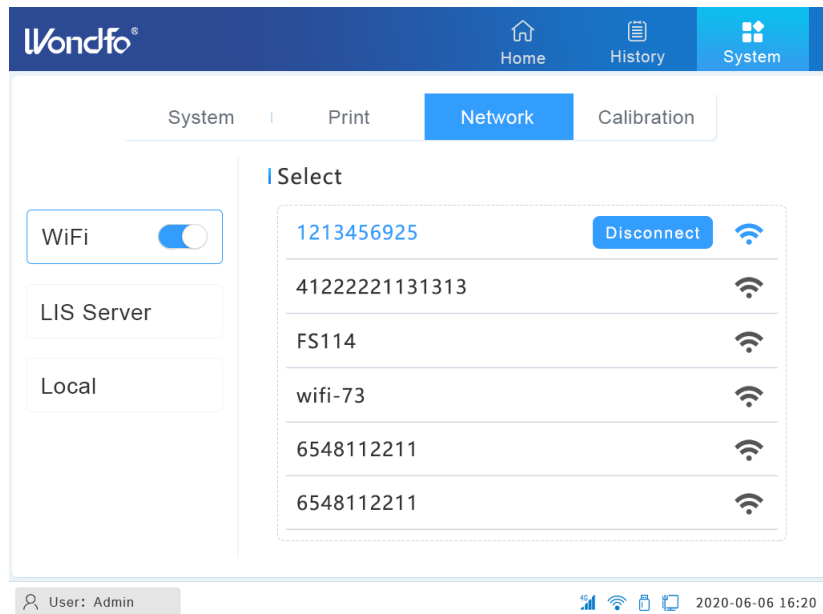


Fig. 3.15 Wi-Fi Setting Page

Select the network you want to connect to from the list of discovered network names. Click **Connect** or **Disconnect** to enable or disable the network connection.

3.8.3.2 LIS Setting

Click **LIS Server** and go to the LIS Server page. The user needs to enter the IP address and port to establish the connection. Consult with your LIS manager for further details.

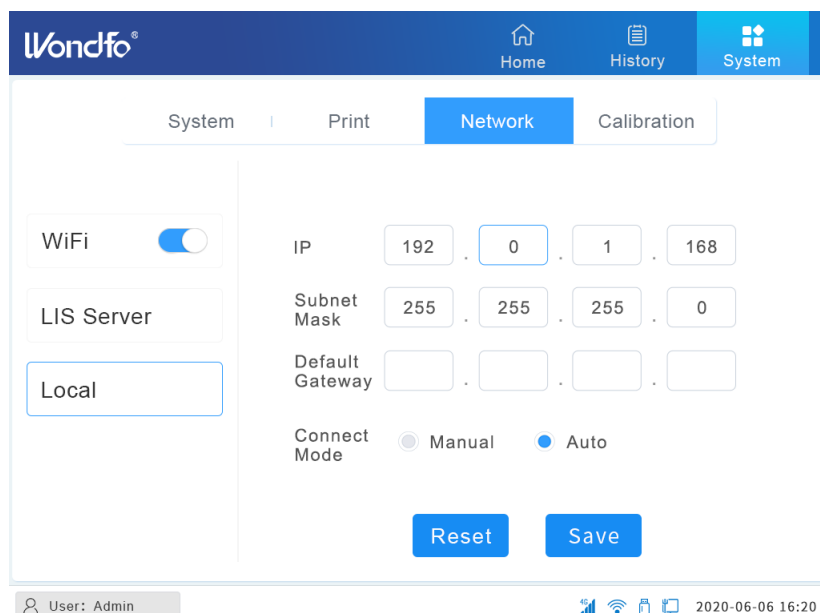


Fig. 3.16 LIS Setting Page

3.8.3.3 Local Setting

Click **Local** to enter the local settings page.

The screenshot shows the Wondfo interface with the 'Local' setting selected. The 'Network' tab is active, showing the following configuration:

- WiFi:
- LIS Server: [Empty field]
- Local: [Selected]
- IP: 192 . 0 . 1 . 168
- Subnet Mask: 255 . 255 . 255 . 0
- Default Gateway: [Empty fields]
- Connect Mode: Auto, Manual
- Buttons: Reset, Save

At the bottom, the user is identified as 'Admin' and the date/time is 2020-06-06 16:20.

Fig. 3.17 Local Setting Page

IP address, subnet mask, default gateway: Manually change input Settings.

Connection Mode: Automatic or manual can be selected.

Auto connection mode: After setting the IP address, subnet mask, and default gateway, select **Auto** and click **Save**.

Manual connection mode: After setting the IP address, subnet mask, and default gateway, select **Manual** and click **Save**.

3.8.4 Calibration

The **Calibration** page is used for instrument calibration. It includes the options to run an **Instrument Self Test** and to view the instrument **Calibration History**.

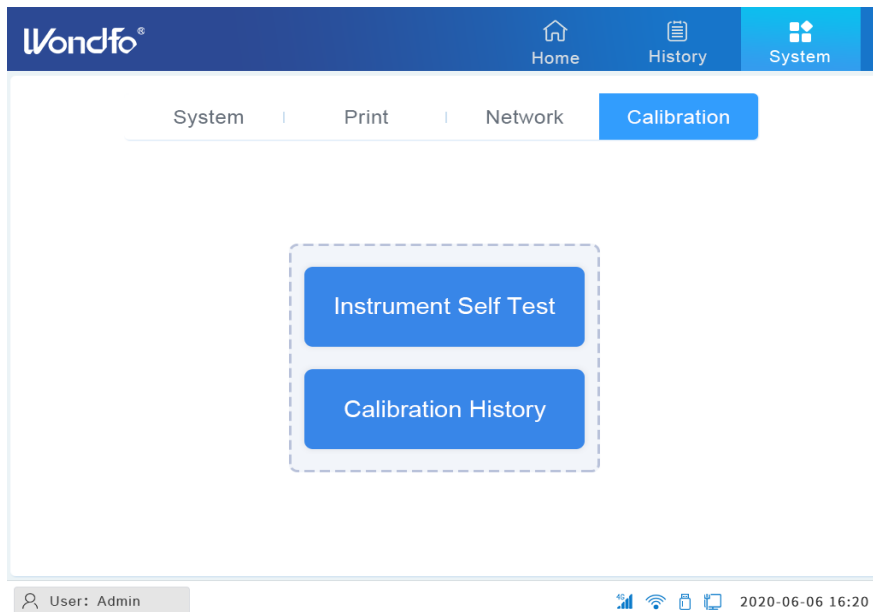


Fig. 3.18 Calibration Page

- **Instrument Self Test** is used for examining all system modules. It is recommended to perform the Instrument Self Test. If the Instrument Self Test fails, stop using the instrument and contact Wondfo according to **Chapter 10: Contact Information**.
- **Calibration History** stores all calibration data from the instrument, including the manufacturer-performed first calibration. Clicking **Report** will open the calibration report.

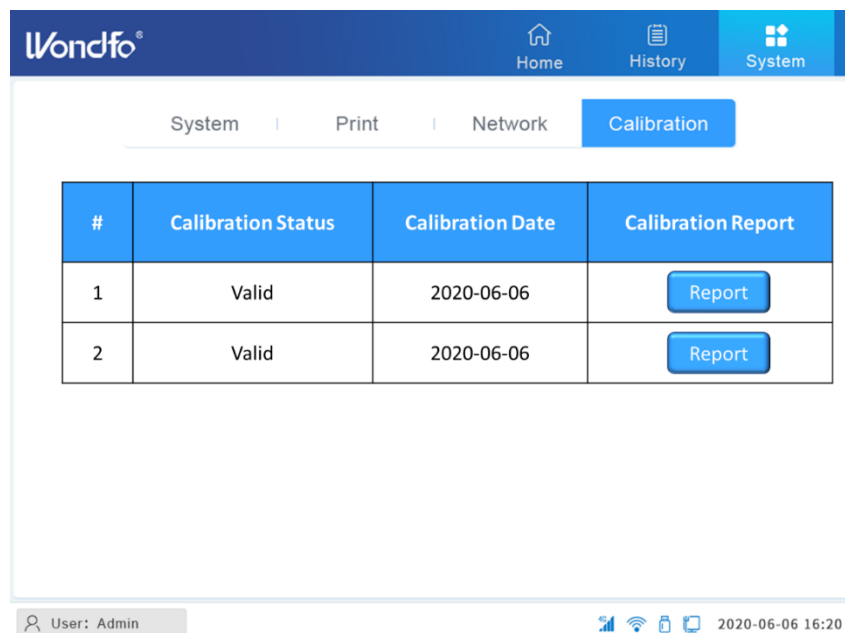


Fig. 3.19 Calibration History

3.9 User Management

Besides the Admin account, there are two types of user accounts for the instrument:

(i) **User**, and (ii) **Superuser**. Table 3.6 lists the different levels of access.

Table 3.6 Operator Access Level

Function	Admin	Superuser	User
System Setting	√	X	X
Perform a Sample Test	√	√	√
Perform a QC Test	√	√	√
Print Result Reports	√	√	√
View Result History	View test results run by all Users	View test results run by all Users	View test results run by current User
Change Password (Current login)	X	√	√
Change Password (Other logins)	√	X	X
Add/Delete Users	√	X	X

User Management is only available under the Admin account. Use the **Admin** account and password (attached in the Warranty Card) to log in to the system (Figure 3.6). Clicking **User Management** will open the User Management page. The tabs available in the User Management interface perform the corresponding functions as follows:

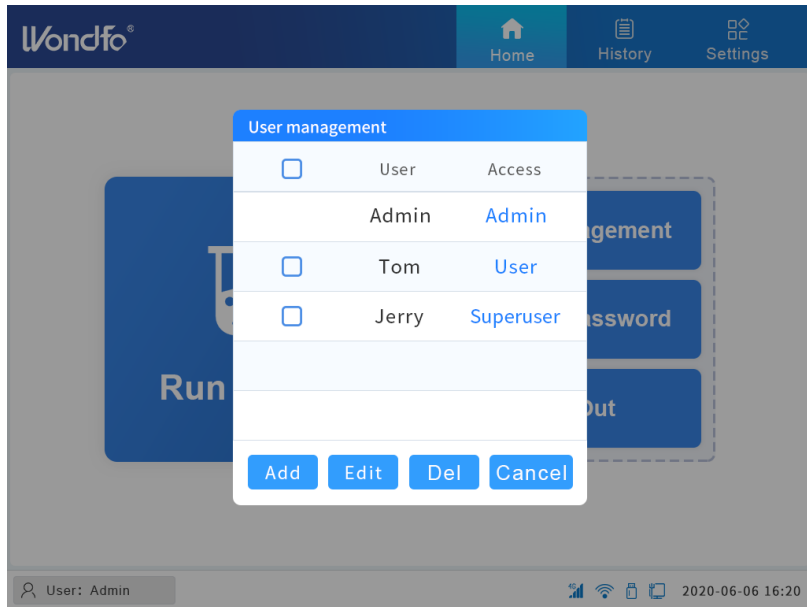


Fig. 3.20 User Management Page

Add: Add new User login.

Edit: Edit Username, password.

Del: Delete User.

Cancel: Return to the previous menu.

Click **Add** to add a new user as shown in Figure 3.21. The **Admin** can specify the user's name, password, and user access.

Both **Superuser** and **User** CAN NOT change the system settings. The **User** will be limited to only view the test results performed by the current user. The **Superuser** will have full access to the test results performed by all Users.

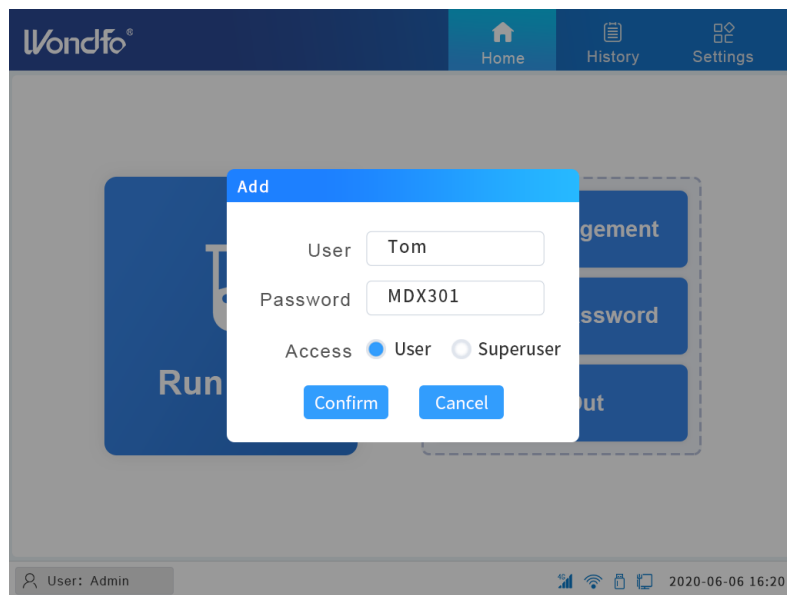


Fig. 3.21 Add New User

Click **Edit**; the Admin can change the user's name and password as shown in Figure 3.22.

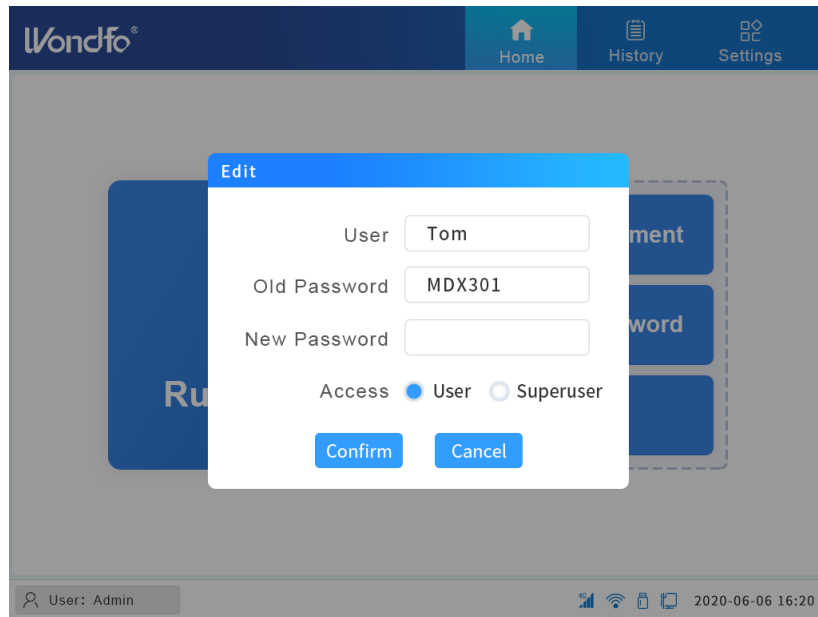


Fig. 3.22 Edit the User

Chapter 4: Test Procedure

4.1 Entering Sample Information

After logging in, click **Run Test**. It will display the **Enter Sample ID** page as shown in Figure 4.1.

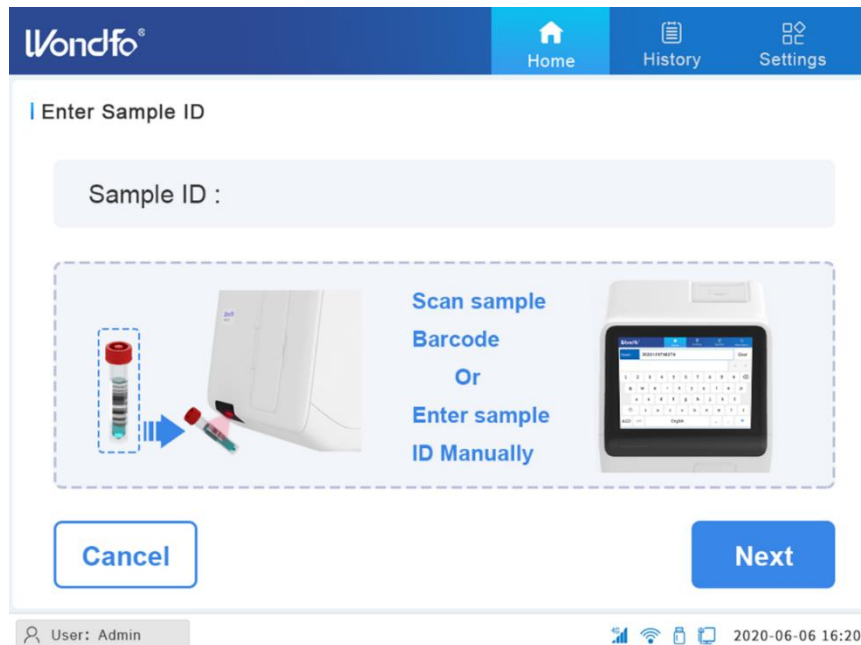


Fig. 4.1 Enter Sample ID

4.1.1 Entering the Sample ID by Barcode

Follow the instruction on the screen. If there is a Sample ID barcode, the user can scan the barcode to input the Sample ID. To scan the Sample ID, hold the barcode in front of the scanner. When the user hears a beep sound, the scanning is successful, and the Sample ID will automatically populate in the Sample ID field.

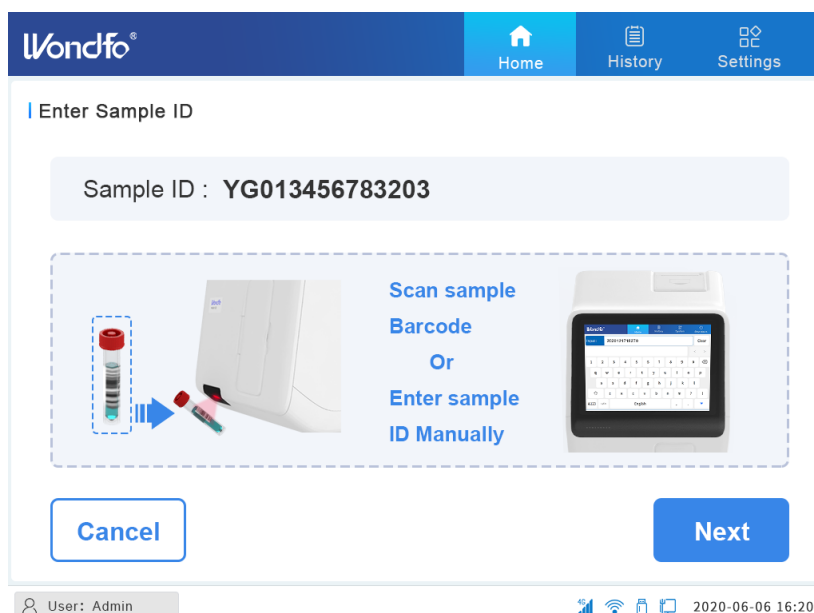


Fig. 4.2 Scanning Barcode to Enter Sample ID

4.1.2 Entering the Sample ID Manually

If the sample does not have a barcode or the scanner is unable to read the barcode (no beep sound is heard or no information is displayed corresponding to sample details), the sample ID can be entered manually. By clicking the blank input field right next to Sample ID, the **Patient Information** page as shown in Figure 4.3 will pop out. The User can enter the sample ID in the first line.

On the **Patient Information** page, a Sample ID is required to fill for the test. The other information, such as age, name, year, etc. is optional. The user could choose to fill or leave them as a blank area. Clicking **Save** will associate the filled-in information to the current test and the user can proceed further to the NEXT page (Figure 4.2). Clicking **Cancel** will go back to the Enter Sample ID page (Figure 4.1).

Wondfo®

Home History Settings

Patient Information

*Sample ID YGO13456783203

Name Bob Song
 Same as Sample ID

Age 16 Year Telephone 1765431238

Gender Female Male
 Other Sample collection date 2020-06-05

Save Cancel

User: Admin 2020-06-06 16:20

Fig. 4.3 Enter Patient Information Manually

4.2 Scanning Cartridge Information

Once **Sample ID** is filled, click **Next** to move to the **Scan Cartridge** page.

Wondfo®

Home History Settings

Scan cartridge

Test : Select

LOT:
 SN:
 MFG:
 EXP:

Cancel Next

User: Admin 2020-06-06 16:20

Fig. 4.4 Scan Cartridge Page

4.2.1 Entering the Cartridge information by Barcode

Follow the instruction on the screen. Hold the cartridge in front of the scanner to activate the scanning function. The instrument will beep when the cartridge scanning is successful. The test information associated with this cartridge will be automatically displayed on the screen as shown in Figure 4.5.

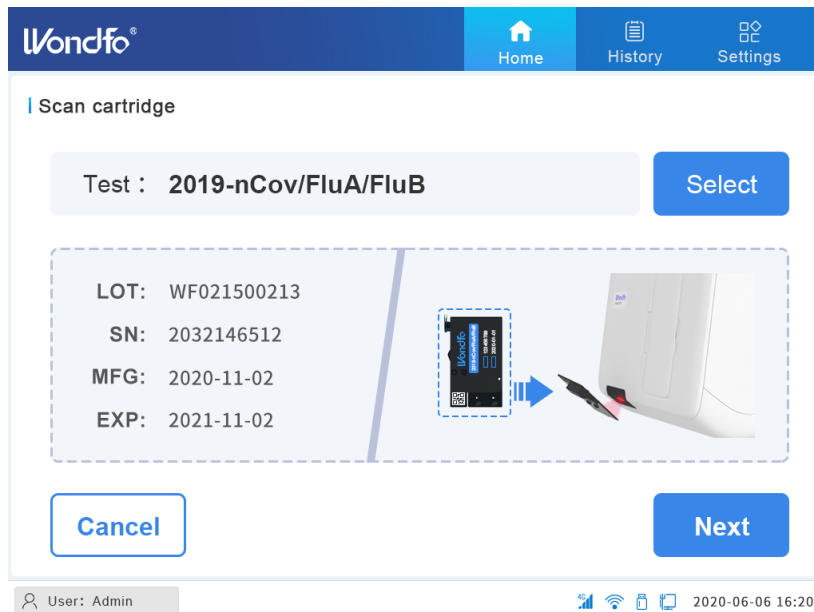


Fig. 4.5 Scan Cartridge

4.2.2 Entering the Cartridge information manually

If the scanner has a problem reading the cartridge information, the user can click **Select** and manually select the appropriate test.

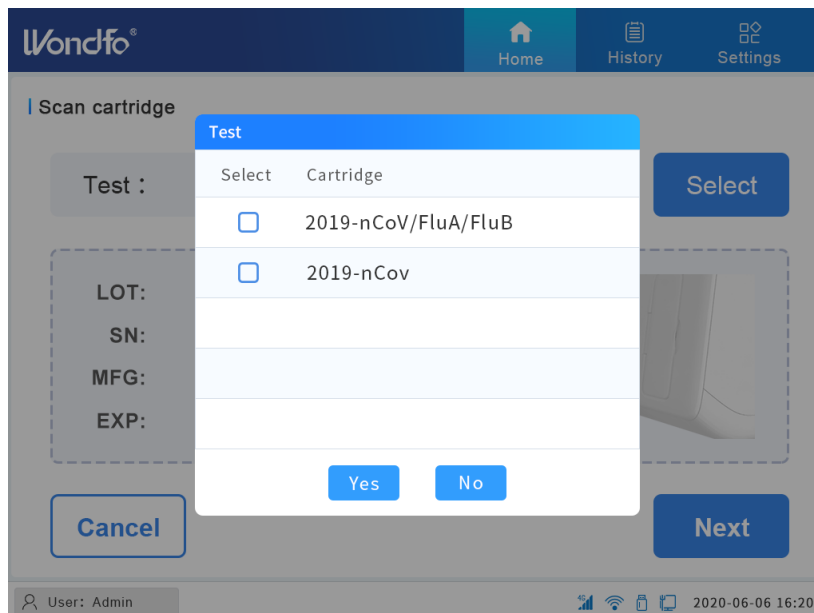


Fig. 4.6 Manually Select the Test

After selecting the test by checking the box next to the intended test of interest, a confirmation warning dialog will pop up to ensure the correct test has been selected (Figure.4.7). Clicking **Yes** will advance to Figure 4.5 with cartridge information displayed.



To achieve accurate test results for the intended analyte, the manually selected test must match the label on the cartridge that the sample was added to.

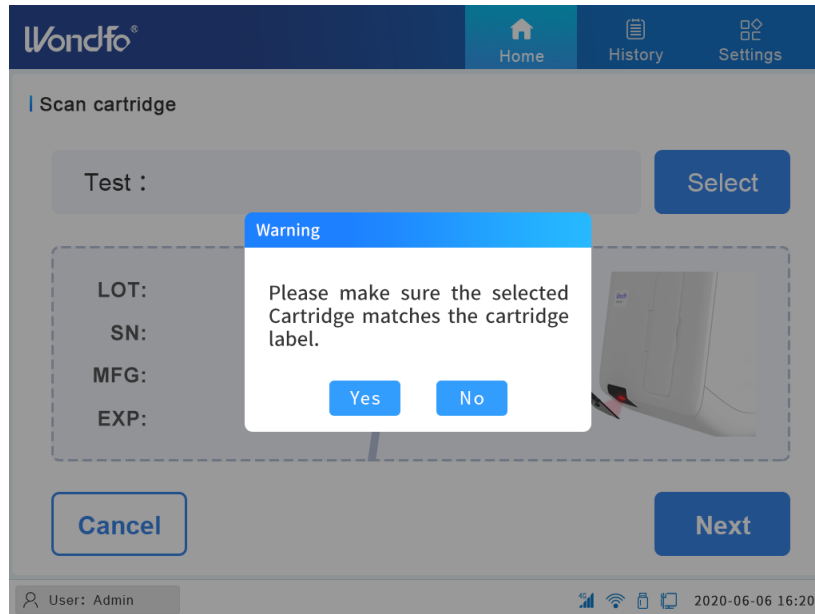


Fig. 4.7 Manually Select Test Cartridge Warning

4.2.3 Loading sample into the cartridge

Clicking **NEXT** in Figure 4.5 will advance to the next page, **Load sample into the cartridge**, as shown in Figure 4.8, follow the instructions and click **Next**.

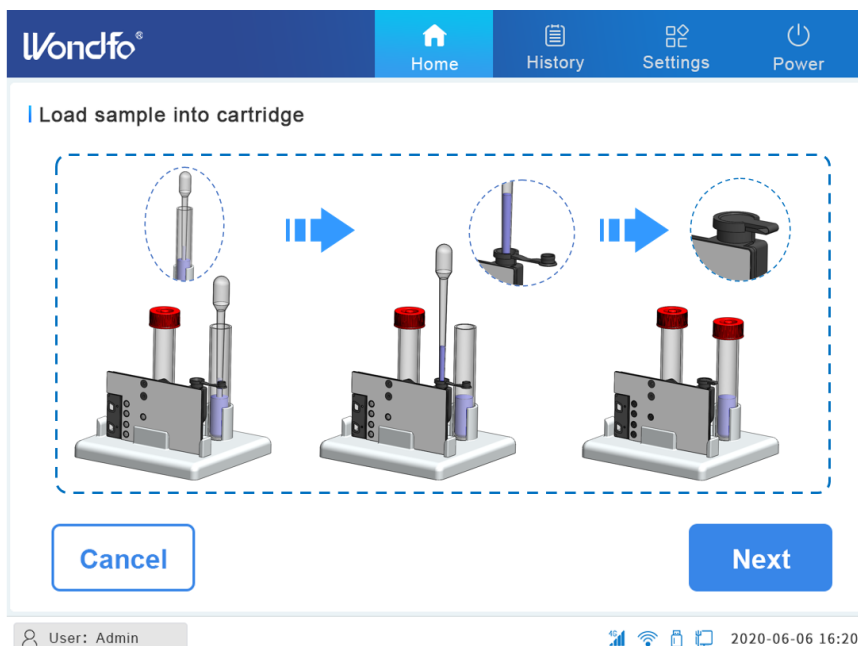


Fig. 4.8 Load Sample into Cartridge


Follow the illustration in Figure 4.9 to insert the cartridge into the instrument. Ensure

the cartridge has been fully inserted into the cartridge slot and close the Cartridge Loading Door. Click **Start** to run the test.



Fig. 4.9 Load Cartridge into Instrument

4.3 Running the Test

Figure 4.10 shows the Run Test screen of a test in progress. The **Sample ID** and **Test** information, along with the remaining time of the current cartridge can be seen on the Run Test screen. By clicking the  icon next to the Sample ID field, the user can view/edit the sample/patient information.

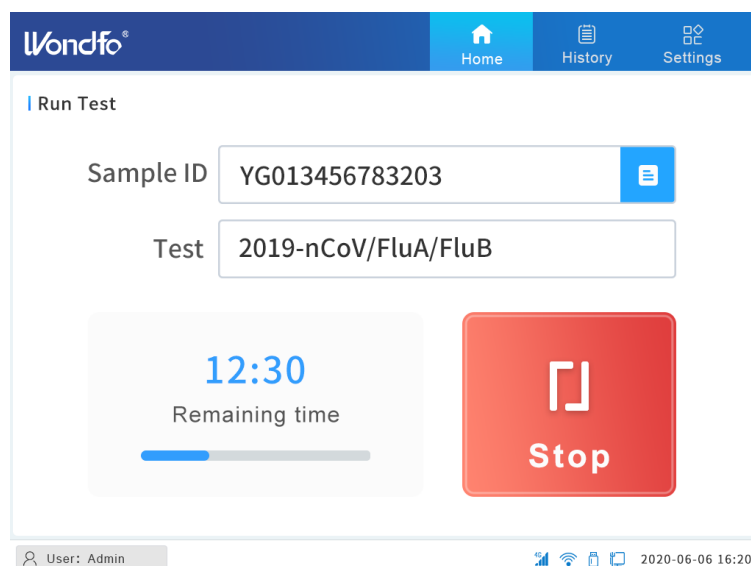


Fig. 4.10 Test in Progress

If the user wants to ABORT the test during the middle of the run, click the **Stop** icon.

Stopping a test in the middle of the run requires the user to confirm the action by entering their password to continue.

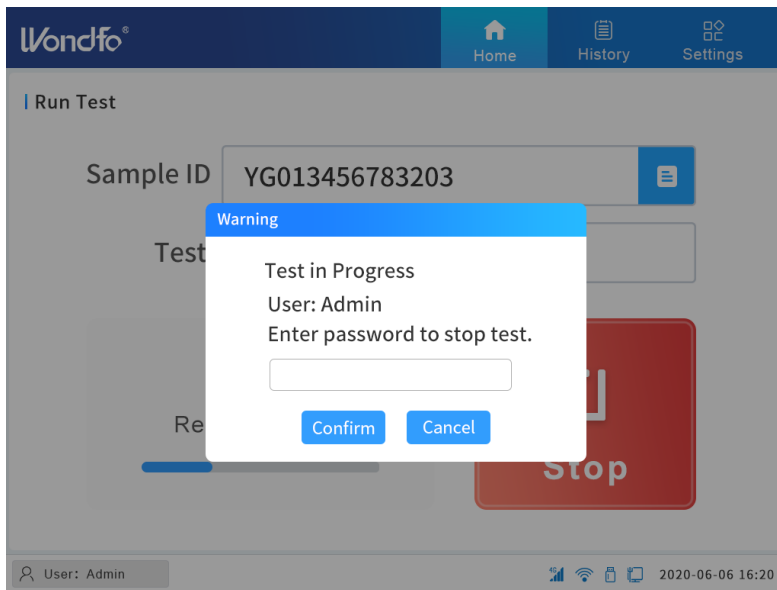


Fig. 4.11 Abort the Test

After the test has finished, the system will display the following screen to indicate that the test has been completed successfully and that the test results are available to view.

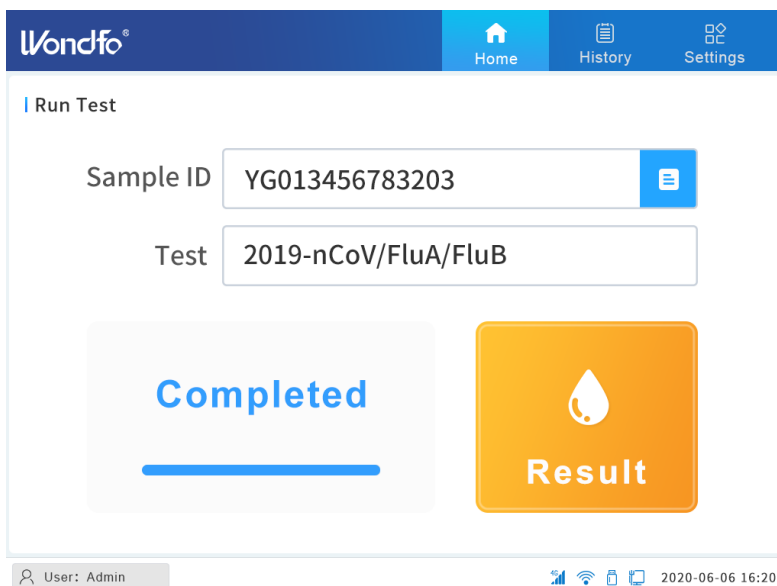


Fig. 4.12 Test Complete

4.4 Checking the Test Results

Press the **Result** icon to view the test results. The Test Result page will appear (Figure.

4.13).

The screenshot displays the Wondfo test result interface. At the top, there is a navigation bar with the Wondfo logo and three buttons: Home, History, and Settings. Below the navigation bar, the title 'Test result' is displayed. The main content area contains patient and test information:

Sample ID	YG013456783203	Name	Bob Song
Test	2019-nCoV/FluA/FluB	Gender	Female
Collection date	2020.06.05	Age	16 Year
SN	8754213012	Telephone	1765431238

Below the patient information, there is a section for test results:

Test time : 2020/06/06 16:20:22 Internal Control: Valid

2019-nCoV: **Positive** Influenza A: **Positive** Influenza B: Negative

At the bottom of the main content area, there are three buttons: Print, LIS, and Return. The bottom status bar shows 'User: Admin' on the left and signal, Wi-Fi, and battery icons along with the time '2020-06-06 16:20' on the right.

Fig. 4.13 Test Result

The test report can be printed from the instrument printer or uploaded to the institution's LIS database.

To end the current test or begin a new test, click on the **Home** button on the top of the screen to return to the Home page.

Chapter 5: Quality Control (QC) Test

Internal Controls

Every U-Card Dx Cartridge contains an Internal Process Control (IPC) which undergoes the same process steps as the patient sample. If the result of the IPC does not meet the passing criteria, the test cartridge will be invalidated, and no test results will be reported.

External Run Controls

Users may be required to perform the external Quality Control (QC) testing, where QC samples of a known status (positive and negative samples) are run on the test cartridge. In general, external QC testing should be performed with each new lot of cartridges, or according to a regularly set schedule. Wondfo provides QC samples with a barcode label by customer request.

Running an external QC sample follows the same steps as running a patient sample cartridge, as described in **Chapter 4**. When the external QC sample is scanned, the system will identify the sample as a positive QC sample or a negative QC sample; and will select the appropriate QC procedure for the test. Figure 5.1 provides an example of the external QC sample interface.

Wondfo®

Home History Settings

QC Information

Sample ID: QCP13456782103

Test: QC 2019-nCoV/FluA/FluB Positive

QC Type: Positive Negative

Exp date: 2020-12-15

Save Cancel

User: Admin 2020-06-06 16:20

Fig. 5.1 QC Sample Info

When the external QC test is finished, the result page will show the external QC test result: **PASS** or **FAIL**. The external QC results are saved in the test **History** for future reference.

Wondfo®

Home History Settings

QC result

Sample ID: QCP13456782103

Test: 2019-nCoV/FluA/FluB

QC Sample Type: QC 2019-nCoV/FluA/FluB Positive

SN: 8754213010

PASS
QC Result

QC time: 2020.06.06 16:20:59 Internal Control: Valid

2019-nCoV: Positive Influenza A: Positive Influenza B: Positive

Print LIS Return

User: Admin 2020-06-06 16:20

Fig. 5.2 QC Test Result

Chapter 6: History Record

The Wondfo U-Card Dx Instrument records all test results. Press **History** on the Main Menu to view the recorded test results. There are two types of records, Test records (results from patient samples) and QC records (results from external QC samples, described in **Chapter 5**).

6.1 Test Records

After clicking the **History** button, the **Test Records** page will be displayed.

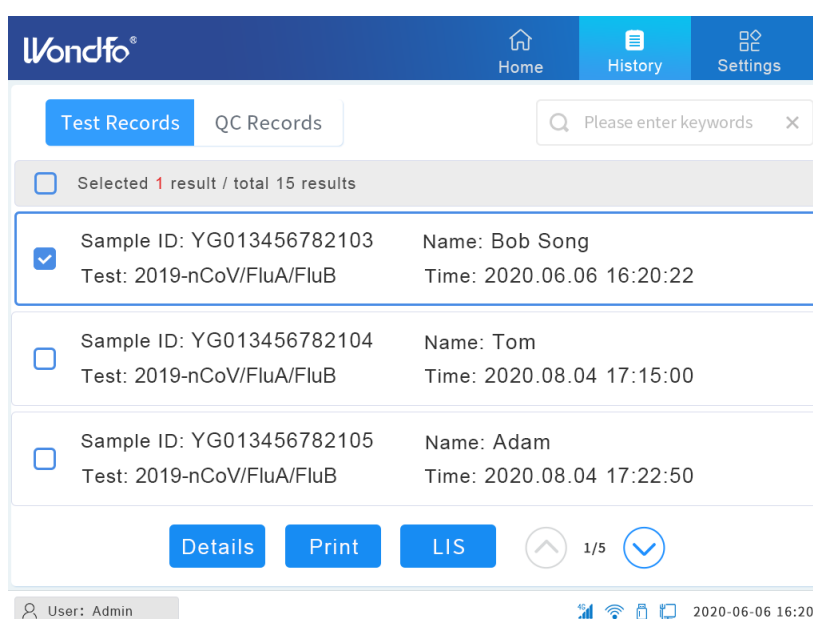


Fig. 6.1 Test Records


Select a record by clicking the checkbox at the beginning of the record. Actions on this page are listed below.

Click **Details** to view the detailed report of the selected test.

Click **Print** to print the report of the selected test.

Click **LIS** to upload the report of the selected test to a LIS system.

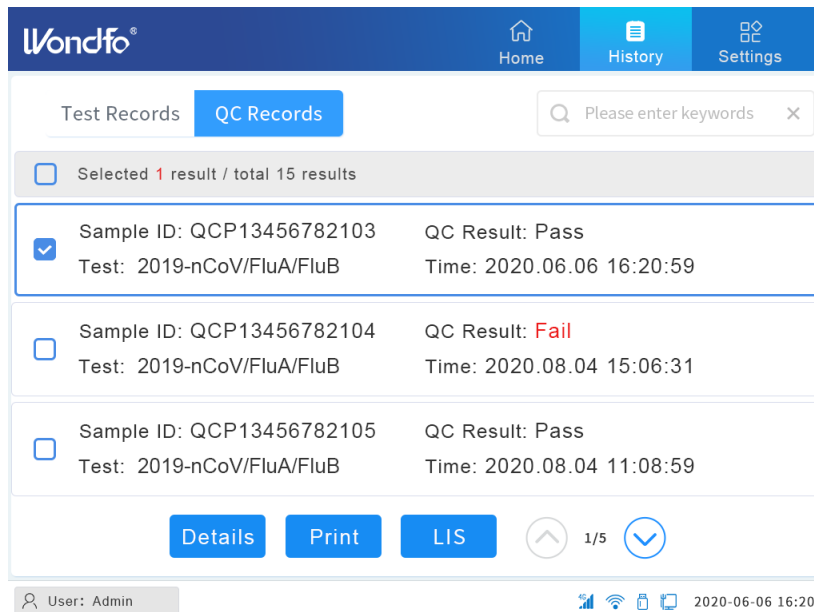
Click  to view the previous page of test records.

Click  to view the next page of test records.

In Figure 6.1, selecting the highlighted record and clicking **Details** will display the detailed test report, which is the same page as in Figure 4.13.

6.2 QC Records

Clicking **QC Records** will display the results from the External QC testing.



The screenshot displays the Wondfo application interface for QC Records. The top navigation bar includes 'Home', 'History', and 'Settings'. Below the navigation, there are tabs for 'Test Records' and 'QC Records', with a search bar on the right. A summary bar indicates 'Selected 1 result / total 15 results'. The main content area shows a list of three test records:

Sample ID	QC Result	Test	Time
QCP13456782103	Pass	2019-nCoV/FluA/FluB	2020.06.06 16:20:59
QCP13456782104	Fail	2019-nCoV/FluA/FluB	2020.08.04 15:06:31
QCP13456782105	Pass	2019-nCoV/FluA/FluB	2020.08.04 11:08:59

At the bottom of the list, there are buttons for 'Details', 'Print', and 'LIS', along with a pagination indicator '1/5'. The footer shows 'User: Admin' and the date '2020-06-06 16:20'.

Fig. 6.2 QC Records

Actions on this page are the same as actions on the **Test Records** page.

In Figure 6.2, selecting the first record and clicking on **Details** will display the QC results report, which is the same page as in Figure 5.2.

Chapter 7: Maintenance

Although the U-Card Dx Instrument is designed to ensure accurate results under minimal maintenance, it is recommended to check and clean the instrument periodically as a precautionary measure.

Table 7.1 Instrument Maintenance

Task	Frequency	Section
Cleaning the instrument surfaces	Regularly	Section 7.1
Replacing the fan filters	Regularly	Section 7.2
Replacing the fuse	As necessary	Section 7.3
Printer Maintenance	Regularly	Section 7.4
Manually Performing an Instrument Self Test	As necessary	Section 7.5
Calibrating the instrument	Required if the Instrument Self Test fails	Section 7.6

7.1 Cleaning the Instrument Surfaces

Regular cleaning of the U-Card Dx Instrument, by following the procedure described below, is recommended:

1. Shut down the instrument software, turn OFF the instrument power button, and unplug the power cord.
2. Dampen a lint-free wipe with 10% sodium hypochlorite solution (or equivalent).
3. Wipe the instrument surfaces thoroughly.
4. Discard the used lint-free wipe as per your local regulations.
5. Wait for 10 minutes until the solution dries.
6. Dampen a lint-free wipe with 70% ethanol or 70% isopropyl alcohol solution.
Please contact the manufacture of the detergent for any questions.
7. Wipe the instrument surfaces to remove the dried sodium hypochlorite solution.
8. Discard the used lint-free wipe as per your local regulations.



Avoid excessively wetting the instrument and avoid splashing fluid into the instrument's air vents.

7.2 Replacing the Fan Filter

Wondfo recommends replacing the fan filters on a bi-monthly schedule, or whenever the filter becomes clogged with debris. To replace the fan filters:

1. Turn OFF the instrument power, unplug the power cord.
2. Remove the three screws on the back panel as shown in Figure 7.1 to remove the side panel that has the air inlet.

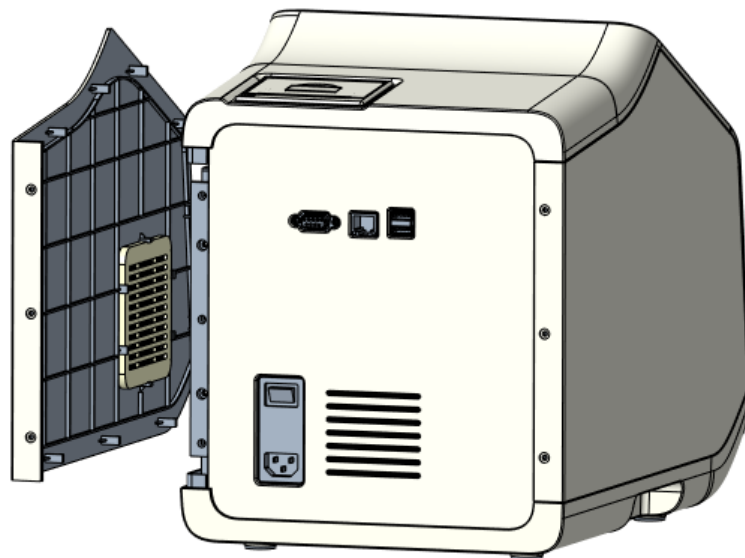


Fig. 7.1 Remove the Side Panel

3. Gently take the filter cover off from the housing as shown in Figure 7.2

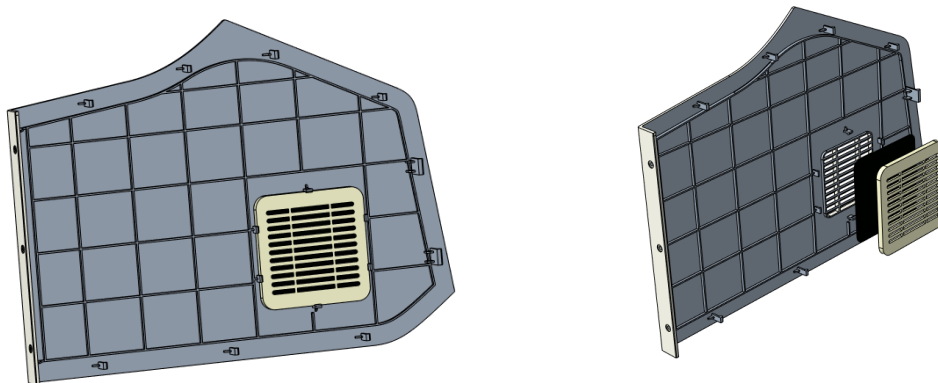


Fig. 7.2 Remove the Filter on Side Panel

4. Install the replacement filter in the housing. Put the cover back onto the housing.

5. Reattach the side panel to the instrument. Tighten the screws on the back panel. Wash the old filters with water and dry them for future replacement.

7.3 Replacing the Fuse

Wondfo recommends examining and replacing the fuse if the system power could not be turned ON:

1. Turn OFF the instrument power, unplug the power cord.
2. Find the fuse box located at the power plug and power switch panel area, unscrew the screws.
3. Identify the broken fuse.
4. Replace the fuse and install the fuse box. The backup fuses come with the package, and it is cartridge fuse type with 10A protection.
5. Test the system.

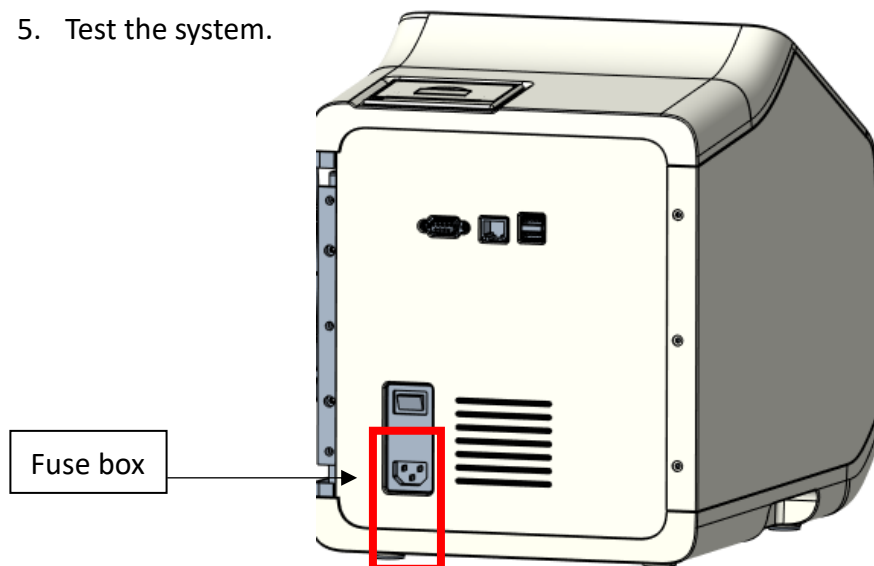


Fig. 7.3 Replace the fuse

7.4 Printer Maintenance

The residual stains and dirt on the thermal print head will affect printing quality, so regular cleaning of the printer head surface should be performed (at least once a month or whenever the print quality declines).



Fig. 7.4 Printer

Follow the steps below to clean the printer head:

1. Open the printer paper compartment cover and remove the printer paper roll.
2. Gently wipe the print head's surface with a clean lint-free cloth dipped in a small amount of 70% alcohol or IPA. The print head is the long metal surface that lies on the bottom of the compartment.
3. After drying the residual alcohol from the print head surface, replace the printing paper roll into the printer paper compartment and close the cover.



Immediately after printing, the thermal print head will be very hot. Do not open the printer paper compartment or touch the print head surface, or attempt to clean the print head until it becomes cool (generally 30 minutes after the last print job but it may vary depending on ambient conditions).



Do not damage the thermal head by touching it with your fingers or any hard object.

7.5 Manually Performing an Instrument Self Test

The U-Card Dx Instrument automatically performs a self-inspection during startup. The system status is also collected during each cartridge run to ensure the instrument is functioning correctly. However, the user can initiate an **Instrument Self Test** to check

the instrument status as necessary. Please refer to **Chapter 3.8.4**.

7.6 Calibrating the Instrument

The U-Card Dx Instrument does not require any calibration protocols to be performed by the end-user. Wondfo performs all of the necessary calibrations before the user receives the instrument. However, if the system Instrument Self Test fails, a calibration service will be needed. Please contact Wondfo Technical Support to schedule a calibration. See **Chapter 10** for the contact information.

7.7 Product Life

The U-Card Dx Instrument comes with a service life of five years under normal use. This suggested service life from Guangzhou Wondfo Biotech Co., Ltd., is based on normal usage but could vary according to the specific use.

7.8 Disposal

At the end of the life cycle of this product, dispose of the product per local ordinances and regulation.

Chapter 8: Troubleshooting

This chapter lists the possible problems you might encounter during the instrument's operation.

Table 8.1 Troubleshooting and Related Solutions

Problem	Possible cause	Solution
The instrument does not start	Power failure	Check the power cable
	Poor connection between the power cable and power port	Pull out the cord and reconnect firmly
	Main switch is off	Turn it on
	Fuse is blown	Change fuse
Self-inspection test fails	Optical hardware failure	Contact Wondfo technical support
	Thermal hardware failure	
	Electronics failure	
Barcode scanner fails to scan	The cartridge surface is dirty	Clean the cartridge QR code area
	Scanner is broken	Contact Wondfo technical support
	Scanner surface is dirty	Clean the scanner surface
	Barcode format is not recognized	Manually type the information
Printer failure	The thermal printer cannot print automatically	Open the cover of the thermal printer paper bin, straighten the printing paper, close the cover of the printer paper bin, and click print again
	Paper jam for thermal printer	Carefully adjust the paper position inside printer. If this error persists, contact Wondfo technical support
	Out of paper	Reload the paper
Communication failure	Cannot connect to the Internet via the built-in WIFI	Verify that the wireless networking strength and network settings in the System settings are correct
	Unable to communicate with the LIS system	Check whether the network or WiFi connection is successful, and then

		check whether the LIS system IP Settings in the System settings item are correct
Login failure	Wrong username or password	If a general user forgets Username and password, contact the system administrator. If the system administrator forgets Username and password, contact Wondfo technical support.
Fan blower noise becomes louder	Filter is clogged with debris	Change fan filter
Touchscreen does not respond to user inputs	Software or hardware problem	Restart the system, if it still fails, contact Wondfo technical support
Loss of power in the middle of a test	Cable loose or fuse blown	Adjust the cable or replace the fuse, restart the instrument, restart the test using a new cartridge

Chapter 9: Bibliography

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Chapter 10: Contact Information

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