Automated Nucleic Acid Detection System

Instructions for Use

Model: FlashDx-1000-E

IVD For *In vitro* Diagnostic Use

Rev 1.1e. Jan 2022

Preface

Dear user:

Thank you for choosing FlashDx-1000-E Automated Nucleic Acid Detection System! Before you use this product, We strongly recommend that you read IFU carefully before using product.

This IFU aims to provide you with instructions on how to operate FlashDx-1000-E Automated Nucleic Acid Detection System. We strive to be comprehensive and straightforward in the layout. You can also learn about safety features and maintenance protocol for the device.

Thank you for your cooperation!

Thank you for choosing this product

Please read instructions for use carefully before using this device!

[Manufacturing date and expiration date] See the packaging and label

[Manufacturer] FlashDx Shenzhen Inc.

[Address] Suite C705, Building A3;Suite 4C, Building B6 & Suite A201, Building B5, China Merchants GuangMing Science Park, Guangming District, Shenzhen, Guangdong, P. R. China.

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Chapter I Safety

1.1 Convention

	Note that the item contains particularly important information, please read it carefully. If you fail to follow the requirements specified in the IFU, it may cause damage or malfunction to the device.
	Warning message requires you to be especially careful to operate a certain step or a method. If you fail to follow the requirements, it may cause serious personal injury.

1.2 Safety

Following basic safety measures must be followed in all stages of operation, maintenance, and repair of this device. Failure to follow the measures, warnings and precautions specified in the IFU may affect the basic protection provided by the device. At the same time, this will also undermine safety standards for designing and manufacturing of the device and intended use of the device. Our company bears no responsibility for any consequences caused by user's failure to comply with following requirements.

1.2.1 Symbols

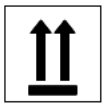
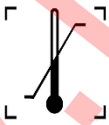
1) Warning symbols

	This device is a product that meets standard IEC 61010-1; and it is an *in vitro* diagnostic (IVD) medical device that meets standard IEC 61010-2-101.

Symbol	Description
	**High temperature warning:** in order to avoid burns, please do not directly touch the areas with a high temperature warning symbol or high temperature areas described in this IFU!
	**Electric shock warning:** please strictly follow the requirements of electric shock warning to avoid electric shock accidents!
	**Be careful, dangerous:** in all cases identified with this symbol, you shall consult the document to identify potential hazard and any countermeasures that must be taken!
	**Prevent mechanical risks:** please beware of mechanical dangers and watch your hand in the areas identified with this symbol.

IVD	**In vitro diagnostic medical device:** labeled on the nameplate of the device.
	**Biological hazard:** labeled on the chamber door of the device.

2) Product packaging identification

Meaning	Symbol	Description
Upright		Correct position for shipping package is upright.
Fragile		Shipping package contains fragile products and should be handled carefully.
Not resist rain		The package cannot resist rain.
Stacking layer limit		Maximum number of stacking layers for the package is 5.
Temperature limit		Device package should be maintained within listed temperature range.
Humidity limit		Device package should be kept withinlisted humidity range

1.2.2 Safe use

Before using this device, please read following content carefully and be sure to pay attention to basic safety measures. Failure to follow these measures or warnings may affect normal use of the device, even damage the device and injure personnel.

1). It is forbidden to use the device in a humid, dusty, high temperature, or strong magnetic environment;

2). It is forbidden to open the device without permission or touch the internal components with objects;

3). It is forbidden to use any objects to block vents. Beware of gloves or rags being sucked into air inlet of the device;

4). Keep the device clean and maintained in a timely manner.

In case of following situations, immediately unplug power plug from power socket and contact supplier for repair.

1) The device has been infiltrated by rain, water or liquid;

2) The device is not working properly, especially if there is any abnormal sound or smell;

3) The device function has changed significantly.

1.3 Warnings and precautions

1.3.1 Warnings

1) This product is used for *in vitro* diagnosis only.

2) Verification test using FlashDx-1000-E Automated Nucleic Acid Detection System can only be used to illustrate general capabilities of the device. All diagnostic tests developed for the device should be fully verified in all aspects of performance.

3) FlashDx-1000-E Automated Nucleic Acid Detection System can only be used in conjunction with *in vitro* diagnostic reagents and supporting software approved by national regulatory authorities. For specific information, please refer to the corresponding IFU of *in vitro* diagnostic reagents.

4) Patient privacy, human genetic resources and bio-information safety management involved should be consciously managed following the laws, regulations and related stipulations.

1.3.2 Cautions

1) The personnel who operate this product should have professional knowledge of laboratory science and test operation. They should strictly follow the safety requirements for biological tests with sufficient protections. The personnel who have not received professional trainings is not allowed to operate the device. This device should not be used by the patient for self-examination.

2) This product shall not be used for test of unintended items. The detection reagents not mentioned in this IFU shall not be used.

3) Test results shall not be used for the diagnosis of unintended diseases or undeclared clinical purposes.

4) Test articles or reagents, chemical liquids or metal objects should not be spilled in the product, otherwise it will cause a short circuit, even smoke or fire.

5) Reagents and samples should be regarded as substances that may be harmful to human body, which may damage skin, eyes or mucous membranes if accidentally contacted or inhaled. Therefore, please wear personal protective devices (such as laboratory protective clothing, safety goggles, masks and gloves, etc.) before operation.

6) The chamber door of the device is a movable part. Please pay attention and avoid injury.

7) After maintenance or disuse of the device, the device should be subject to nucleic acid removal treatment regularly to prevent contamination. The personnel should take personal protective measures to avoid potential biological hazards.

Chapter II Overview

This chapter mainly describes the scope of application, basic principles, specifications and models, main components and device structure of FlashDx-1000-E Automated Nucleic Acid Detection System.

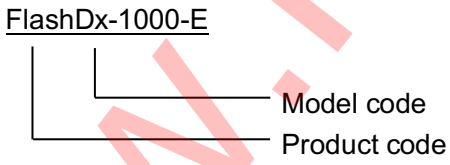
2.1 Scope of application

The product is based on fluorescent polymerase chain reaction and is used in conjunction with compatible test cartridges. It is used for *in vitro* amplification and analysis of nucleic acids (DNA/RNA) derived from genetic materials, including various pathogens.

2.2 Basic principles

This product is used in conjunction with compatible test cartridges. According to the operating parameters with control system, the product provides required temperature environment through temperature control components, for denaturation, annealing, and extended cyclic amplification of nucleic acid. Fluorescent signals generated during amplification process are collected by photoelectric components in real time, and data are analyzed and processed by software for amplification and analysis of specific target nucleic acid sequences.

2.3 Specifications and models



2.4 Structural composition

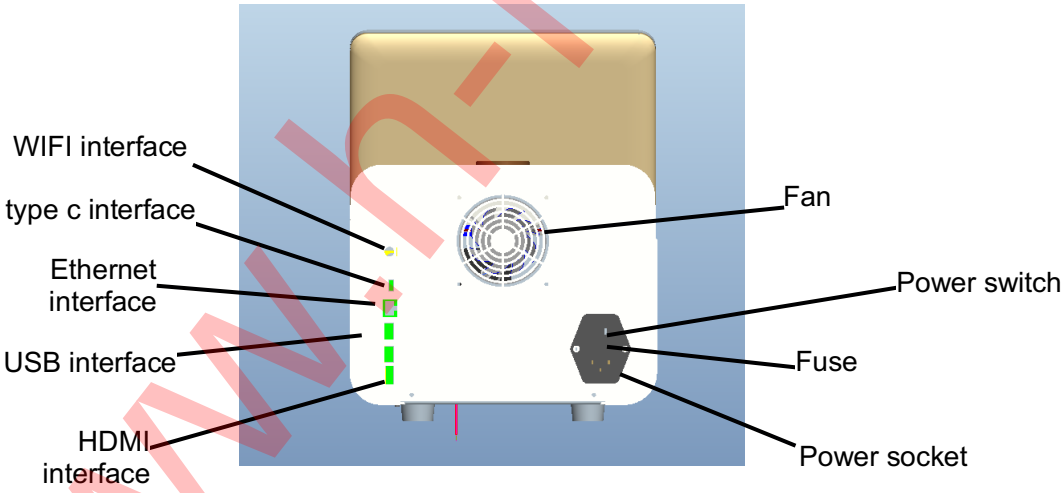
Automated Nucleic Acid Detection System is composed of main body and system software (release version: V1). Main body is composed of central control components, temperature control components, transmission components, power supply components, display components, housing components and photoelectric components.

2.5 Device structure

A. Main body

●Indicator light - indicator of operating state of the device (it is blue when the device is in standby mode, green when the device is in operation, and orange when then device break down)

●Touch screen - interactive operation and interface display of the device



● Fuse - 2 pcs of 3.15A fuse

● Power switch - turn the device power on or off

● Power socket - power cord socket

● Fan - device cooling and exhaust air

● WIFI interface - connection port between main body and wireless network (For reserved use only)

● Ethernet interface-connection port between main body and wired network

● HDMI interface - connection port between main body and external display

● USB interface - connection port between main body and barcode scanner, printer, software upgrade, and external memory

● USB Type-C interface - connection port for main body system upgrade

The above interface needs to meet standard IEC 60950 or IEC 61010-1.

Chapter III Installation of Device

3.1 Packaging content

When you receive FlashDx-1000-E Automated Nucleic Acid Detection System, please open the box and check whether it includes following items:

Items	Quantity
Device	1
Power cord (single-phase 3-wire)	1
Spare fuse (T3.15AH250V)	2
IFU	1
Certificate of Compliance	1
Certificate of Warranty	1

In case of inconsistency, please keep original packing box and contact us immediately.

3.2 Shipping and storage conditions of the device

Environment temperature: -20°C~55°C

Relative humidity: ≤85%

Original packaging must be used for shipping to avoid damage to the device.

3.3 Normal operating conditions

1) Power supply: 100-240V~, 50/60Hz, 300VA

2) Indoor use;

3) Altitude: no more than 2000m;

4) Environment temperature: 10°C~35°C;

5) Relative humidity: 20%~85%;

6) Overvoltage category: Class II;

7) Pollution category: Level 2;

8) Do not block the vents at the bottom or back of the device, and do not place any other objects within 15cm of the back of the device to ensure that the device is ventilated smoothly.

The device must be grounded reliably to avoid electric shock accidents!

3.4 Installation requirements

1) The device must be placed on a stable and level work surface, protected from direct sunlight, and avoid proximity to heating equipment;

2) Do not install the device next to other devices with strong electromagnetic interference or high inductance;

3) Do not place the device in a position where it is difficult to be disconnected. The device must be placed at least 15cm away from the surrounding objects or walls to facilitate heat dissipation and ventilation of the main body, and to allow user to access power switch in the back of device.

4) The device should be used under normal working conditions. The device should be powered by A.C.100-240V network power supply, and voltage fluctuation should not exceed 10%. It is recommended to use an uninterrupted AC power supply to ensure the safe and stable operation of the device.

3.5 Network requirements

1) Operating environment

Hardware configuration: CPU: ARM 400Hz or above; memory: 4G or above; hard disk: 64GB or above.

Software environment: Ubuntu 16.04 or above, Qt 5.12.2 or above.

Network conditions: the product can operate in an environment without network.

2) Security software

Antivirus software cannot be installed on the device.

3) Interfaces of data and devices

● WIFI interface-connection port between main body and wireless network

● Ethernet interface-connection port between main body the wired network

● HDMI interface- connection port between main body and external display

● USB interface- connection port between main body and barcode scanner, printer, software upgrade, and external memory

● Type-C interface-connection port for main body system upgrade

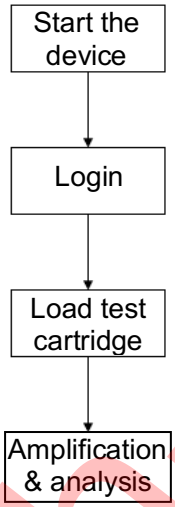
4) User authority

This product supports two levels of user access control, administrator and ordinary user. Administrator has the highest authority. Both administrator and ordinary user can log in with a username and password, and both can perform experimental tests. There are different system menus for users with different authorities to log in. Ordinary user can only use three items, “language”, “password modification”, and “about” while administrator can use all items in the menu.

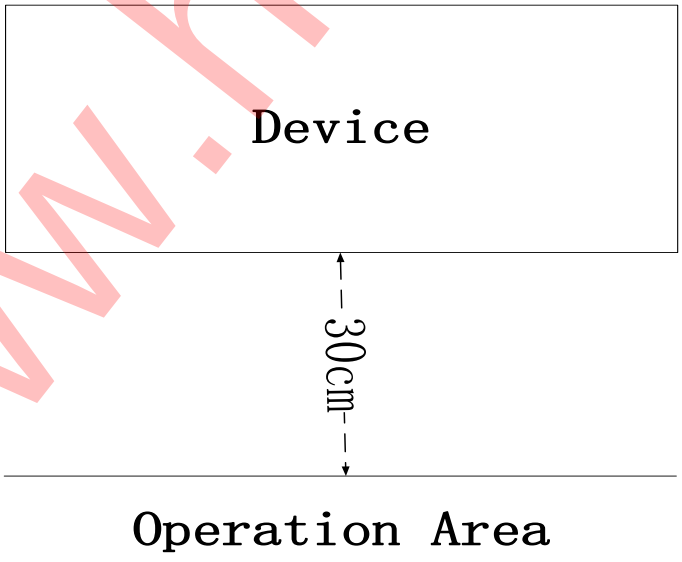
Chapter IV Operating Instructions

Testing process

Product is easy to operate with full functionality. The process is as follows:



The operator should refer to the figure below to operate the device.



4.1 Powering on the device

Connect power cord to the back of the device, plug it into power socket, and turn power

switch to the “-” position. After the device is powered on, LCD screen will light up, and a self-test interface will be on display after operating system is started up (Figure 1).

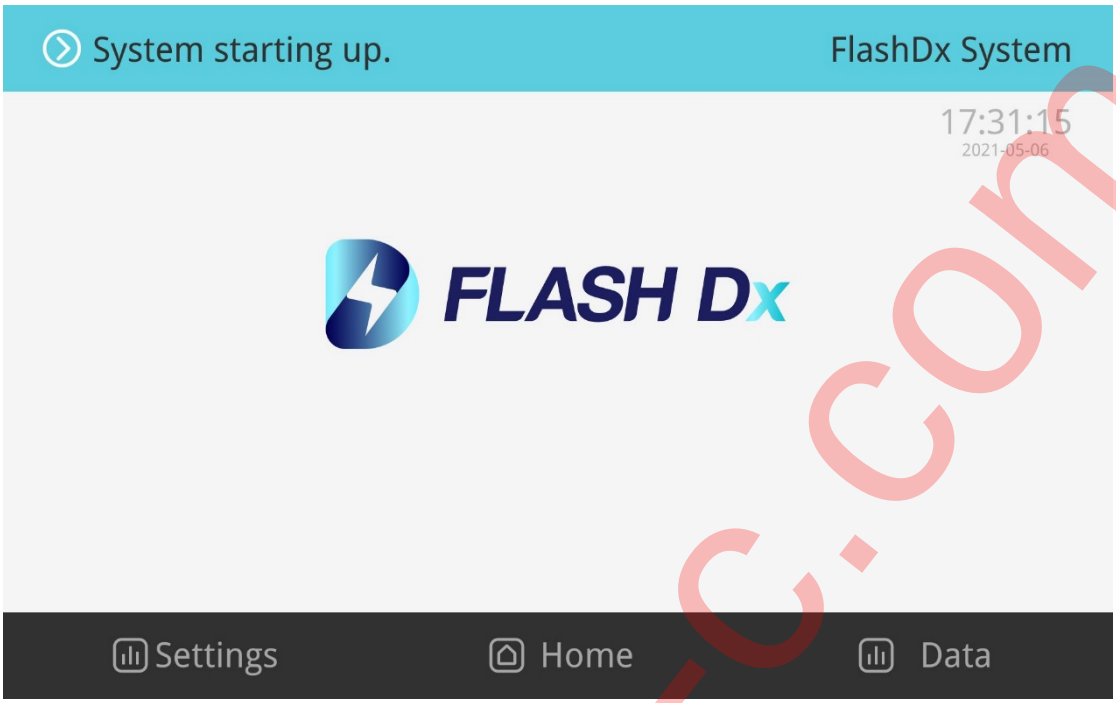


Figure 1. Startup

During self-test, system Automated ally identifies open/close status of sample bay (Figure 2) and whether any test cartridge if present in sample bay (Figure 3).

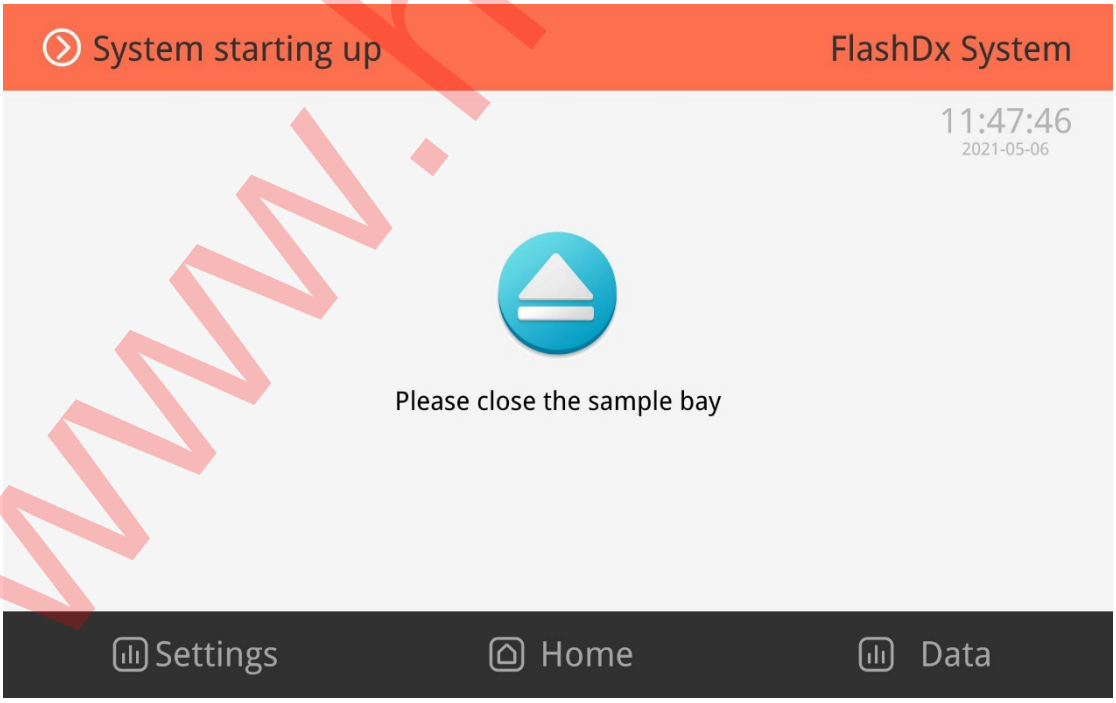


Figure 2. The sample bay is not closed during self-test

If the sample bay is not closed properly, click the button “Please close the sample bay” to close the sample bay.

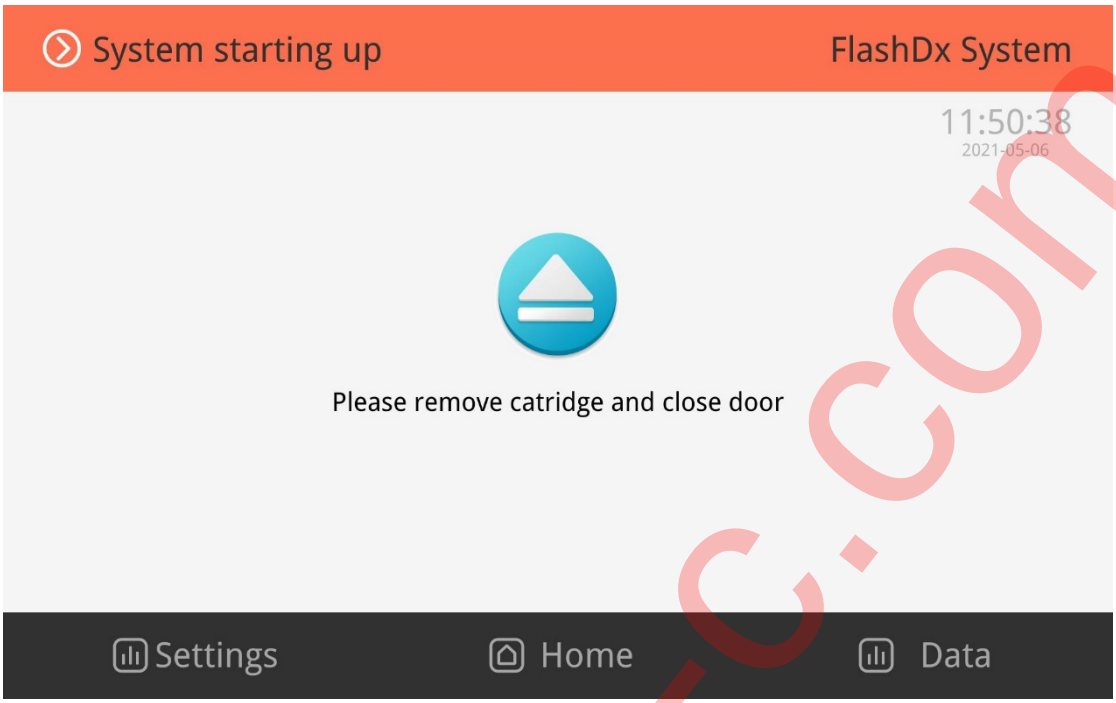


Figure 3. a cartridge is identified in the sample bay during self-test

If a cartridge is left in the bay from previous run, please take out cartridge first, and then click the button “Please remove cartridge and close door”. After the button flashes, sample bay will be Automated ally closed and login interface will appear .

4.2 Login

Once self-testing is completed, system Automated ally transits to login interface (Figure 4). Enter user name and password in “Username” and “Password” boxes respectively, and click “Log in” button.

Initial user name: admin, initial password: 123456

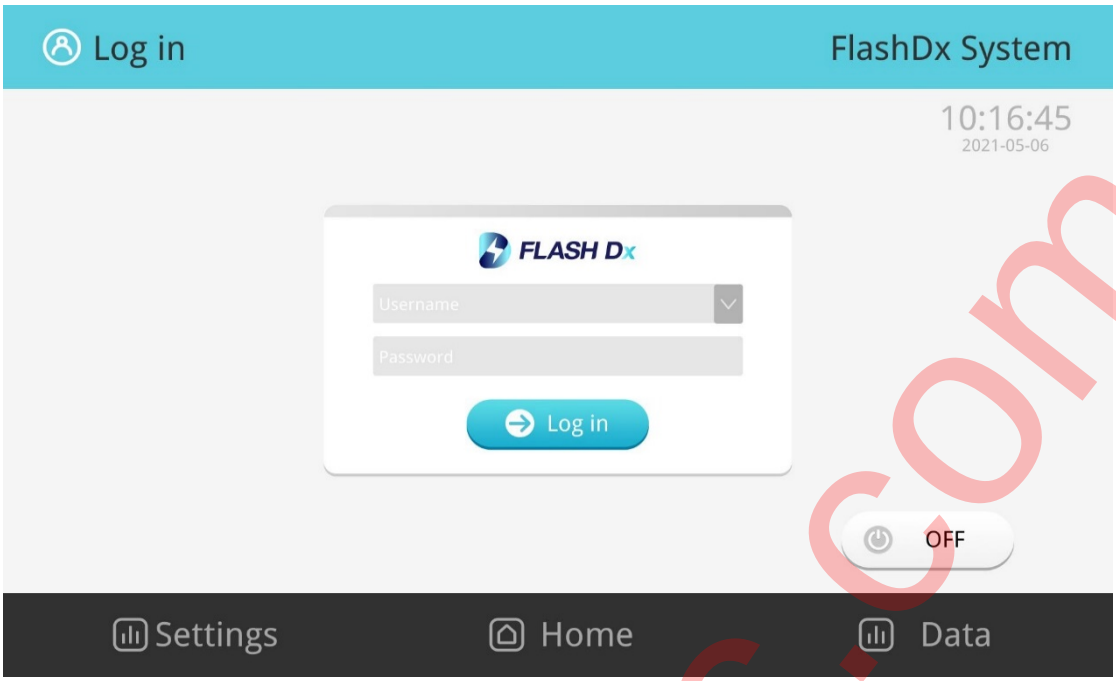


Figure 4. Login

4.3 Load test cartridge

After successful login, “Standby” interface appears (Figure 5). You can click “OFF” button to shut down the device, or you can click “Log out” button to log out current user and return to login interface (Figure 4).

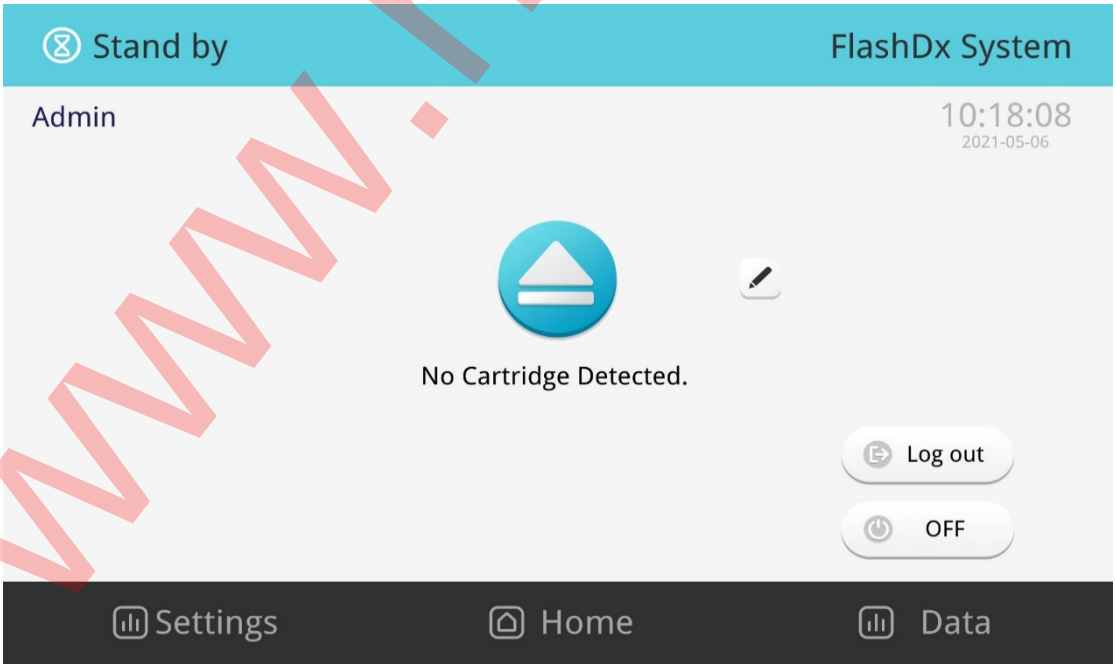


Figure 5. Standby

Before loading test cartridge, click the "✎" button to enter sample information. Sample information can also be entered after loading test cartridge.

Optionally, sample information can be directly scanned by barcode reader.

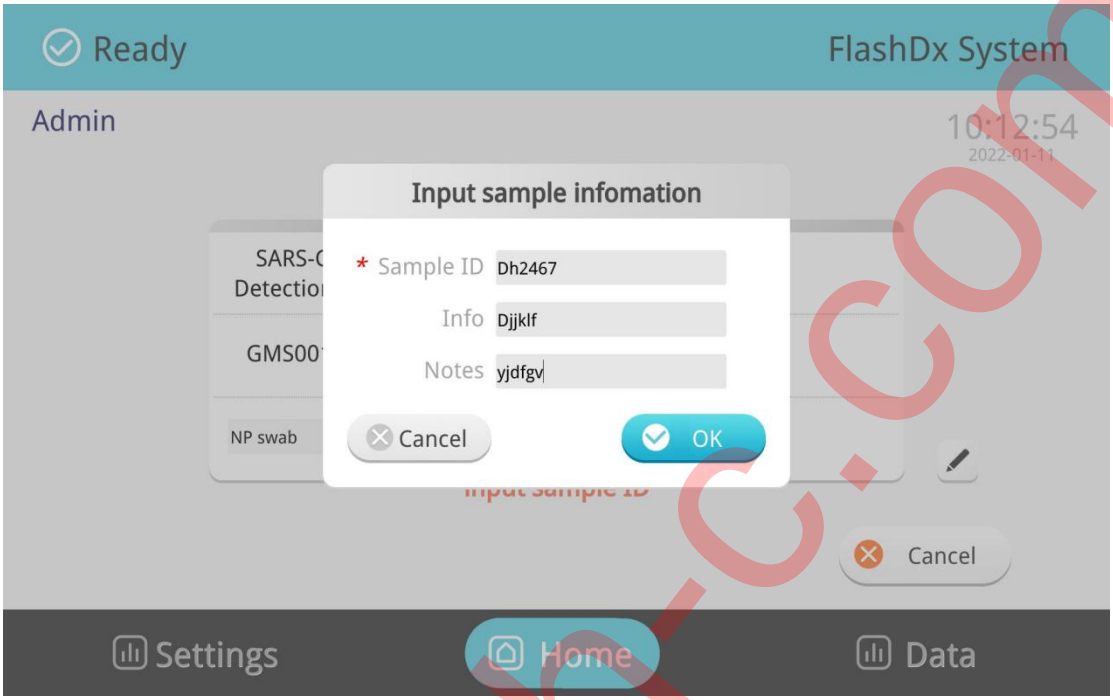


Figure 6. Sample information entry

After entering sample number and sample information, click "OK" button to complete the entry or press "Cancel" button to cancel the test.

After completing sample information entry, click "No Cartridge Detected" button, The button should flash and sample bay will open.

Figure 7. Load test cartridge

First remove the protective cover of cartridge to expose the black chip. Orient the loaded cartridge so exposed chip is pointing leftwards. Align loaded cartridge to the receiving cartridge dock on sample tray, pressing down to feel a soft click. The instrument should now detect a cartridge in place and message should switch to “Test Cartridge Ready”. Use the touchscreen to click the open/close button to retract sample bay.

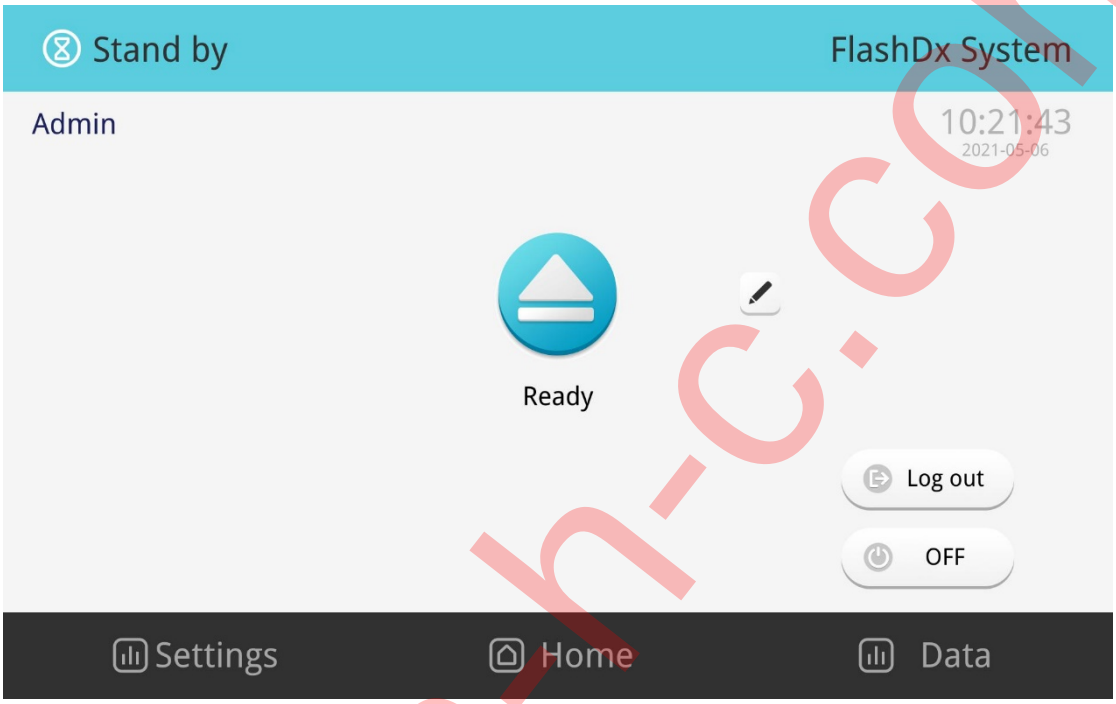


Figure 8. Test cartridge ready

After sample bay is retracted into place, system should Automated ally identifies QR code information on the cartridge and selects the correct test program, as shown in the following figures(Figure 8 and Figure 9):

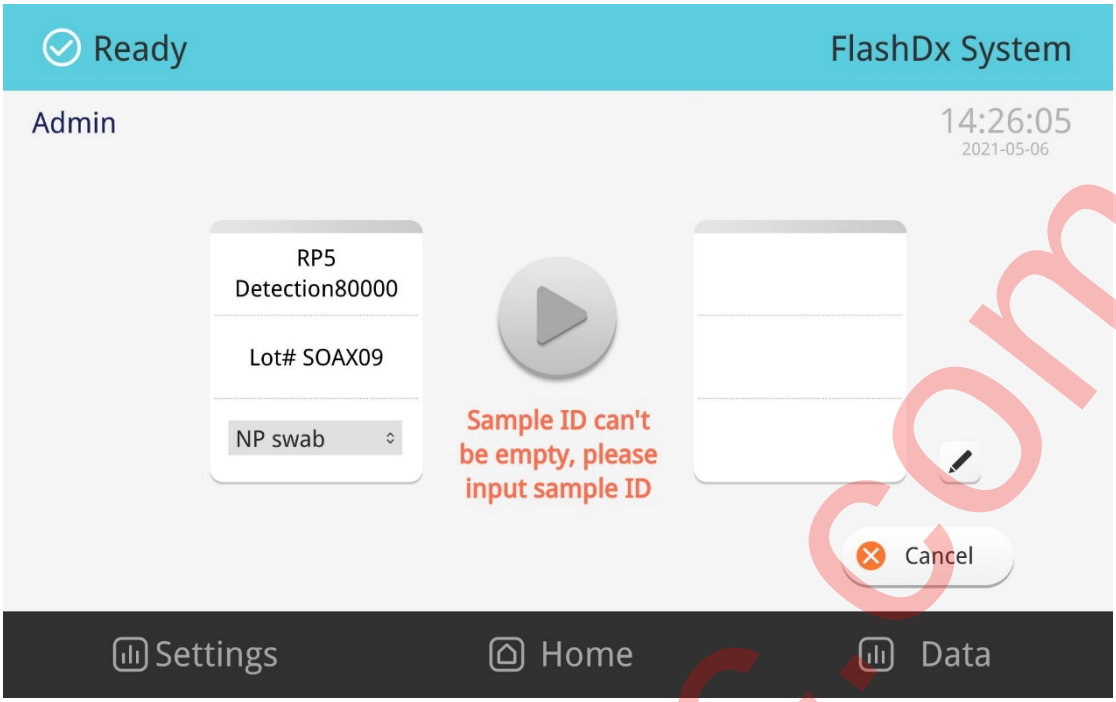


Figure 9. Identify and select correct test program (sample information is not entered in advance)

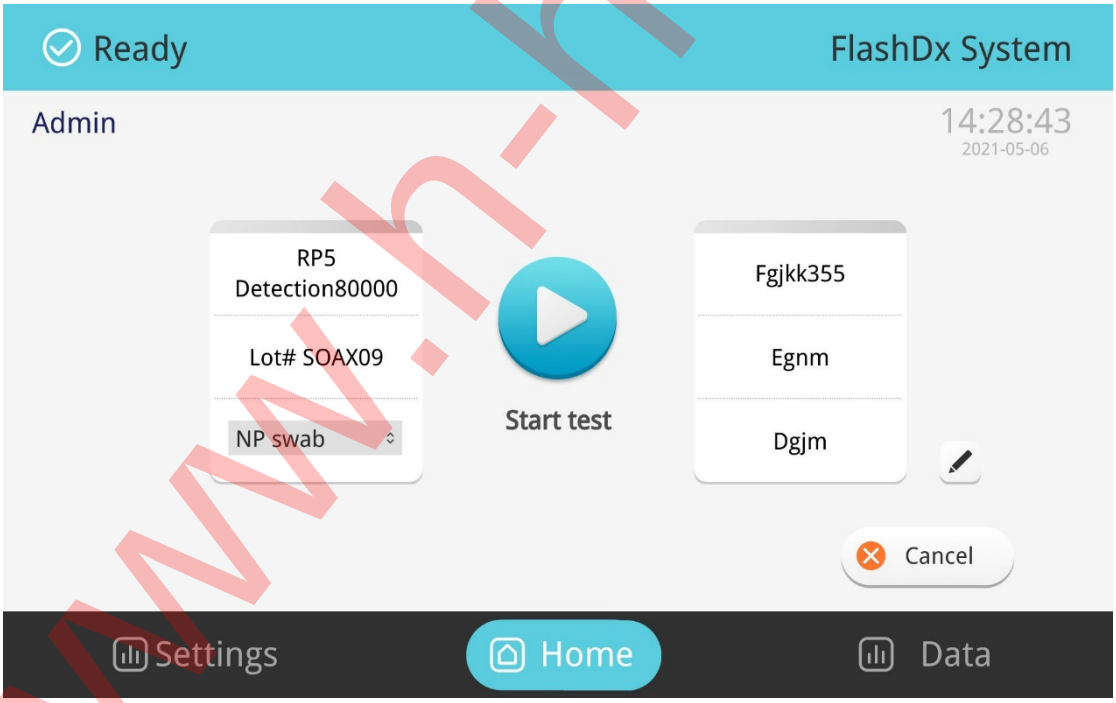


Figure 10. Identify and select correct test program (sample information is entered in advance)

If system detects an invalid loaded cartridge in the sample bay, for example, if cartridge is empty and insufficient sample (Figure 10-1, Figure 10-2), or QR code cannot be recognized (Figure 11-1, Figure 11-2), please remove the cartridge and check. The system will go back

to status before loading cartridge. Please verify the cartridge and take appropriate actions. If a new cartridge is needed, you can repeat the test. If you believe this is an error, notify technical support.

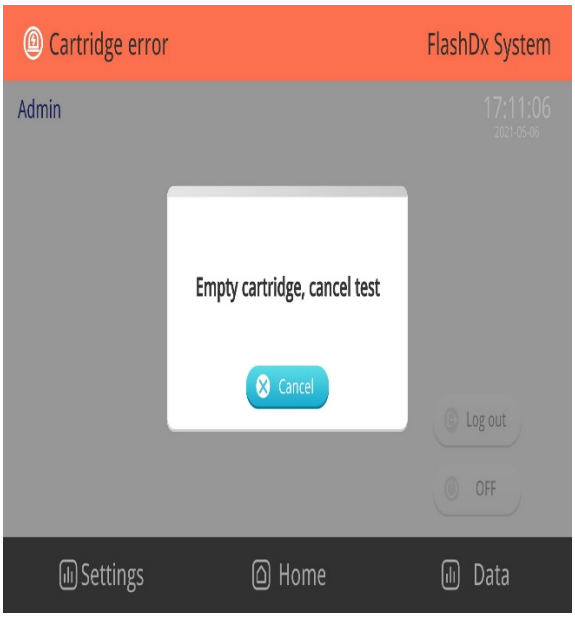


Figure 11-1. Prompt of empty cartridge

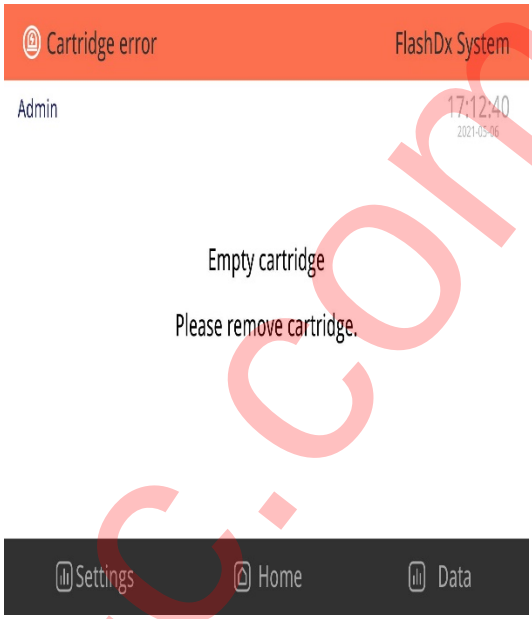


Figure 11-2. Remove empty cartridge

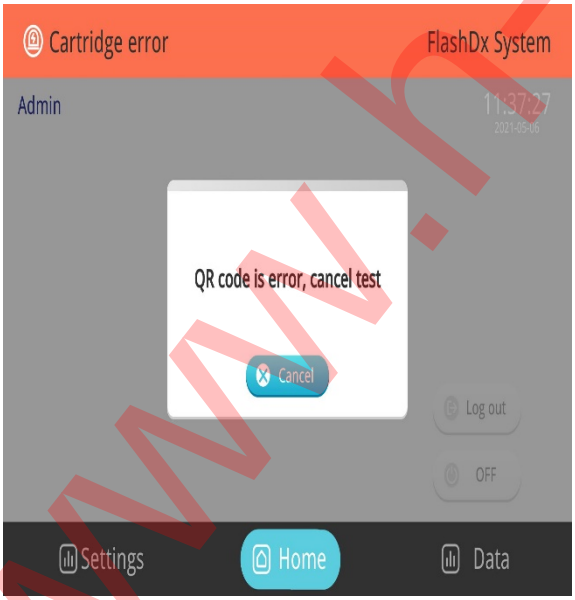


Figure 11-3. QR code cannot be recognized

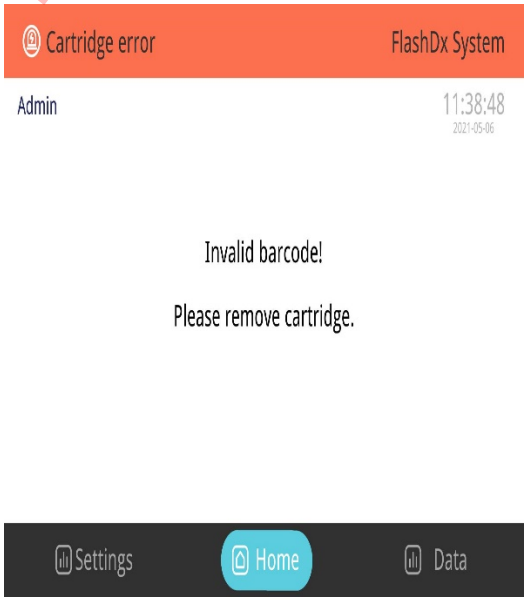


Figure 11-4. Remove unrecognized cartridge

4.4 Run test program

Verify that amplification program and sample information are both correct, then click “Start Test” button on the interface to start test.

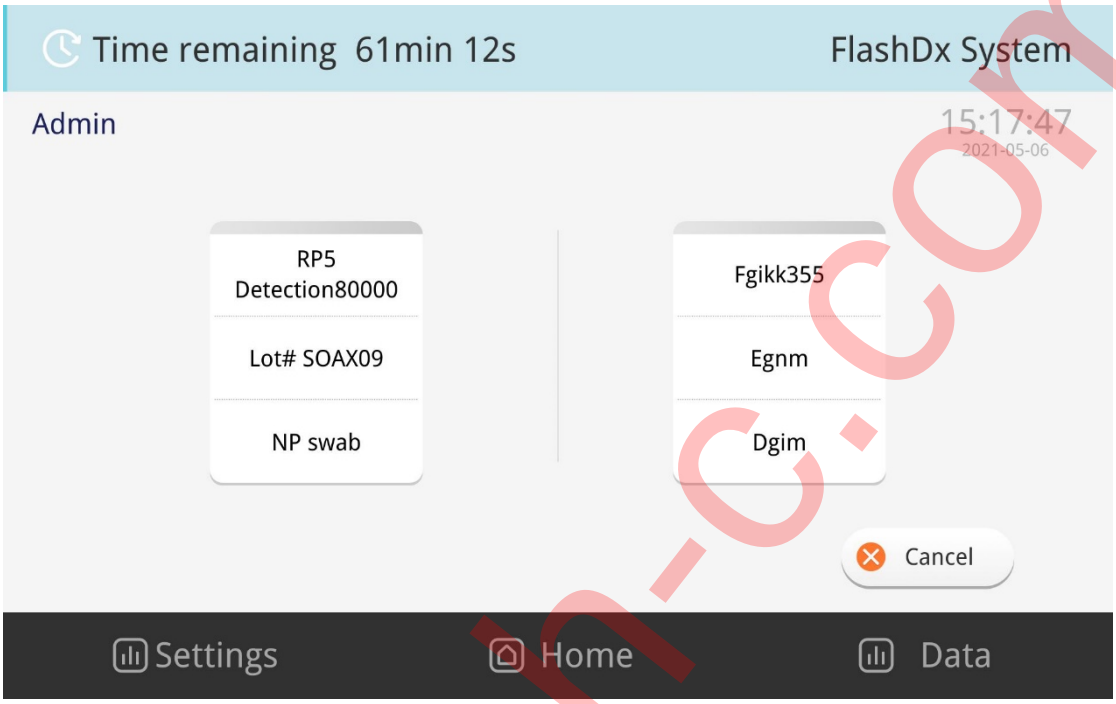


Figure 12. Amplification program is in progress

A test cannot be started unless sample number field is valid.

After a test program is initiated, a test can not be cancelled in principle. If you need to cancel the test, click “Cancel test” button in lower right corner of the figure above, and following interface will pop up (Figure 13).

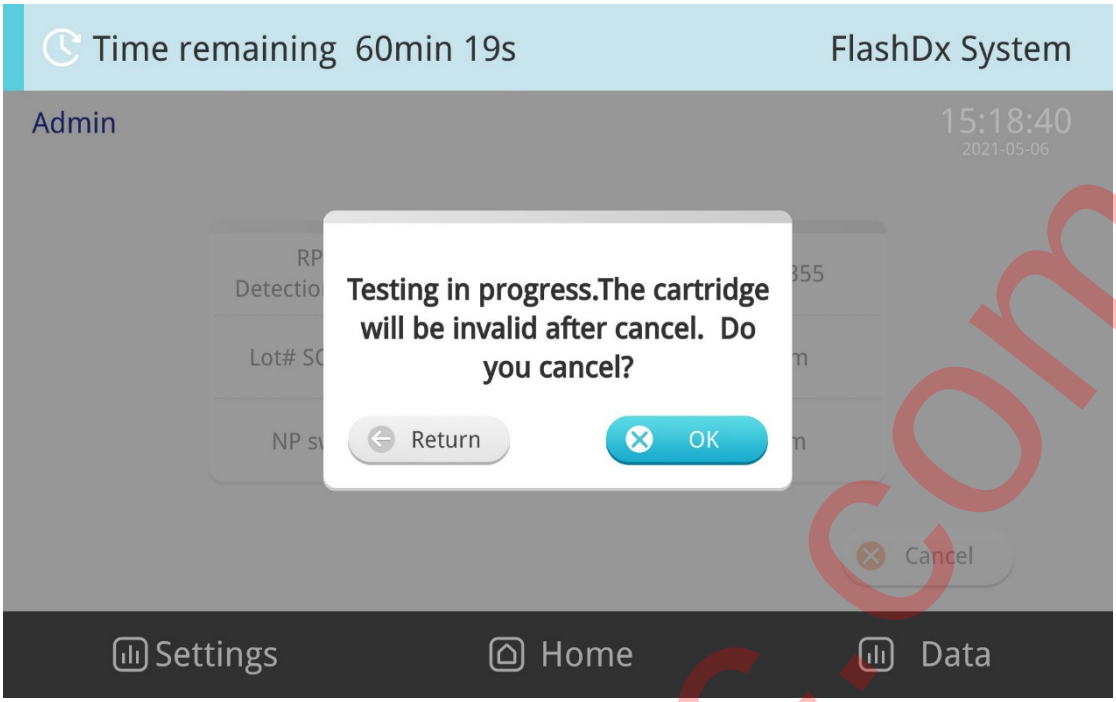


Figure 13. Interface of canceling test

Click “OK” button again to confirm cancelation of the test. You can not reuse cartridge from a cancelled test or resume test. In this situation, no test result will be generated, and system will return to main menu to standby.

After test program is completed, system Automated ally transits to test result interface (Figure 14).

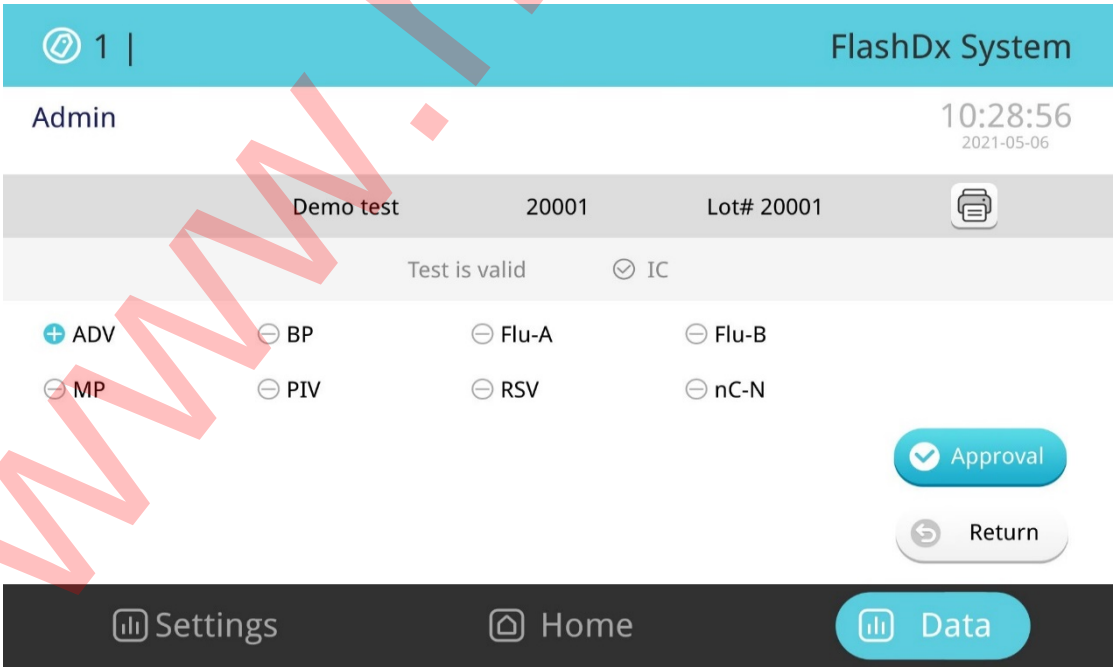


Figure 14. Test Result interface

"-" in the figure represents a negative test result, and "+" represents a positive test result. If the results are correct, click the "Approval" button to review test results.

If necessary, you can click the "-" or "+" button next to a test target in the test result interface to view details about amplification curve of corresponding test result. Use return to go back to test report page when you are done with detail page.

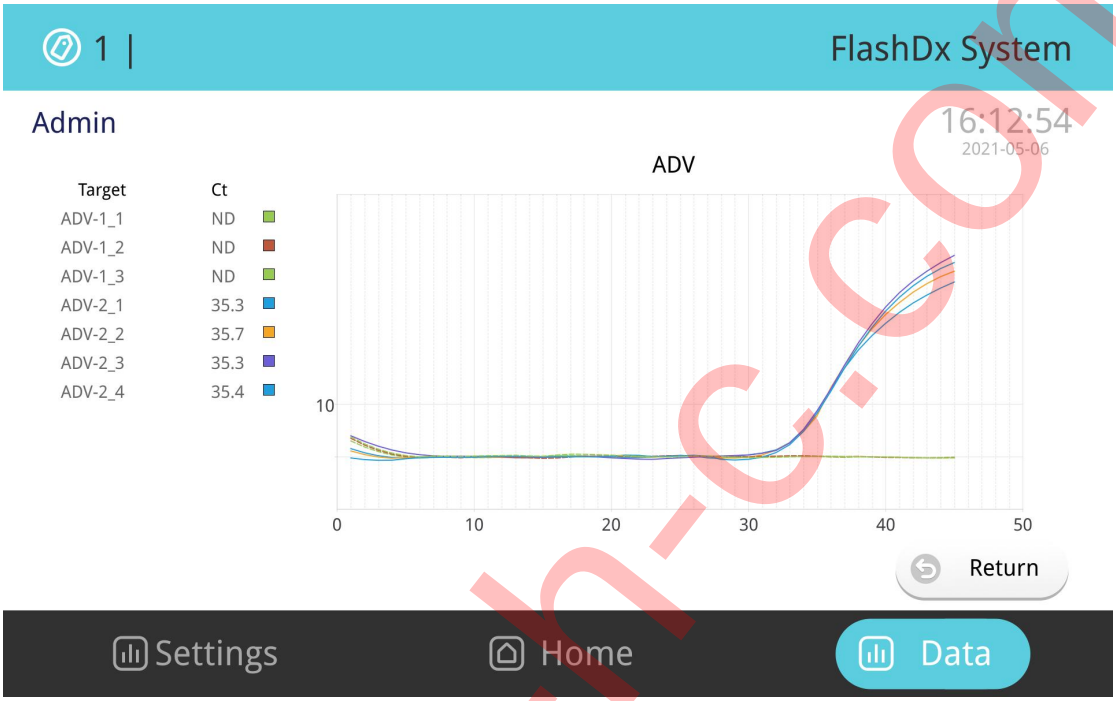


Figure 15. Test details: Amplification curve

If you have any questions about test information and results, click "Reject" button to review test information again.

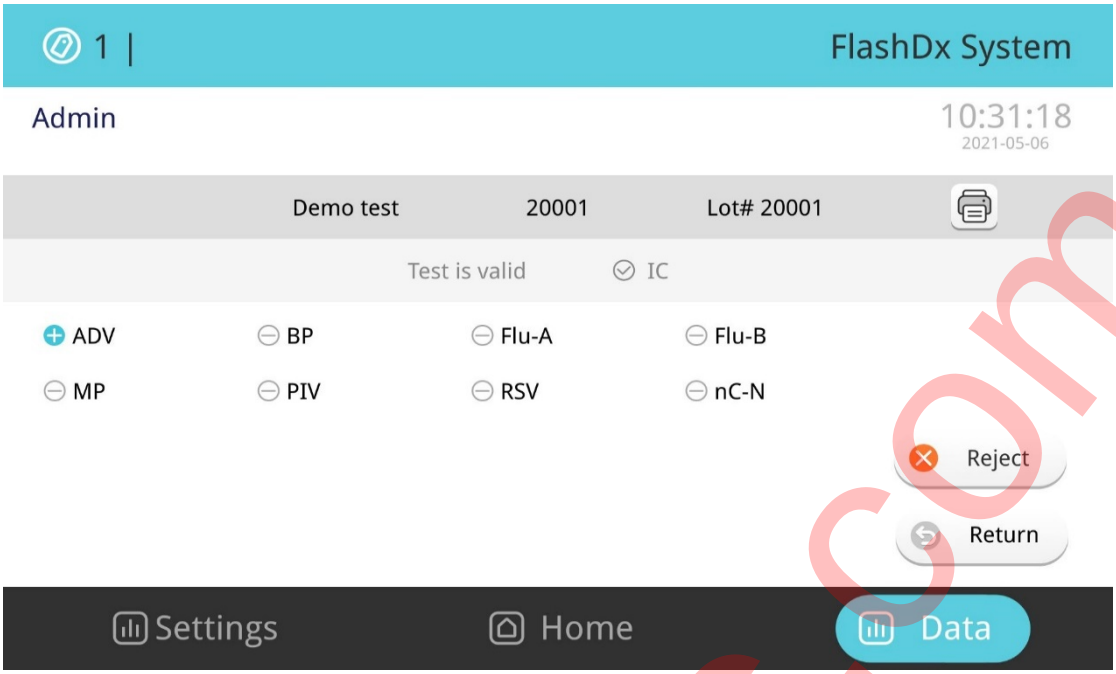
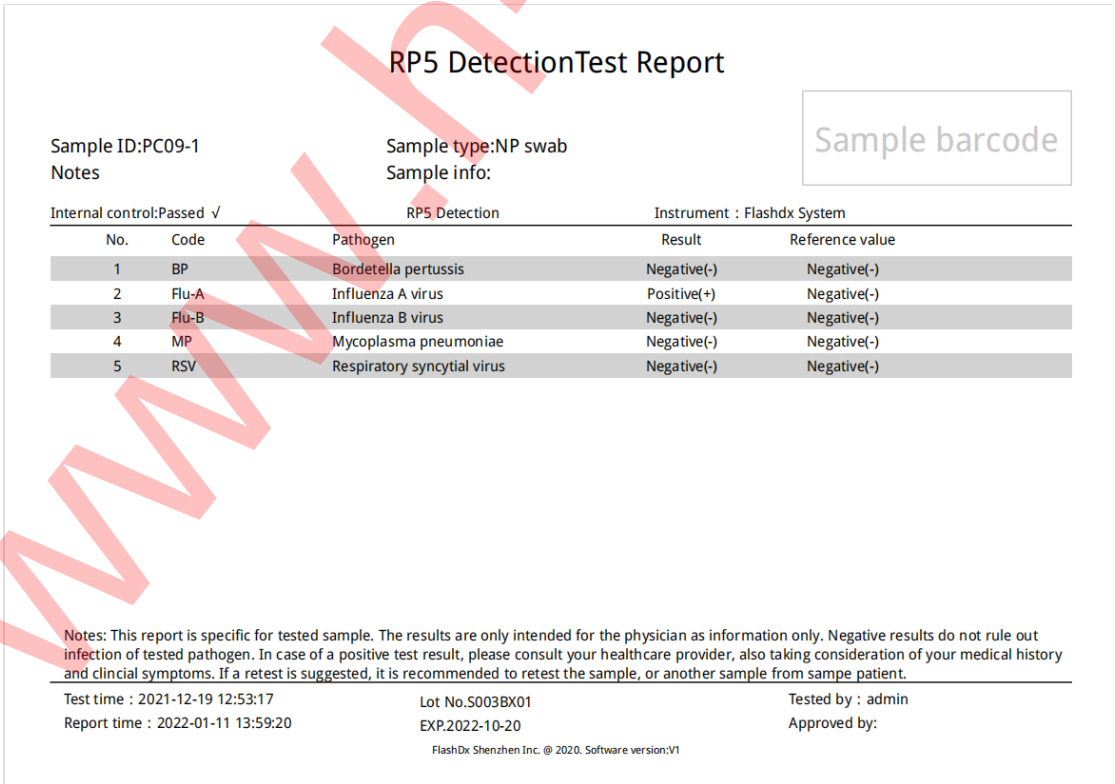


Figure 16. Withdraw review

If you click “Return” button in Figure 16, system will return to standby interface and you can start a new test.

If test information is correct, click printer button in Figure 14 to print out test report and generate following test report, as shown in Figure 17.



RP5 DetectionTest Report

Sample barcode

Sample ID:PC09-1
Notes

Sample type:NP swab
Sample info:

Internal control:Passed √ | RP5 Detection | Instrument：Flashdx System

No.	Code	Pathogen	Result	Reference value
1	BP	Bordetella pertussis	Negative(-)	Negative(-)
2	Flu-A	Influenza A virus	Positive(+)	Negative(-)
3	Flu-B	Influenza B virus	Negative(-)	Negative(-)
4	MP	Mycoplasma pneumoniae	Negative(-)	Negative(-)
5	RSV	Respiratory syncytial virus	Negative(-)	Negative(-)

Notes: This report is specific for tested sample. The results are only intended for the physician as information only. Negative results do not rule out infection of tested pathogen. In case of a positive test result, please consult your healthcare provider, also taking consideration of your medical history and clincial symptoms. If a retest is suggested, it is recommended to retest the sample, or another sample from sampe patient.

Test time：2021-12-19 12:53:17
Report time：2022-01-11 13:59:20

Lot No.S003BX01
EXP.2022-10-20

Tested by：admin
Approved by:

FlashDx Shenzhen Inc. @ 2020. Software version:V1

Figure 17. Example of test report

4.5 Data query

When the system is not running, click “Data” button on main interface to view historical data.

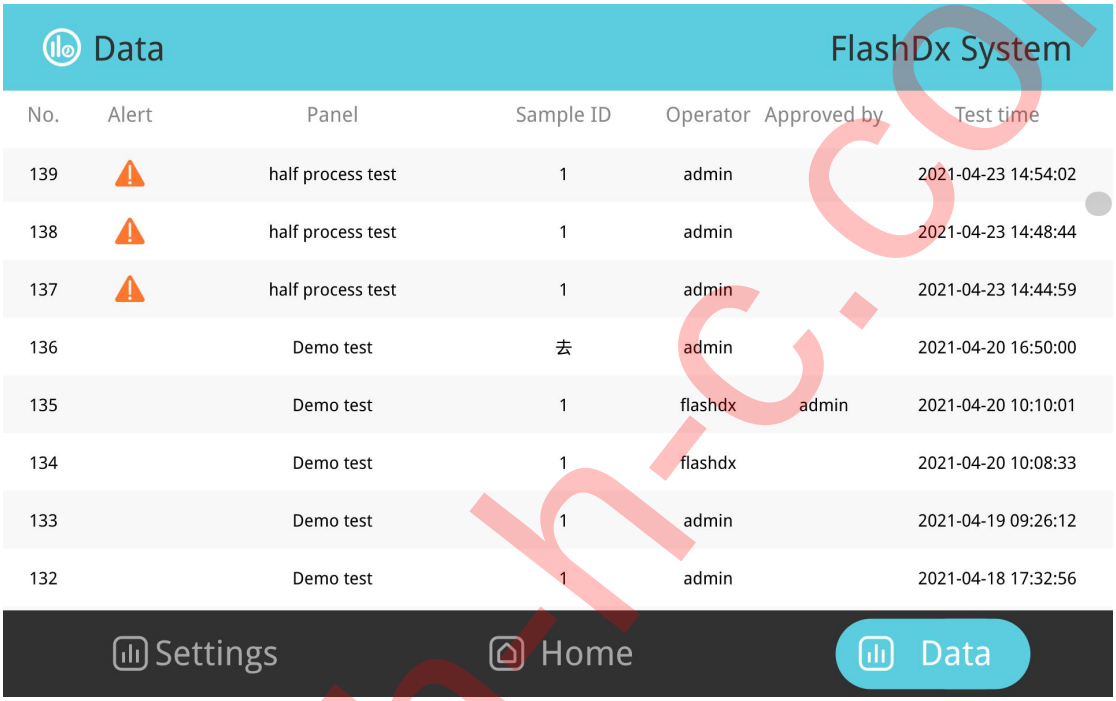


Figure 18. Historical data

4.6 Shutdown

When the device is idle for a long time, you can enter “Homepage” in main interface and click “Off” button to shut down the device. When following interface pops up (Figure 19), click “OK” button to shut down the device.

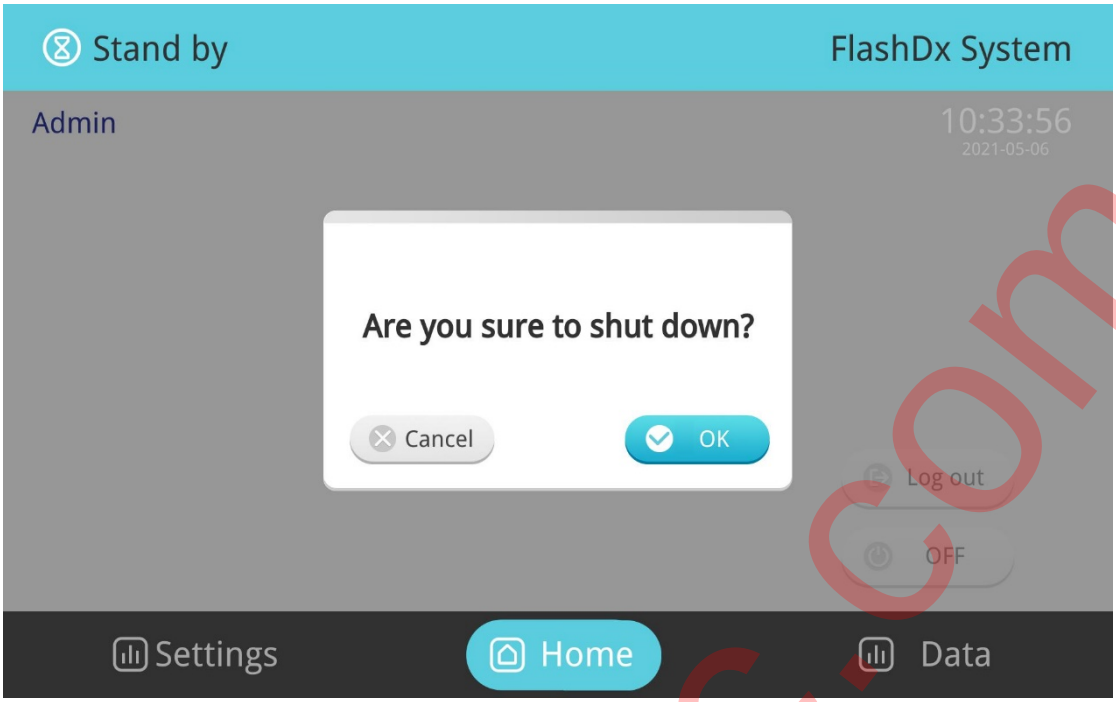


Figure 19. Shut down the device

When the device is completely shut down, turn off the power switch on the back of the device and disconnect power supply.

4.7 Settings

After “Settings” button is clicked, setting menu (Figure 20) is in display, as shown in the figure. The setting contains the options to modify system settings, set the lock screen time, language, modify password, wireless network, wired network, time setting, user account setting, data maintenance and about.

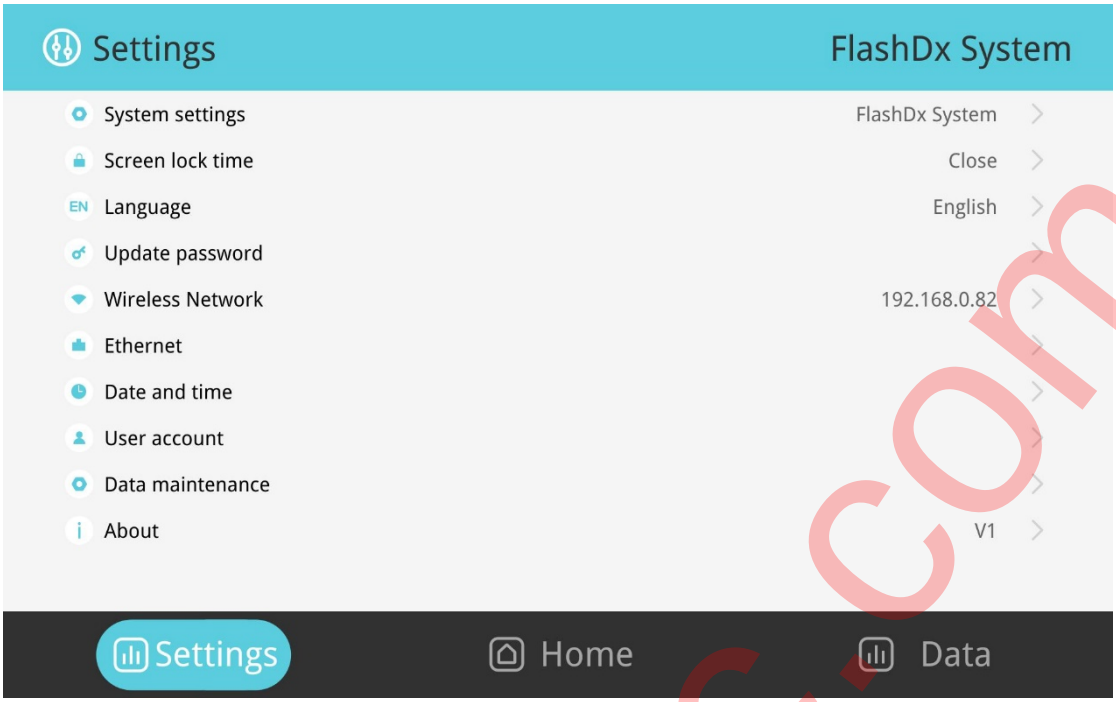


Figure 20. Settings

4.7.1 System settings

Click “System settings” on setting interface to set hospital name, device name, printer settings, etc. It is recommended that customers perform system settings before starting the device for the first time, as shown in Figure 21.

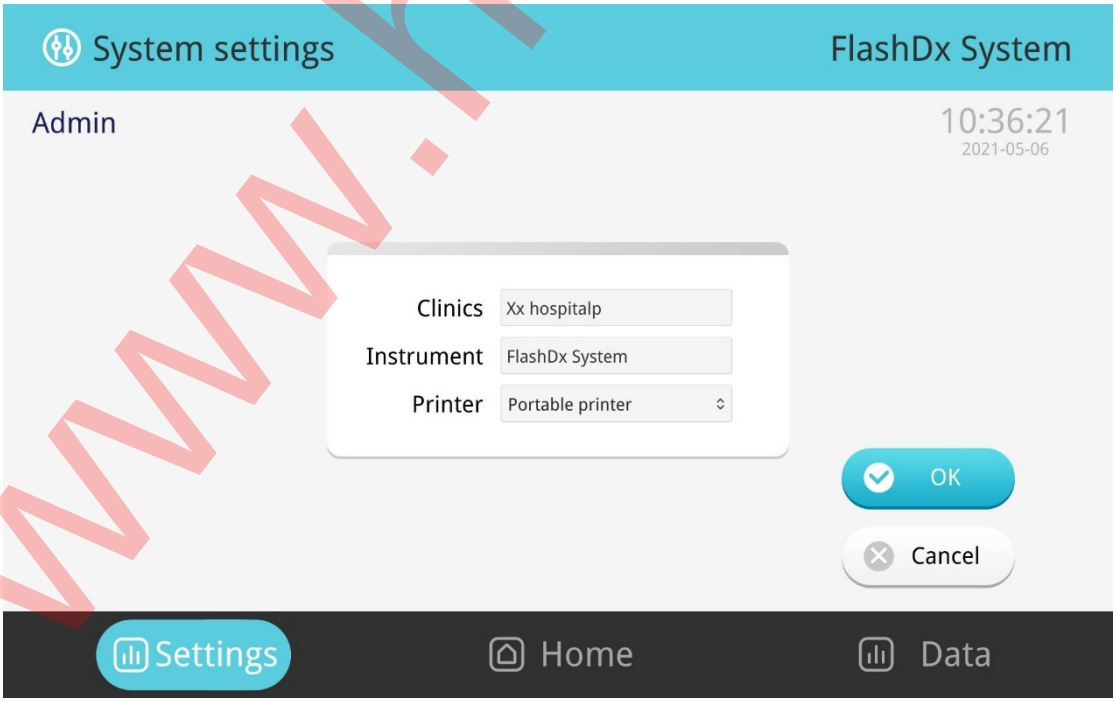


Figure 21. System settings

4.7.2 Screen-lock time setup

"Screen lock time" in setting interface can be set if the device will not be used for a certain period of time or for the purpose of preventing other personnel from touching the device accidentally when the device is in operation. Enter the lock screen time setting shown in Figure 22 to choose whether to activate lock screen function and select g lock screen time.

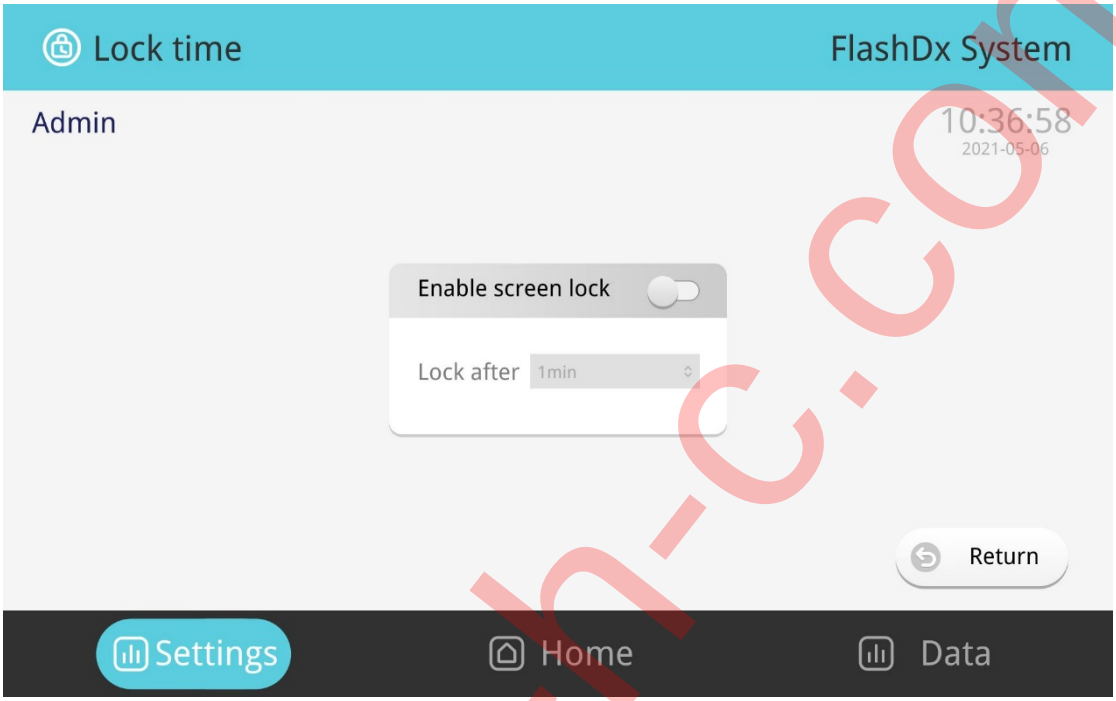


Figure 22. Lock time

Lock screen time (1min, 3min, 5min, 10min, 15min, 30min) can be selected.

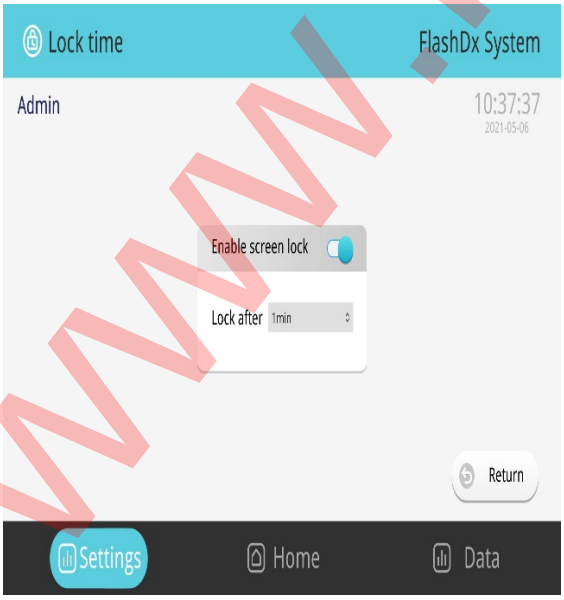


Figure 23-1. Activate lock screen function

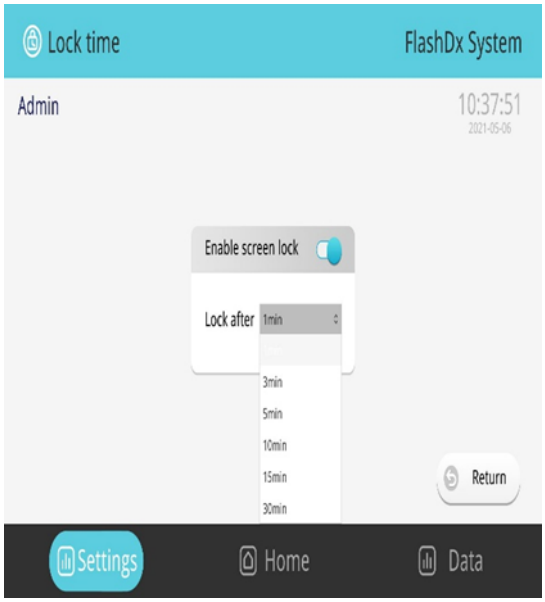


Figure 23-2. Select lock screen time

When the system locks the screen, it can be operated continuously only after the password is entered, as shown in Figure 24.

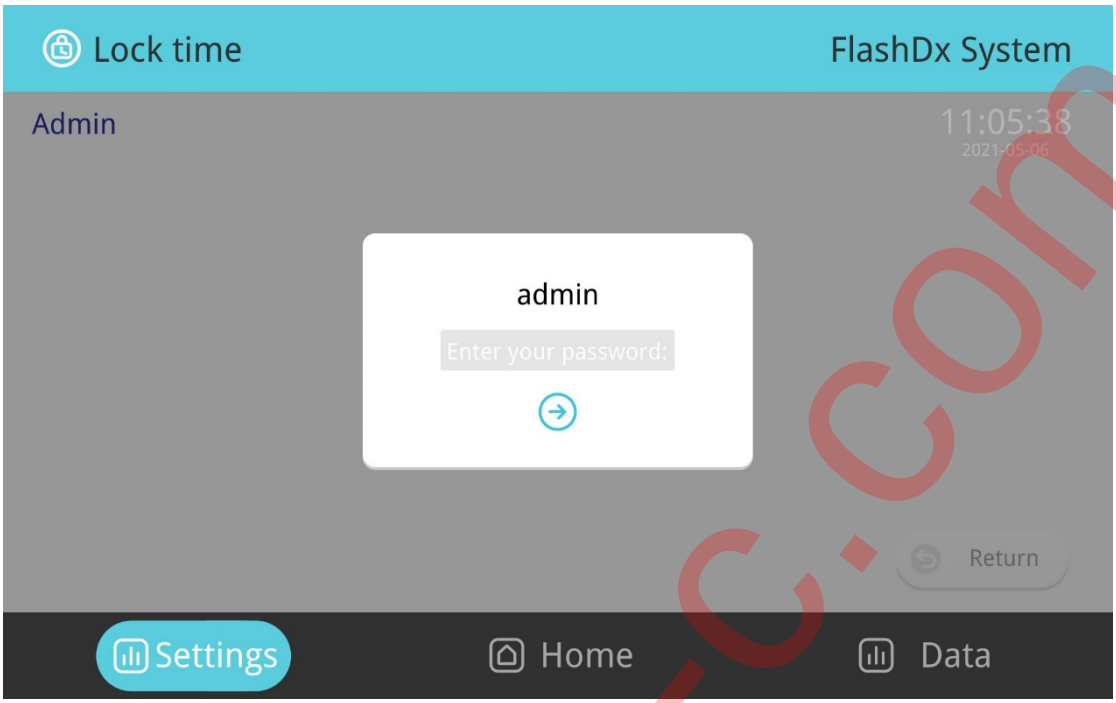


Figure 24.

4.7.3 Language

Click “Language” in setting interface to select a language from “Chinese” and “English”, as shown in Figure 25.

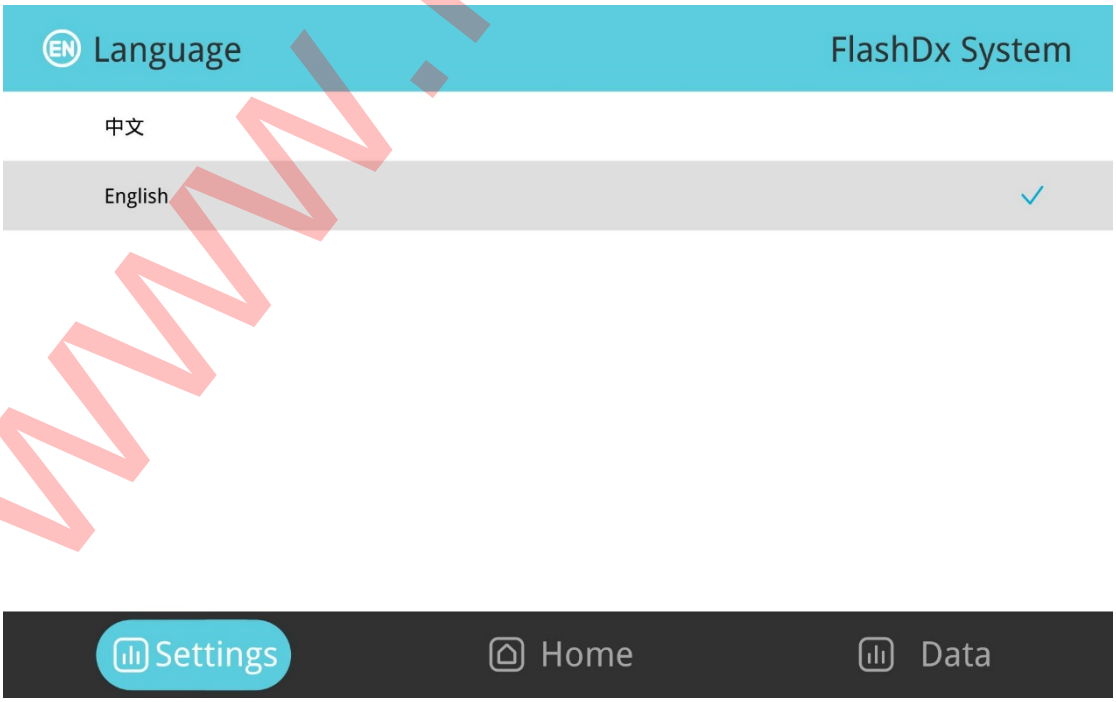


Figure 25. Language

4.7.4 Modify password

Click “Modify password” to modify the users’ password, as shown in Figure 26.

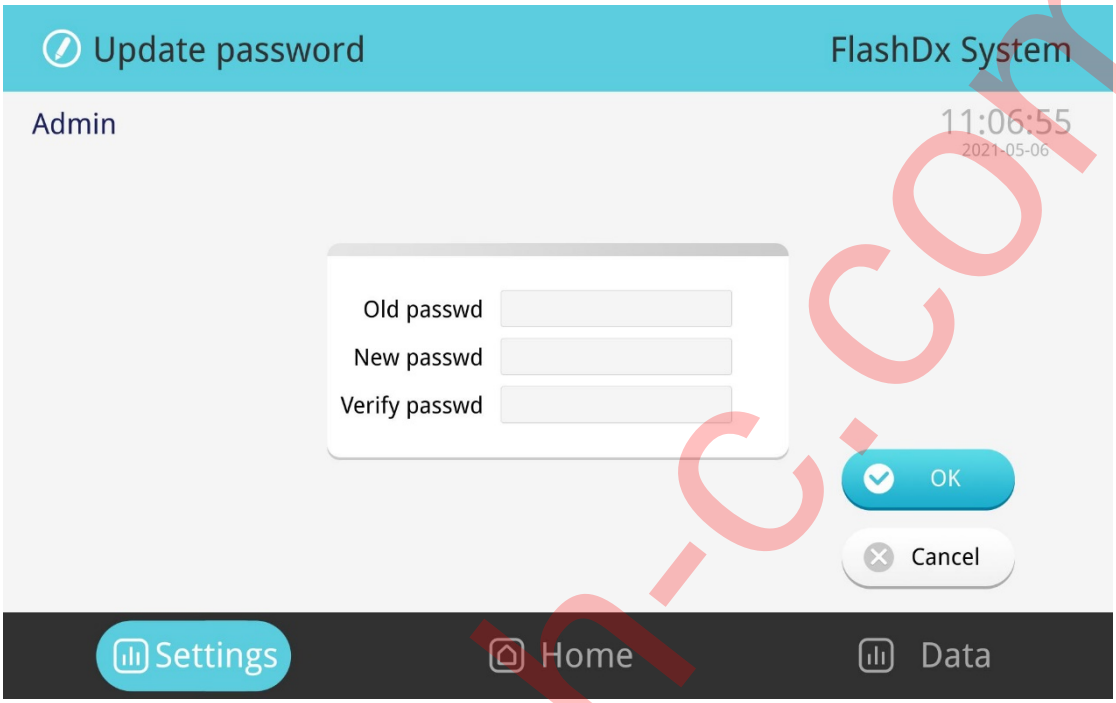


Figure 26. Modify password

4.7.5 Wireless network

Click “Wireless network” to enter wireless network interface shown in Figure 27. Connect to the corresponding wireless network in accordance with Figures 28-1, 28-2, 28-3 and 28-4, respectively.

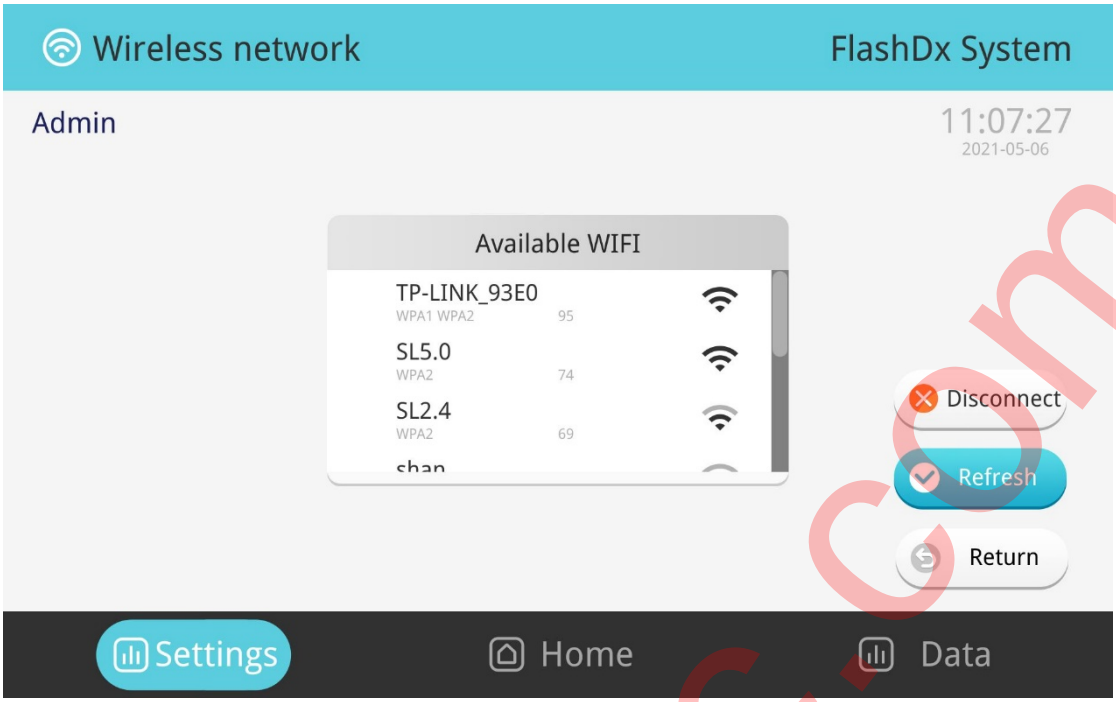


Figure 27.

Figure 28-1.

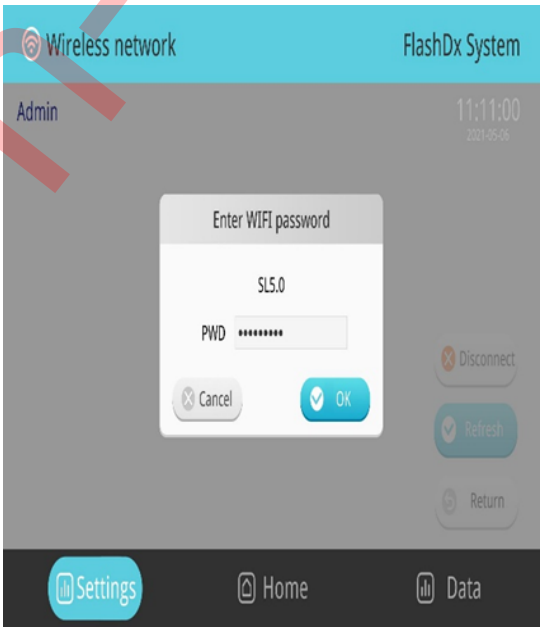


Figure 28-2.

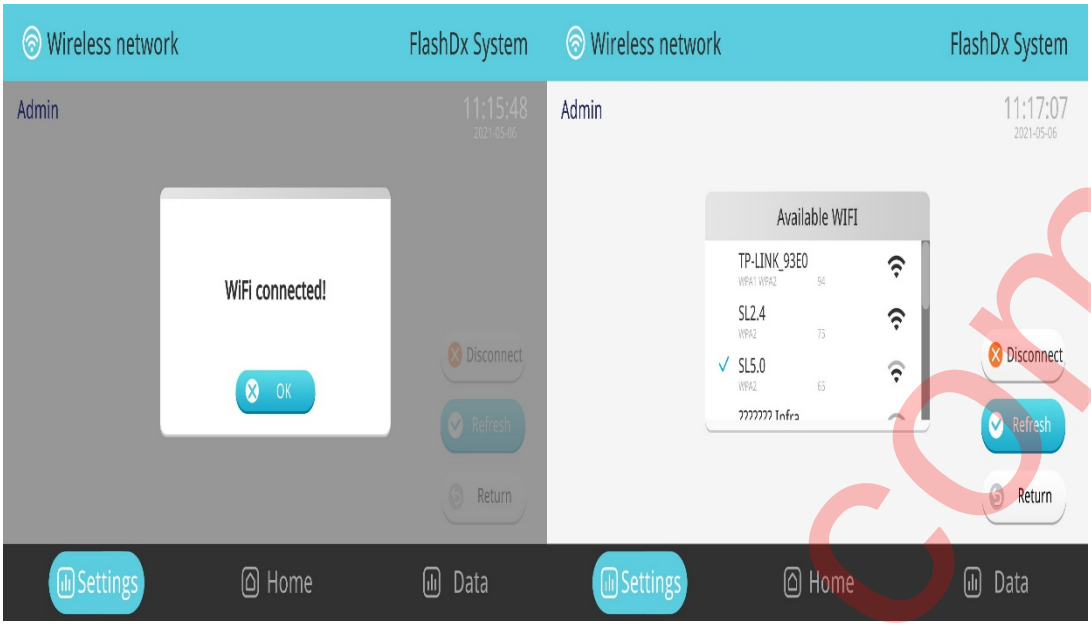


Figure 28-3.

Figure 28-4.

4.7.6 Wired network settings

Click “Wired network” as shown in Figure 29, to connect to wired network after setting the IP address, subnet mask and gateway.

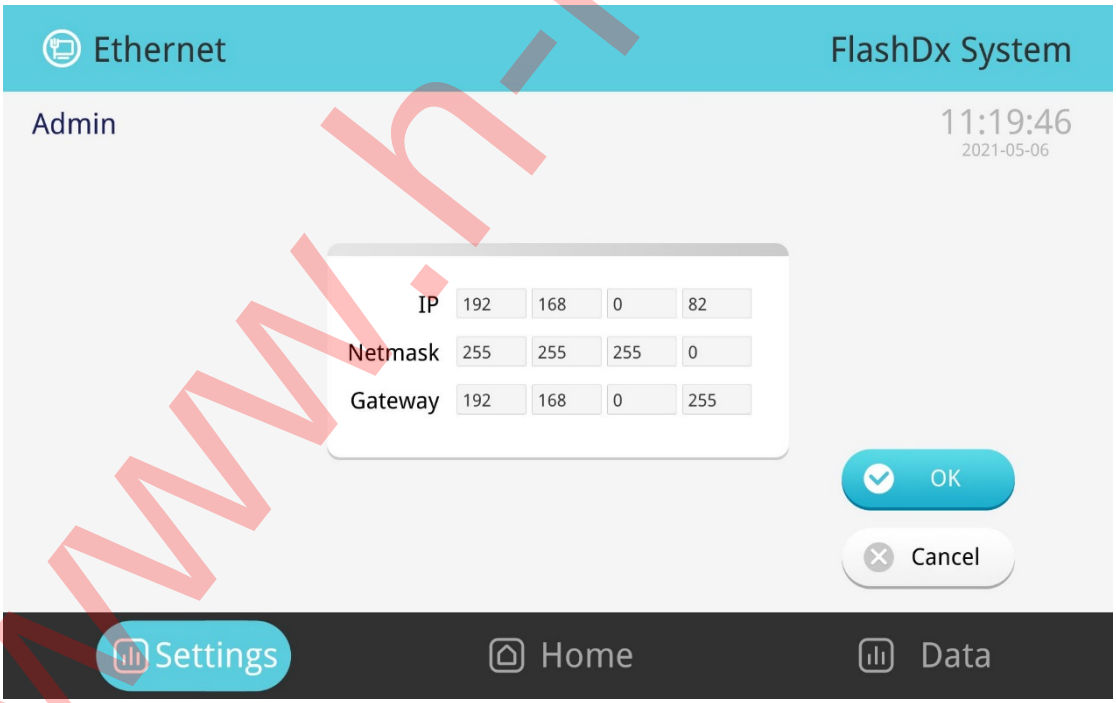


Figure 29. Wired network settings

4.7.7 Time settings

Click “Time” i as shown in Figure 30, to modify year, month, day, hour, and minute.

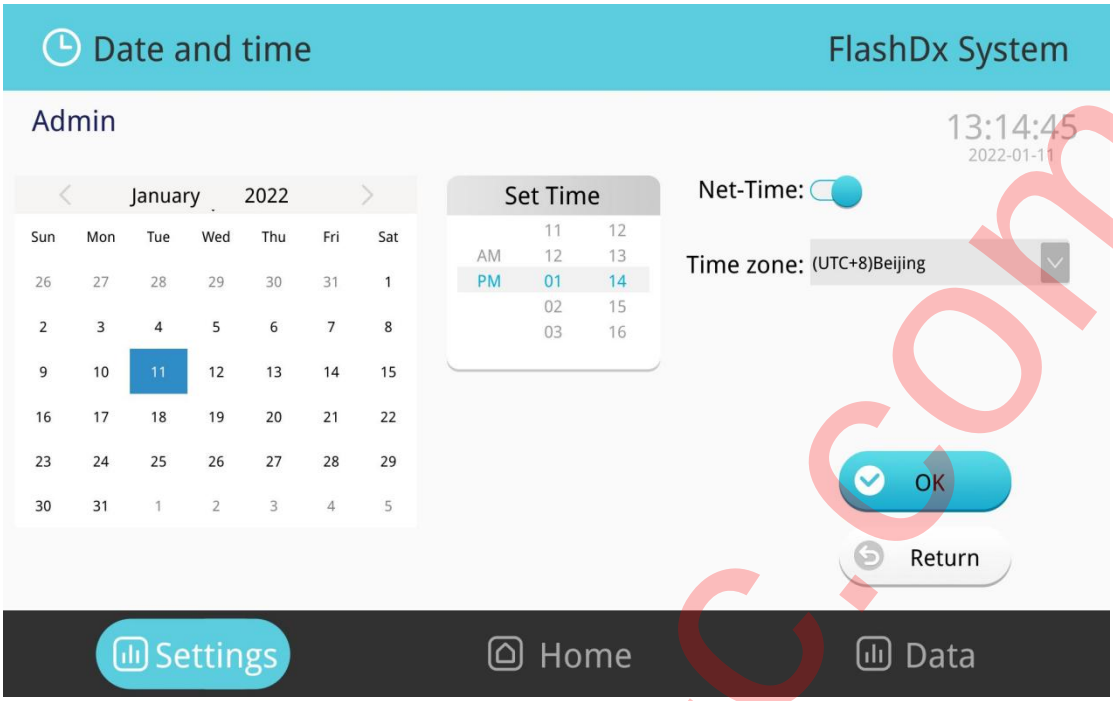


Figure 30. Time settings

4.7.8 User account settings

Click “User account” as shown in Figure 31, to delete, modify, and add user accounts.

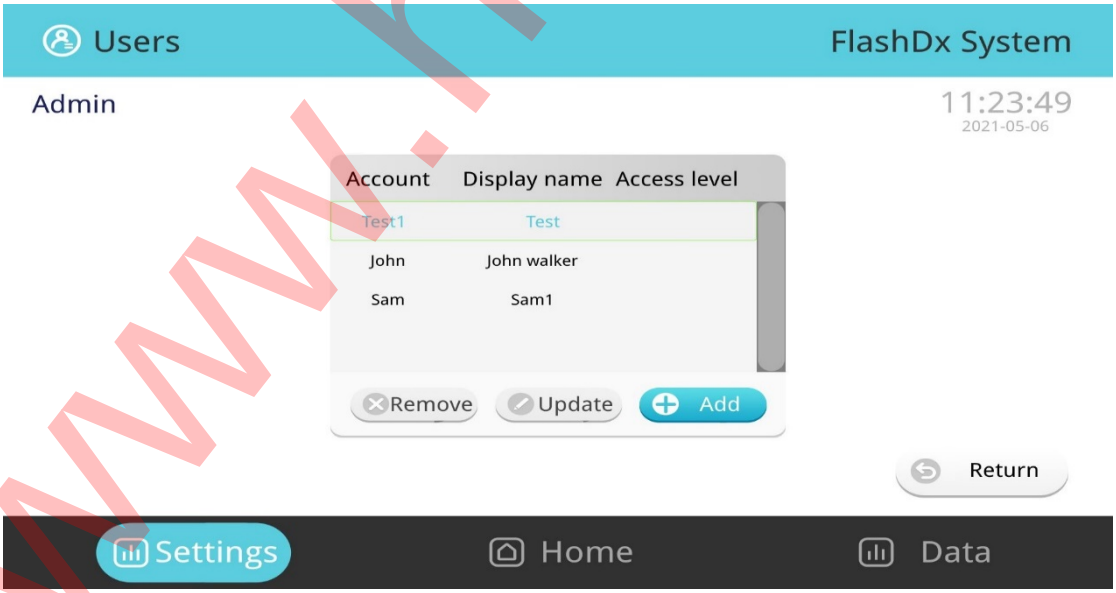


Figure 31. Users account management

Delete user account

Click to select the account to be deleted, as shown in Figure 31, and then click "Delete" button to enter the interface shown in Figure 32.

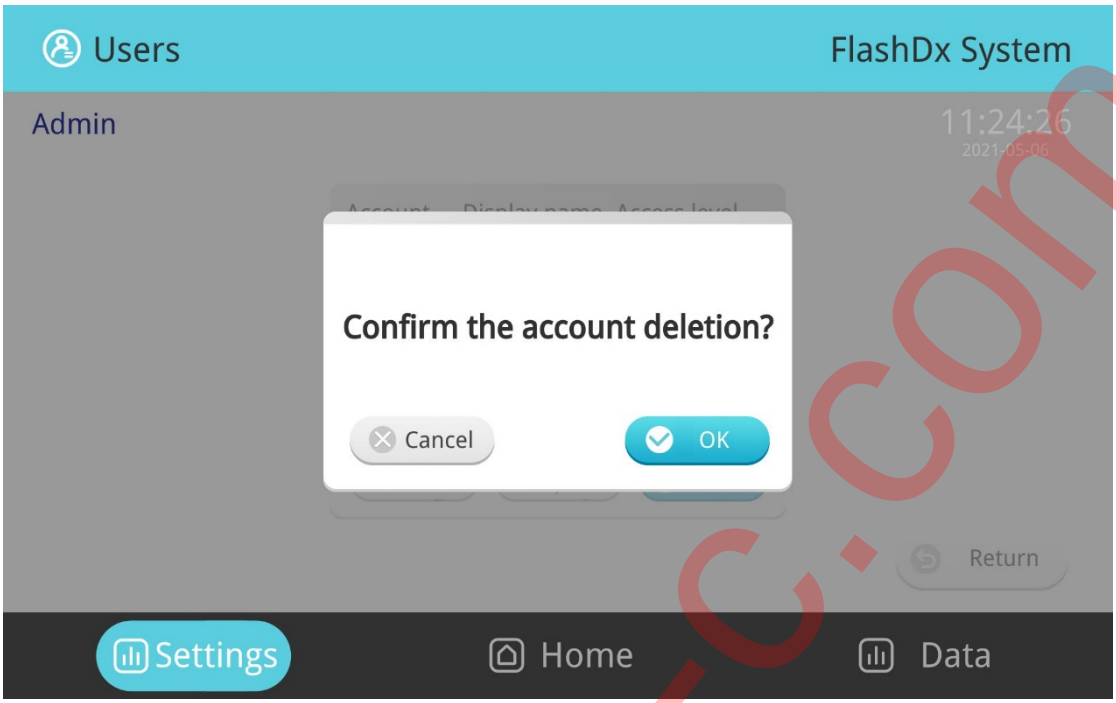


Figure 32.

User account can be deleted after "OK" button is clicked. The operation can be cancelled if "Cancel" button is clicked.

Modify user account

Click to select the account to be modified, as shown in Figure 31, and then click "Modify" button to enter user account modification interface (Figure 33) to modify display name, password, and review authority of the user account.

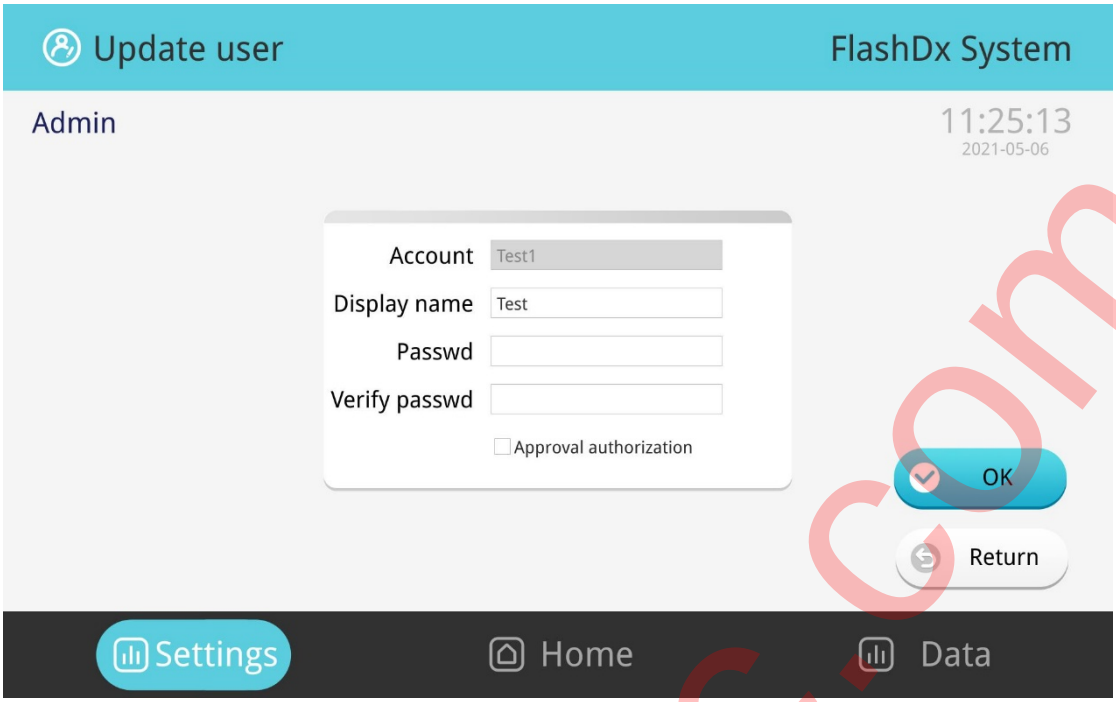


Figure 33.

After completing the modification, click "Confirm modify" button to complete the modification, as shown in Figure 34.

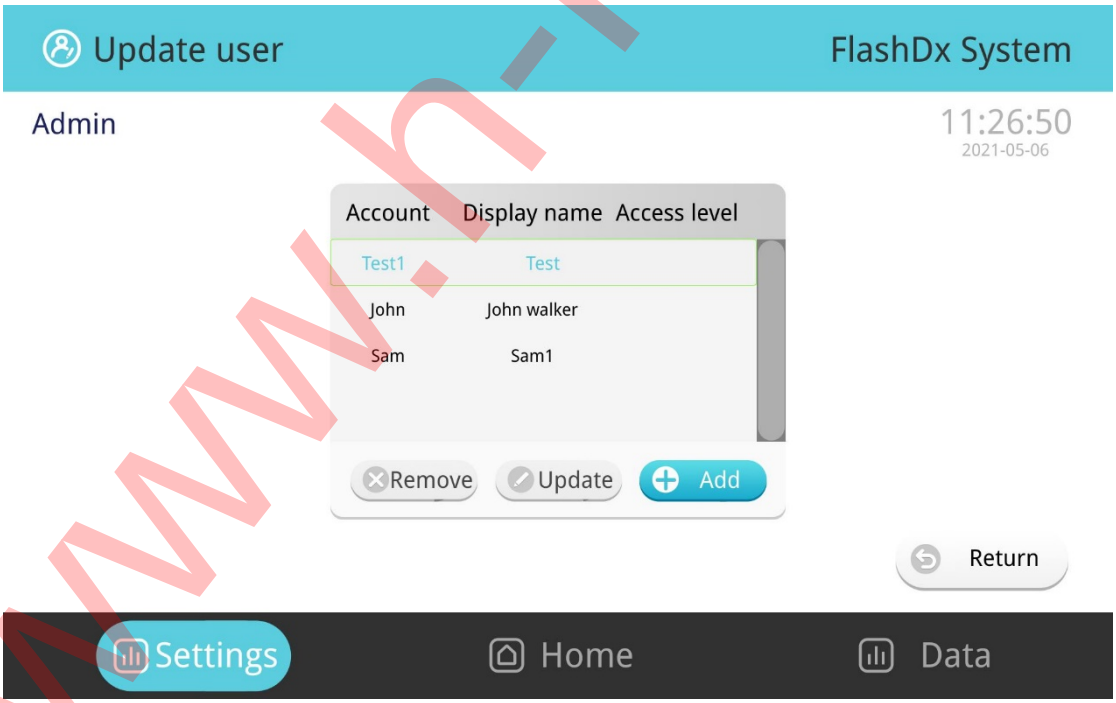


Figure 34.

Add user account

Click “Add” button shown in Figure 31 to enter the setting interface of adding account, as shown in Figure 35-1, to set account, display name, password (password is required) and review authority. After completing the setting, click “Confirm add” button shown in Figure 35-2 to complete adding of user account (as shown in Figure 35-3).

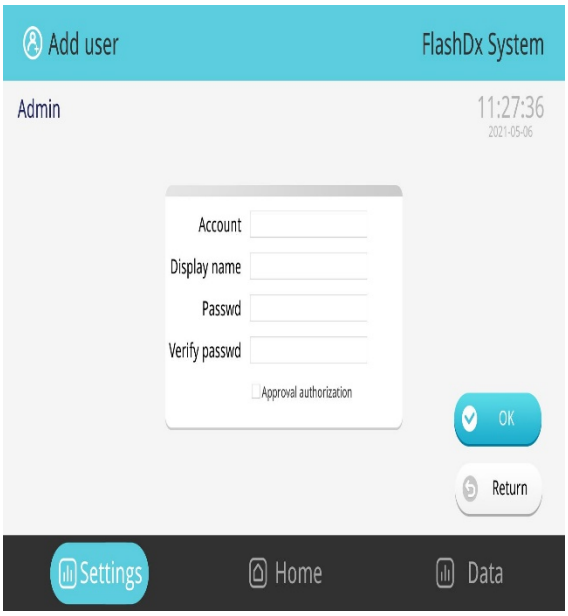


Figure 35-1.

Figure 35-2.

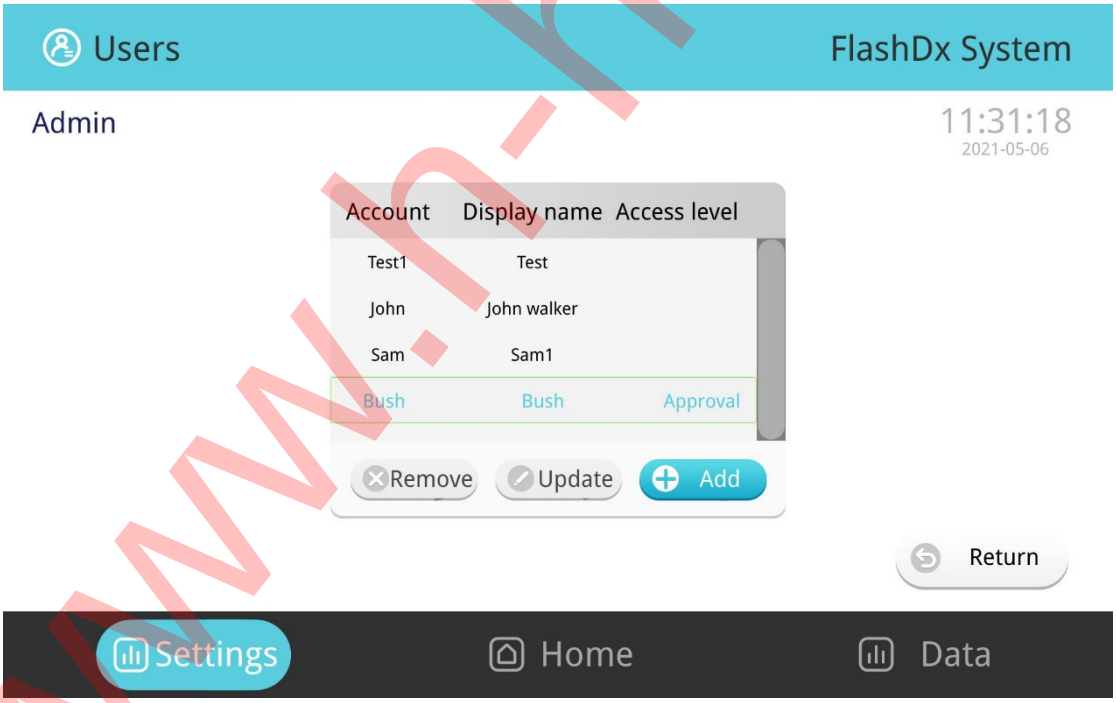


Figure 35-3.

4.7.9 Data maintenance

In data maintenance interface shown in Figure 36, data can be deleted and transferred out. The device has a memory capacity of 64GB. When remaining storage capacity is only

10GB, it will prompt that the memory is insufficient but the test can still be performed; when remaining storage capacity is only 1GB, the device cannot perform test. During daily use, users should pay attention to the deletion and copying of data.

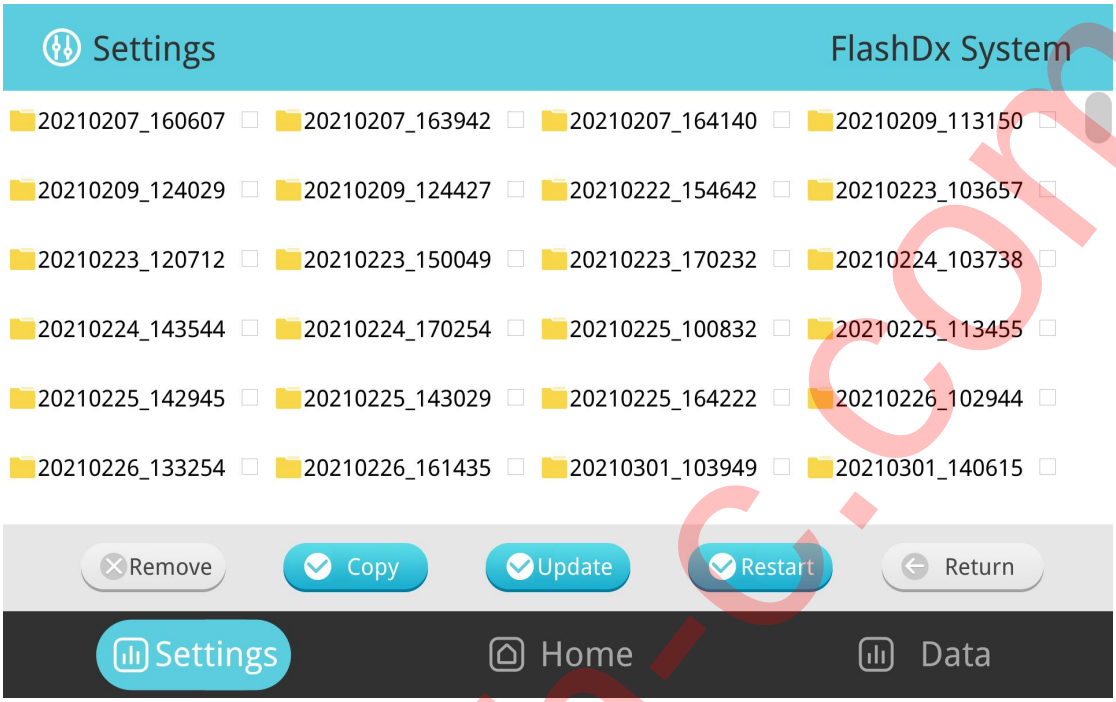


Figure 36.

Click “Upgrade” button in this interface to upgrade device software.

Click “Restart” button in this interface to restart the device

4.7.10 About

Click “About” in the setting interface to check the software release version number, complete software version number, device specification and model, MAC address and serial number, as shown in Figure 37.

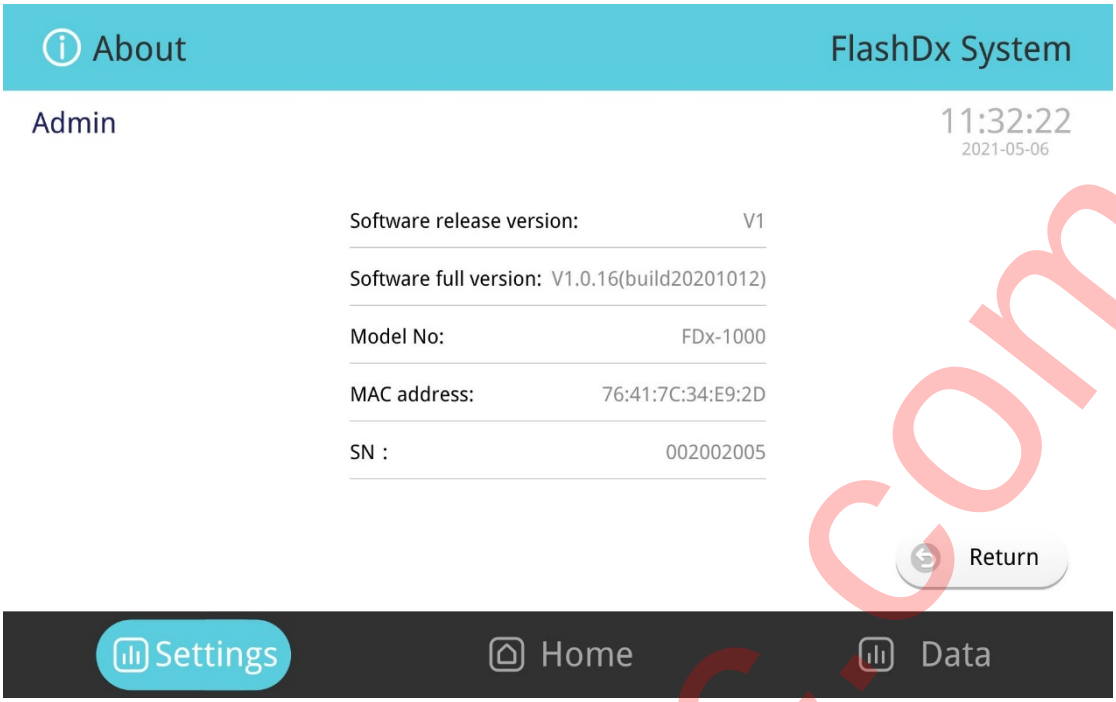


Figure 37.

Chapter V Maintenance

This chapter introduces maintenance practice for the device and its components. Please perform maintenance as required to ensure normal operation of the device.

5.1 Cleaning of device

1) Cleaning of the surface

The surface should be regularly cleaned with a soft cloth and a small amount of water, and should be wiped dry after cleaning. If dangerous substances such as reagents leak on the surface of the device, use a soft cloth and 75% alcohol to wipe it clean.

2) Cleaning of the reaction chamber

i. If the reaction chamber is contaminated with dust or impurities, the temperature response and fluorescence detection will be affected. Therefore, the reaction chamber should be cleaned regularly. It is recommended to wipe it with a soft cloth at least once every 3 months, and then gently blow with a blowing balloon after it is dry.

ii. If any reactants (reagents, samples, etc.) contaminate the reaction chamber, wipe it clean with a soft dust-free cloth and 75% alcohol.

1) Before cleaning the device, power must be turned off and power cord must be unplugged.

2) If you use a disinfectant or cleaning agent that is not recommended by manufacturer, you should consult manufacturer or its agent.

3) If hazardous substances leak on the surface of the device or enter the inside of the device, proper disinfection should be performed.

4) Do not use cleaning agents or disinfectants that chemically react with parts of the device or materials contained in the device to cause hazard.

5) If you have any doubt about the compatibility of disinfectant or cleaning agent with parts of the device or materials contained in the device, you should consult manufacturer or its agent.

6) It is strictly forbidden to use strong corrosive solvents or organic solvents to clean the device.

5.2 Replacement of fuse

This device is equipped with a fuse. If use is damaged due to voltage fluctuation, please refer to the following steps for replacement.

i. Set power switch to “0” position and remove power cord;

ii. Use a flat-blade screwdriver to rotate in the direction of arrow against flat-shaped slot of fuse holder, and pull out fuse;

iii. After taking out the 3.15A 250V fuses, if it is damaged, replace a fuse and reinsert new fuse in fuse holder, and then use a flat-blade screwdriver to rotate in the opposite direction indicated by arrow on fuse holder to install it back to its original position.

If the device still fails after the replacement, please notify our company for troubleshooting.

5.3 Protection of device

i. Do not switch the device frequently, and interval between the two switches shall not be less than 30 seconds.

ii. Do not turn off the power immediately after test is over. After the device is in standby mode for 10 minutes (fan inside the device is still working) and module temperature drops to room temperature, click “Shutdown” button, and turn off the power after screen goes out.

iii. Please use power cord provided by manufacturer.

iv. It is forbidden to carry out boiling water bath or low temperature protection (such as 4°C) on the device.

v. No maintenance personnel other than those certified by manufacturer are permitted to disassemble the device without authorization. Only the manufacturer or its agent can inspect or supply any parts of the device.

5.4 Waste disposal

After each test, there are amplification products in the test cartridge, which should be disposed of as soon as possible in accordance with relevant regulations to avoid contamination.

Do not open test cartridge after taking it out from reaction module, otherwise high-concentration amplification products will contaminate surrounding environment.

5.5 Device failures and corresponding countermeasures

Serial No.	Failure description	Possible causes and corresponding countermeasures
1	There is no display after the device is powered on	Confirm that power cord is correctly plugged into socket and check power output to make sure it is functional.
2	After turning on power, the device starts to work in the middle of the program	Power supply was cut off before last program ended. Just end the running program.
3	Fan is strong sometimes and weak sometimes	Normal. Fan is only used to dissipate heat during operation, it is not used to achieve the set temperature.
4	When the device is working, there is a slight rattling or squeaking sound	Normal. When accelerating heating or cooling is required, rattling or squeaking sound inside the device is oscillatory sound caused by Automated adjustment of power supply switching.
5	Module temperature rises and falls very slowly	Check whether fan is operating normally.
6	Misalignment appears on the LCD screen	Displacement of display due to electrostatic pulses or power surges, which will not affect the program. Please restart.

If the problem cannot be solved by above methods, please contact the supplier immediately!

5.6 Error messages and solutions

Serial No.	Error code	Possible causes and solutions
1	101	Communication error of temperature control board! Restart or seek technical support
2	102	Temperature difference between two sensors in the

		channel is too large. Restart after cooling down or seek technical support
3	103	Temperature error! (Target temperature cannot be reached) Restart or seek technical support
4	201	Communication error of driver board! Restart or seek technical support
5	301	Camera communication error! Restart or seek technical support
6	401	Error reading configuration file! Restart or seek technical support
7	402	Error configuration file format! Restart or seek technical support
8	404	Disk is full! Delete or export saved data
9	7927	Pierce motor movement timeout! Restart or seek technical support
10	0	Unknown error! Restart or seek technical support

Appendix 1 Declaration of Product EMC

EMC

Caution:

- FlashDx-1000-EAutomated Nucleic Acid Detection System meets emission and immunity requirements specified in IEC 61326-2-6, see the tables below.
- The user is responsible for ensuring electromagnetic compatibility environment of the device so that the device can operate normally.
- It is recommended to evaluate electromagnetic environment before using the device.

Warning:

- FlashDx-1000-EAutomated Nucleic Acid Detection System is designed and tested according to Class A device stated in IEC/CISPR11. In a home environment, this device may cause radio interference, and protective measures should be taken.
- It is forbidden to use the device near strong radiation sources (such as unshielded radio sources), otherwise it may interfere with normal operation of the device.

Table I:

Electromagnetic Emission	
Emission Test	**Compliance**
IEC/CISPR 11 RF emission	Group 1
IEC/CISPR 11 RF emission	Class A
IEC 61000-3-2 Harmonic emission	Not applicable
IEC 61000-3-2 Voltage fluctuation/flicker emission	Not applicable

Table II:

Electromagnetic Immunity			
Immunity Test Items	**Basic Standard**	**Trial Value**	**Compliance Criteria**
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact discharge: ±2kV, ±4kV Air discharge: ±2kV, ±4kV, ±8kV	B
Radio frequency electromagnetic field	IEC 61000-4-3	3V/m, 80MHz~2.0GHz, 80%AM	A
Pulse train	IEC 61000-4-4	Power cord: ±1kV (5/50ns, 5kHz)	B
Surge	IEC 61000-4-5	Line to ground: ±2kV Line to line: ±1kV	B
Radio frequency conduction	IEC 61000-4-6	Power cord: 3V/m, 150kHz~80MHz, 80%AM	A
Power frequency magnetic field	IEC 61000-4-8	3A/m, 50/60Hz	A
Voltage dips and interruptions	IEC 61000-4-11	0% for 1 cycle; 40% for 5/6 cycle; 70% for 25/30 cycle; 5% for 250/300 cycle	B C C C

Performance identification:

A. During the test, performance is normal within specification limits.

B. During the test, function or performance is temporarily reduced or lost, but it can recover by itself.

C. During the test, function or performance is temporarily reduced or lost, but operator intervention or system reset is required

Appendix 2 Product Performance

i. Technical indicators of device

Items	Description
Temperature control range	25.0±2.0°C~99.9±1°C
Average heating rate	1.5°C/s (50°C→90°C)
Maximum heating rate	2.5°C/s (50°C→90°C)
Average cooling rate	1.5°C/s (90°C→50°C)
Maximum cooling rate	2.0°C/s (90°C→50°C)
Module temperature control precision	≤0.5°C
Temperature accuracy	±0.5°C
Module temperature uniformity	±1.0°C
Temperature duration accuracy	Relative deviation±5%
Fluorescence intensity detection repeatability	≤3%
Sample test repeatability	≤3%
Sample linearity	0.980
Fluorescence linearity	0.990

ii. Technical specifications of device

Items	Description
LCD	10.1 inch, 1920×1200 Pixels
Product size	400mm×255mm×325mm (L×W×H)
Net weight of product	9 Kg
Power parameters	100-240V~, 50/60Hz, 300VA
Noise level	<70dB (A)
Data storage	64GB

iii. Shelf life of device

Shelf life of FlashDx-1000-E Automated Nucleic Acid Detection System is 5 years.

Shelf life of this product is determined based on the reliability test results. User should maintain and repair the product in accordance with requirements in instructions for use \. When shelf life expires, please scrap and dispose of the product by yourself according to local laws and regulations. If it is confirmed that basic safety and effectiveness of the product can be maintained after maintenance or repair, the product can be used normally.