Operating Manual for the Mycoplasma DetectInnova Program

Version: A/0

Product No.: 1603106

For Research Use Only

Huzhou Shenke Biotechnology Co., Ltd.

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1. Introduction

The AdvSHENTEK Mycoplasma DetectInnova Cassette, designed for use with the AdvSHENTEK DetectInnova System, integrates magnetic particle separation technology and real-time fluorescence PCR technology. This fully enclosed, single-use cassette contains all necessary reagents for nucleic acid extraction, purification, amplification and detection, enabling an efficient, all-in-one workflow from sample preparation to result analysis.

The integrated design of the instrument and reagent system effectively minimizes operator-dependent variability and reduce environmental requirements, enabling rapid and reliable mycoplasma detection in biological samples.

2. Applications

This procedure is intended to guide new users through the core operations of the Mycoplasma DetectInnova Detection System from user registration to result visualization, data review, and export functions via intuitive touchscreen commands.

3. Materials

AdvSHENTEK DetectInnova System (Product No.: 1603106)
AdvSHENTEK Mycoplasma DetectInnova Cassette (Product No.: 1509100)

4. Procedures

4.1 Power On and Log In

Connect the power cord to the "**Power socket**" on the back panel, and plug the cord into a power source rated above 350W. Turn on the instrument by switching the "**Power switch**" to the "I" position at the lower-left corner on the back of the device (Fig. 4.1). The system will automatically initialize, and the display screen will automatically appear and activate upon startup.

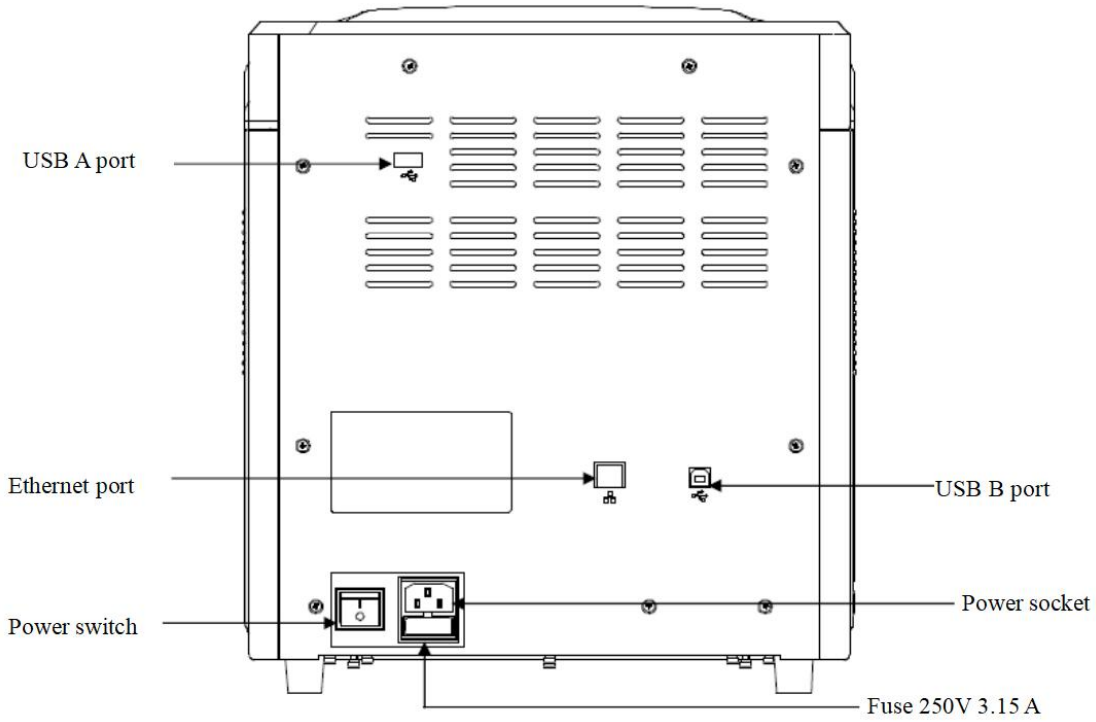


Fig. 4.1

For initial login:

Log in using the "**Admin**" account and the default password "**A888888**" (Fig. 4.2).

It is required to change the password immediately after the initial login to ensure account security. To change the password, click "**Users**" on the main interface (Fig. 4.4), select the Admin account from the list. Click "**Edit**" at the bottom center of the screen to modify the password as shown in Fig. 4.3.

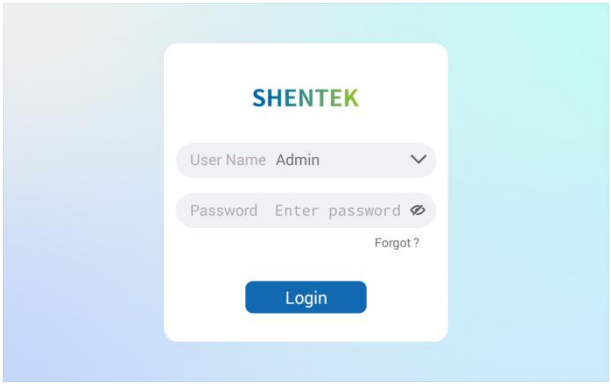


Fig. 4.2

Note: The password must meet specific complexity requirements - including at least two of the following character types: uppercase letters, lowercase letters, numbers, and underscores.

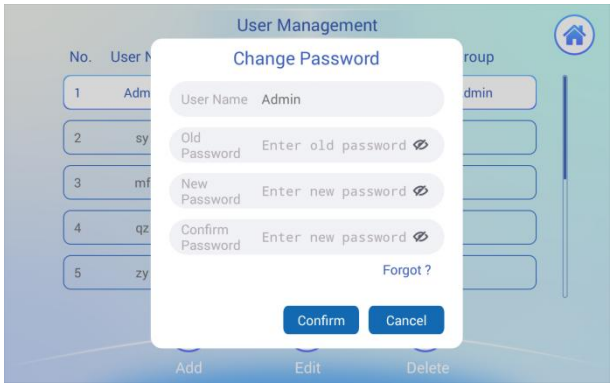


Fig. 4.3

For new users:

User accounts can be created as needed for system operation.

1) To add a new user, click "**Users**" on the main interface (see Fig. 4.4).

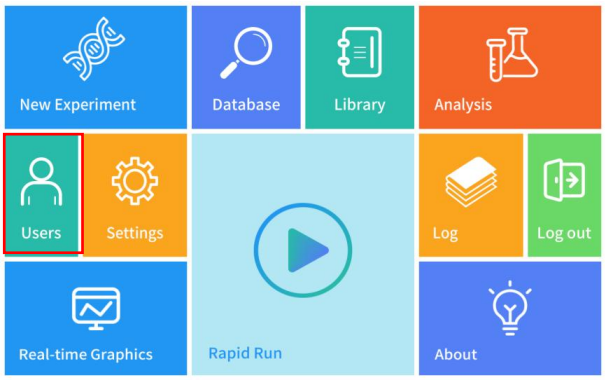


Fig. 4.4

2) In the "**User Management**" panel (see Fig. 4.5), configure the following fields to complete the account setup:

- User Type: Manager, Operator or Auditor;
- Export Type: PDF or CSV (PDF is recommended.)
- Group Name: Set by Admin; maximum 8 characters.

The initial password for all newly created user accounts is set to the default password: A888888. It is required to change the password immediately after the initial login to ensure account security.

Note: The password must meet specific complexity requirements - including at least two of the following character types: uppercase letters, lowercase letters, numbers, and underscores.

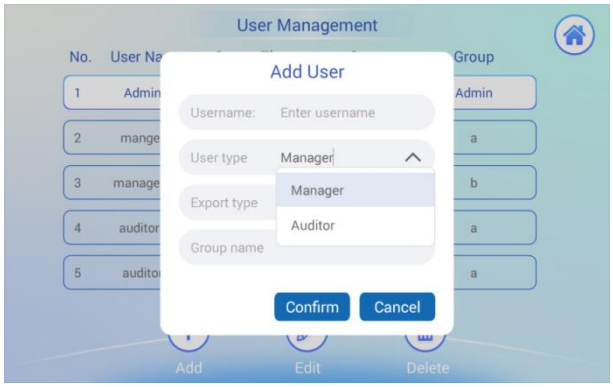


Fig. 4.5

Permission Hierarchy for Account Creation

Account creation is restricted according to the following hierarchical structure:

1) Administrators can create:

- One Manager account per Group
- One Auditor account per Group

Note: Auditor accounts are valid for a maximum of 48 hours.

2) Managers can create:

Operator-level accounts within their assigned Group

Note: Only users with the appropriate access level are authorized to perform account creation operations.

4.2 Verify the MPDI Program

Click "**Library**" on the main interface to verify whether the MPDI program is available (see Fig. 4.6).

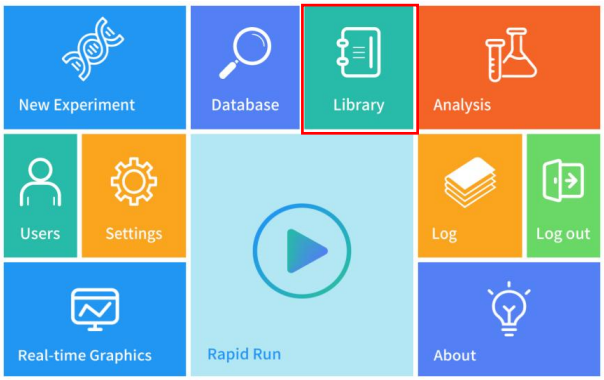


Fig. 4.6

Mycoplasma detection program is pre-installed as the default during the initial system setup. In the event of any unexpected errors or malfunction, the program may be reinstalled by following the procedures described below.

Note: To ensure compatibility, the instrument, reagents, and operating program must be properly matched within the system configuration. Only users with Administrator or Manager-level privileges are authorized to perform program reinstallation.

4.2.1 New Experiment

Click "**New Experiment**" to initiate experiment setup. You may choose between "**Manual Setting**" and "**Scan QR Code**" modes (see Fig. 4.7).

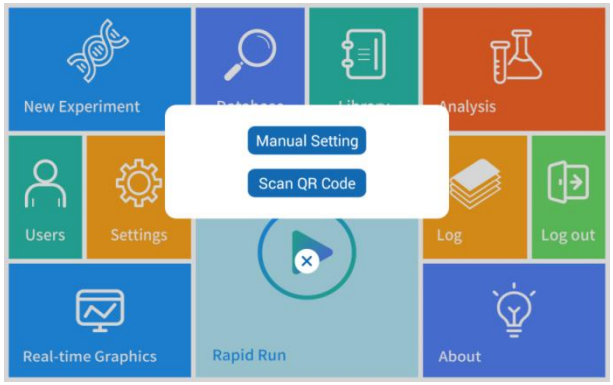


Fig. 4.7

It is recommended that users utilize the "**Scan QR Code**" function for program loading. Click "**Scan QR Code**", then scan the corresponding QR code (see Fig. 4.8). The program will be automatically loaded upon successful scanning.

Note: Please contact the supplier for the program QR code.

Fig. 4.8

If using the "**Manual Setting**" to add the program, it is recommended to consult the **AdvSHENTEK DetectInnova System User Manual** for detailed instructions and parameter configuration.

4.2.2 Library

Click "**Library**" (see Fig. 4.6) to access the program management interface.

The functions of the control buttons located at the bottom of the Library interface are described as follows:

New: click "**New**" (Fig. 4.9) to initiate the setup of a new program.

You may choose between "**Manual Setting**" and "**Scan QR Code**" modes (Fig. 4.7).

It is recommended to use the "**Scan QR Code**" function for program loading, as shown in Fig. 4.8.

Edit: to modify an existing program, select the desired program (see Fig. 4.9).

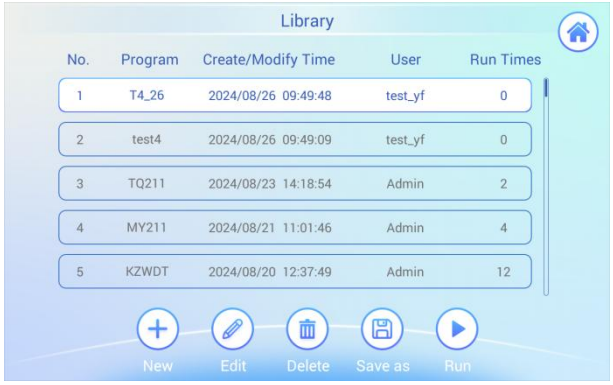


Fig. 4.9

Then click "**Edit**" at the bottom center of the screen to access the program editing interface, as shown in Figure 4.10. From this interface, the selected program can be reviewed and modified as needed.

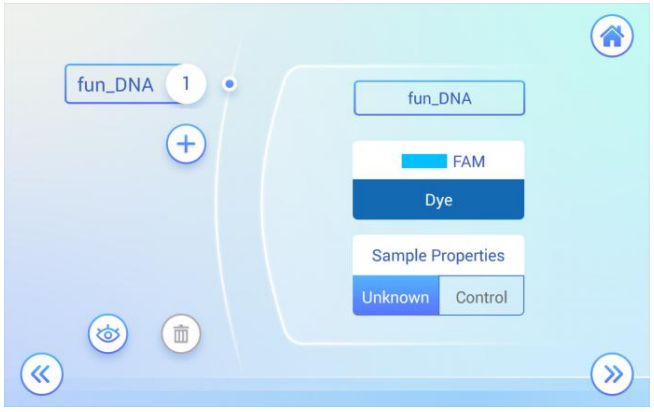


Fig. 4.10

Delete: Perform deletion of the selected program, as shown in Fig 4.11.

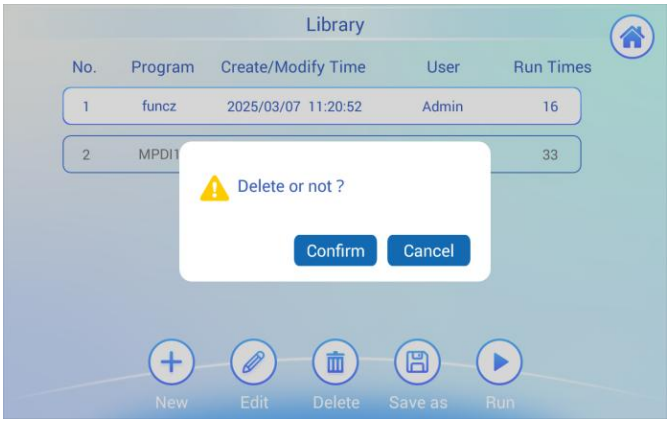


Fig. 4.11

Note: Only the user account with Administrator-level privileges are authorized to perform program deletion.

Save as: Execute a "**Save as**" action on the selected program to generate a new program, as shown in Fig 4.12.

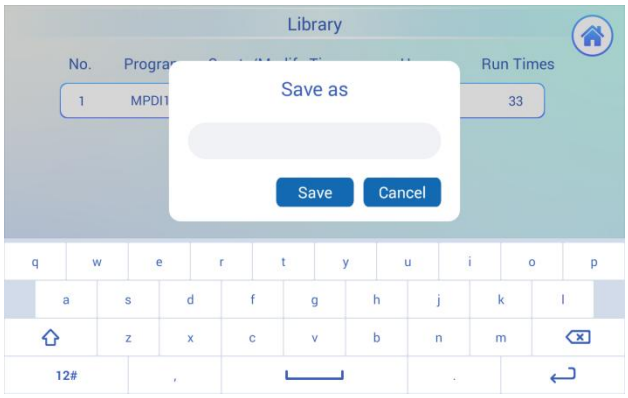


Fig. 4.12

Run: Perform the selected program as shown in Fig 4.13.

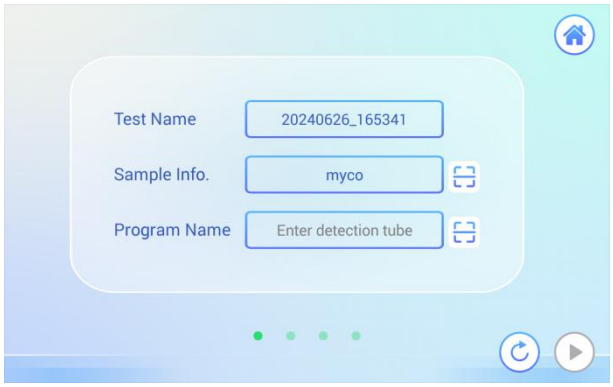


Fig. 4.13

4.3 Sample Preparation

Prepare the samples for Mycoplasma tests as outlined in the **AdvSHENTEK Mycoplasma DetectInnova Cassette User Guide**.

4.4 Run Test

When using AdvSHENTEK Mycoplasma DetectInnova Cassettes, initiate the experiment by selecting "**Rapid Run**" mode (see Fig. 4.14).

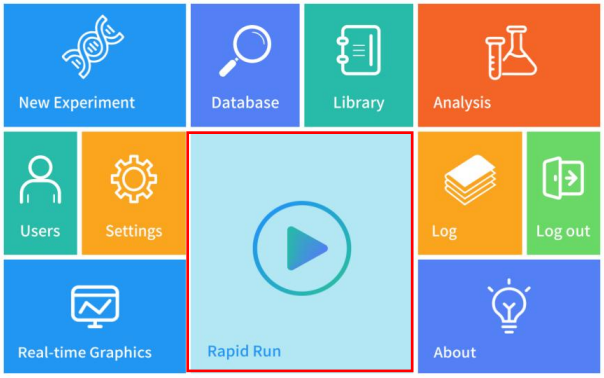


Fig. 4.14

Click "**Rapid Run**" on the main interface to enter the test page (see Fig. 4.15).

In the "**Test Name**" field, you may either modify the name as needed or directly use the default.

Next, proceed to the "**Sample Info.**" field to input the sample name or select the scan

icon ‘ ’ at the far right of the "**Sample Info**." field to capture the sample code via barcode or QR code scanning through the scanner on the front panel.

Then click the scan icon ‘ ’ at the far right of the "**Program Name**" field, and position the cassette with the QR code facing upward near the scanner on the front panel to complete the QR code scan (Fig. 4.16).

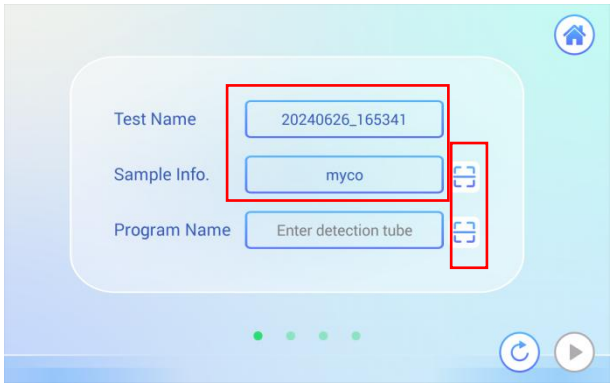


Fig. 4.15

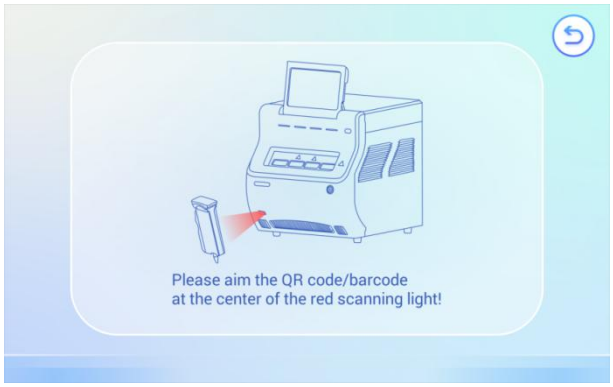


Fig. 4.16

After successful scanning the QR code, select a channel, as shown in Fig. 4.17.

Fig. 4.17

Press the "**Lid Door Switch**" button on the instrument's front panel (see Fig. 4.18) to open the lid door.

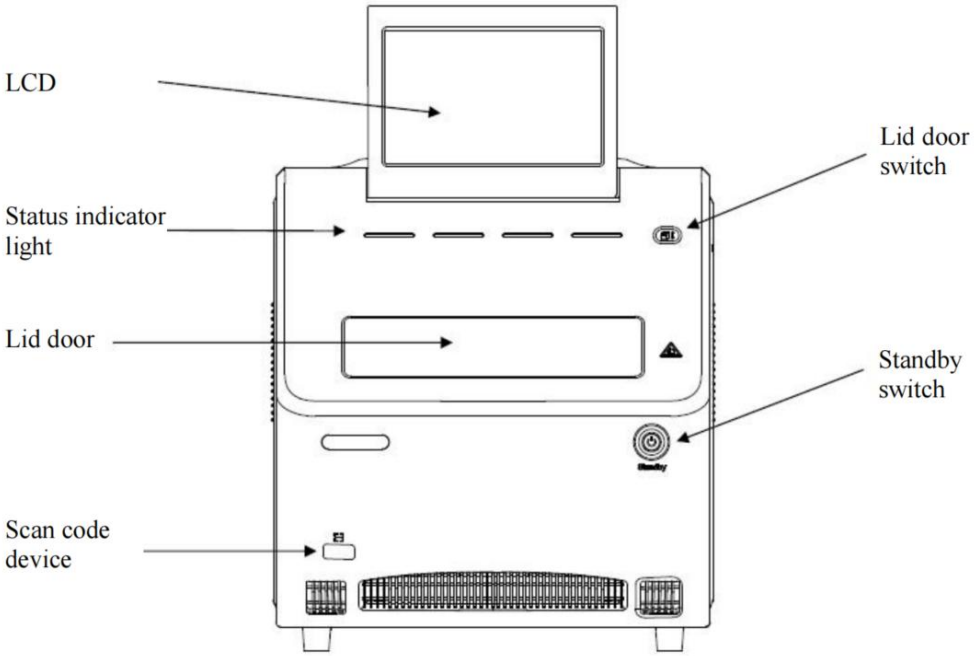


Fig. 4.18

Place the cassettes into the channel as shown in Fig. 4.19. Please verify the cassette orientation to ensure the QR code is facing upward, then press the "**Lid Door Switch**" to close the door.

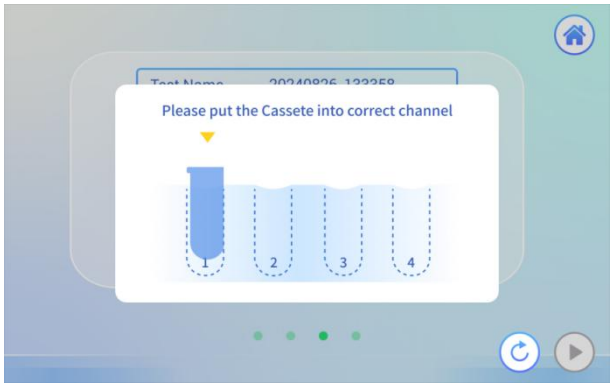


Fig. 4.19

After successful insertion, the interface will display as shown in Fig. 4.20. Verify that all parameters are correct, then click  to proceed to the next step.

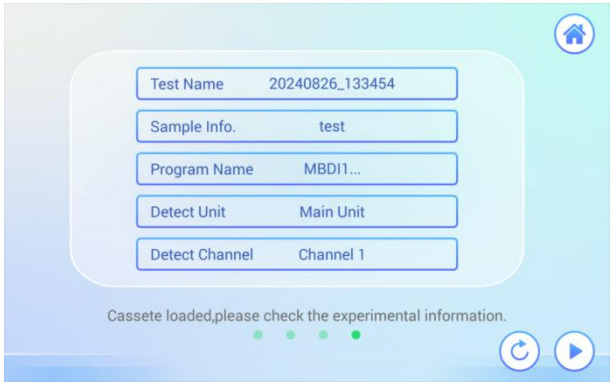


Fig. 4.20

Set the gain values according to the specific detection items by entering them into the corresponding input fields, as shown in Fig. 4.21. For the Mycoplasma DetectInnova test program, default parameters are preconfigured and do not require adjustment.

Simply click  to proceed to the following step.

Note: Gain parameter settings should only be modified by a qualified validation engineer upon successful completion of validation testing.

During routine mycoplasma test experimental procedures, adjustment of gain parameters is **not required**.

Do not alter the **"Gain Parameters"** within the settings menu unless authorized.

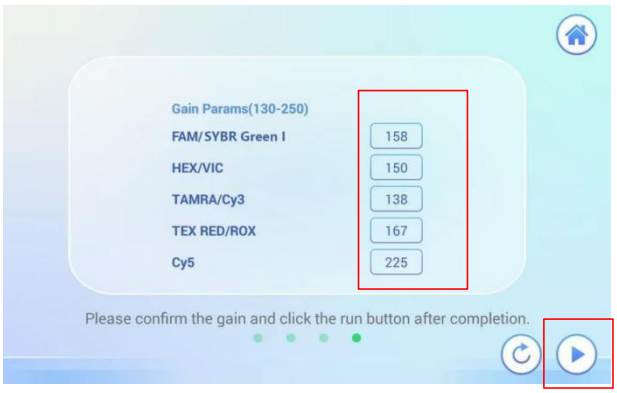


Fig. 4.21

4.5 Review Experimental Data

During test, the interface displays real-time fluorescence curves, temperature curves, running state, real-time data, and operational parameters, as shown in Fig. 4.22.

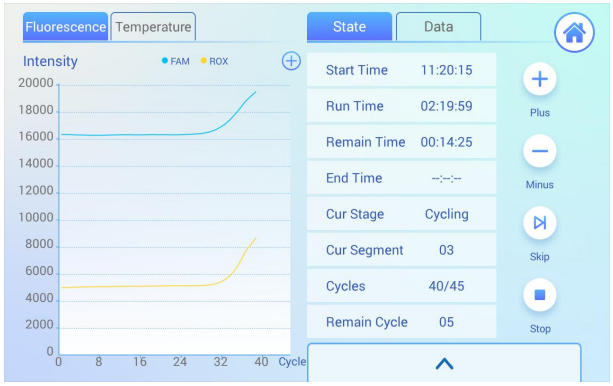


Fig. 4.22

The active channel, highlighted in blue, can be selected via the pull-down menu shown in Fig. 4.23.

Fig. 4.23

Experimental personnel can also monitor ongoing experiments via the "**Real-time Graphics**" on the main interface (Fig. 4.24).

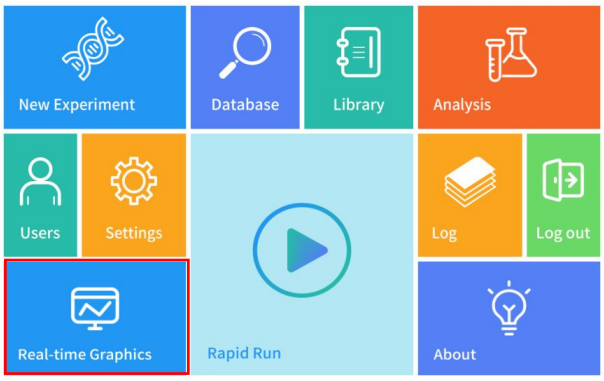


Fig. 4.24

If no program is running, the interface will appear as shown in Fig. 4.25. When a program is running, its real-time status will be displayed, as shown in Fig. 4.26.

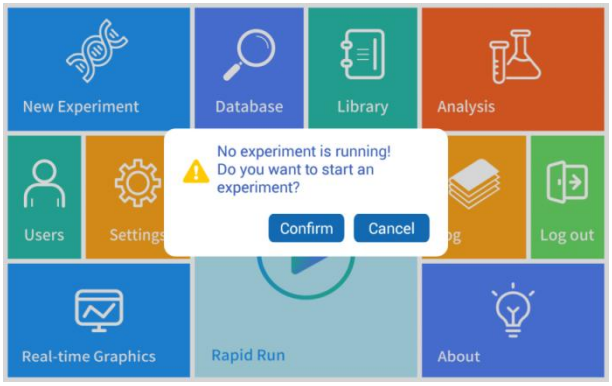


Fig. 4.25

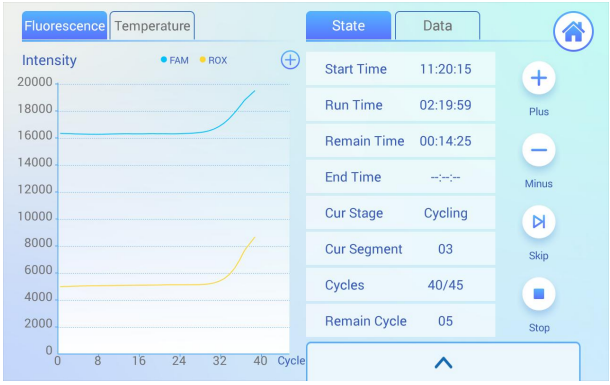


Fig. 4.26

4.6 Data Analysis

After the test is complete, click "**Data**" in the interface shown in Fig. 4.26, then select "**Analysis**" (See Fig. 4.27).

Fig. 4.27

Alternatively, you can click "**Analysis**" on the main interface (Fig. 4.28).

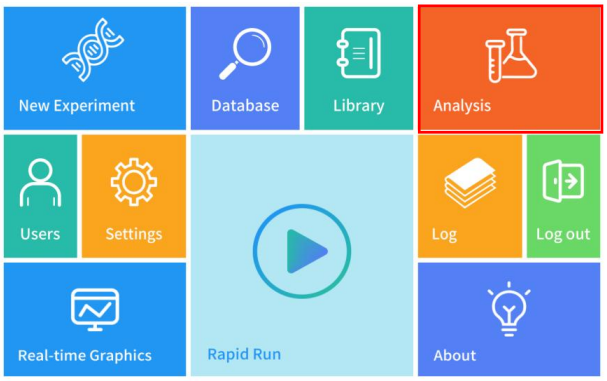


Fig. 4.28

Select the corresponding test results and initiate the analysis by clicking the button  located in the bottom-right corner, as shown in Fig. 4.29.

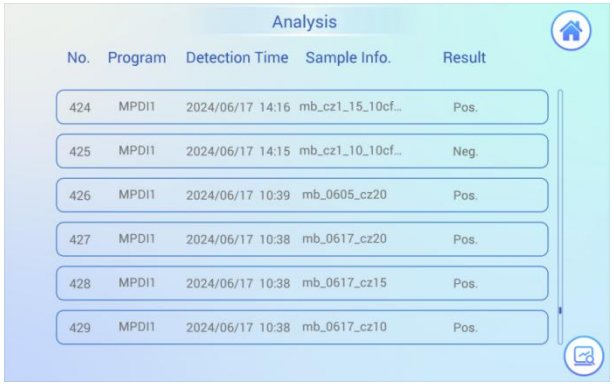


Fig. 4.29

In the data analysis interface, accept the automatic analysis option to view the corresponding curves and parameter settings, as shown in Fig. 4.30. Positive and negative results will be determined automatically.

Fig. 4.30

To perform manual analysis, please follow the steps outlined below:

Press the "**Manual**" button as shown in the Fig 4.27 to launch the manual analysis

interface (see Fig. 4.31). Adjust the analysis parameters as needed by modifying the designated input fields.

Fig. 4.31

After modifying and saving the parameters, the interface will update as shown in Fig 32.

Fig. 4.32

Note: Manual parameter changes do not overwrite the original data file; instead, a new file will be generated to preserve the integrity of the original data.

4.7 Data Review, Results, Export and Backup

Click "**Database**" on the main interface (see Fig. 4.33) to access the data management page. From this interface, users can review analytical results, print reports and export data.

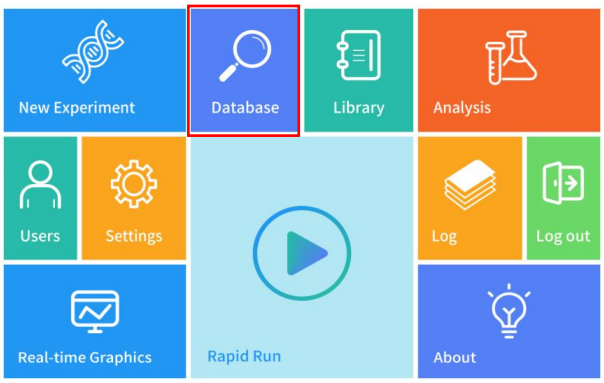


Fig. 4.33

4.7.1 Data Review

Click the button on the right side of each row as shown in Fig. 4.34 to view the details for the selected experiment (see Fig. 4.35).

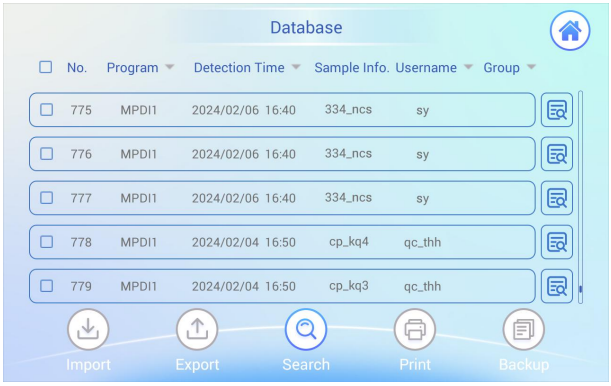


Fig. 4.34

Then Click the corresponding icon as shown in Fig. 4.35 to display the associated fluorescence curves and temperature curves as shown in Fig. 4.36.

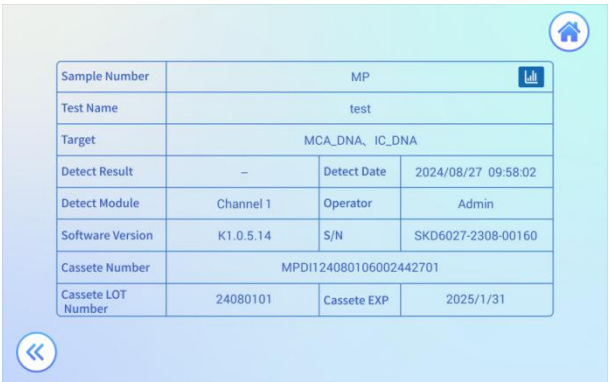


Fig. 4.35

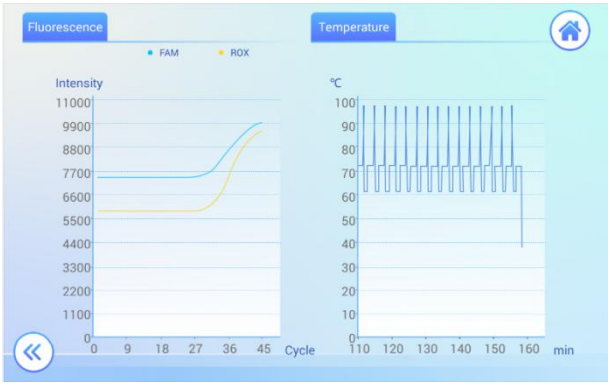


Fig. 4.36

4.7.2 Data Import, Export, Print and Backup

Only the user account with Administrator privileges is authorized to perform "**Import**" and "**Backup**" operations as shown in Fig. 4.37.

User accounts with Administrator, Manager, or Operator roles are authorized to:

- Connect a compatible thermal printer for direct result printing.
- Export experimental files using a USB flash drive.

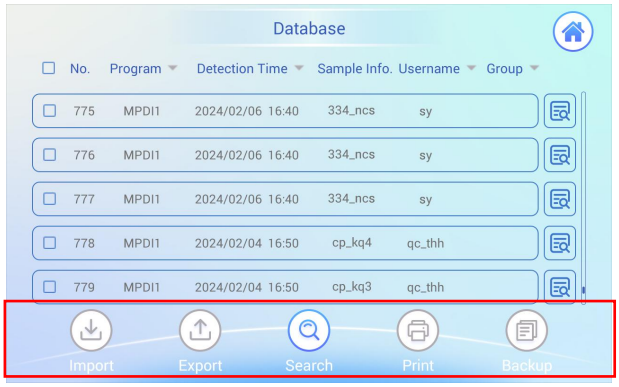


Fig. 4.37

Export: to export a selected file in PDF format, please follow the steps below.

1) Insert the USB Drive

Insert a compatible USB flash drive to "**USB A port**" located on the back panel of the device as shown in Fig. 4.38.

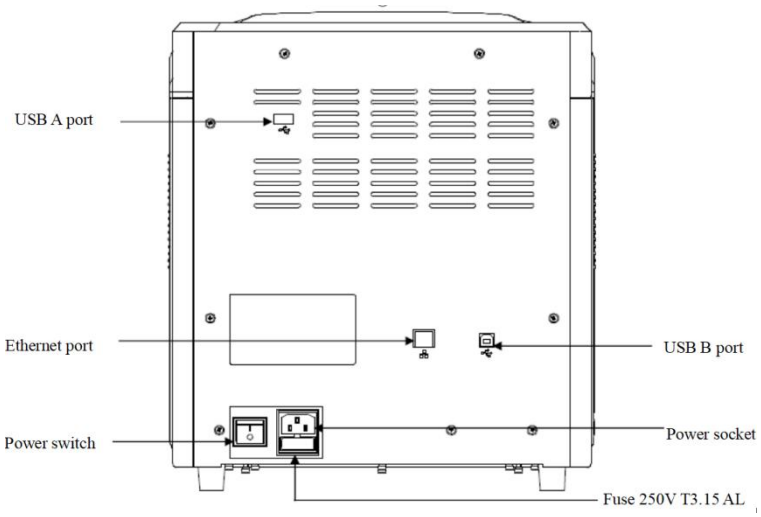


Fig. 4.38

2) Initiate Export

Select the file to be exported and click the "**Export**" button. You will be prompted to verify your credentials by entering your account name and password (see Fig. 4.39 and 4.40).

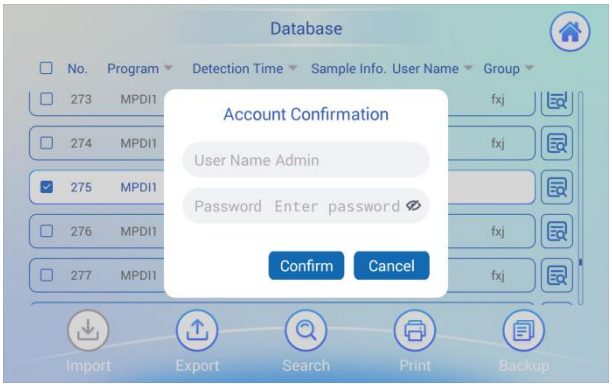


Fig. 4.39

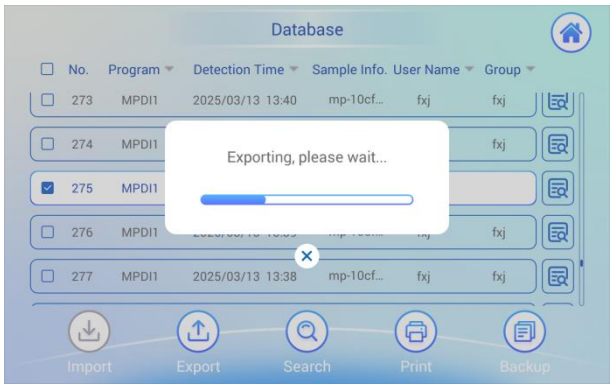


Fig. 4.40

3) Confirmation

After successful authentication, the export process will be initiated. Once completed, a confirmation message - "**Experimental data exported successfully!**" will appear (see Fig. 4.41).

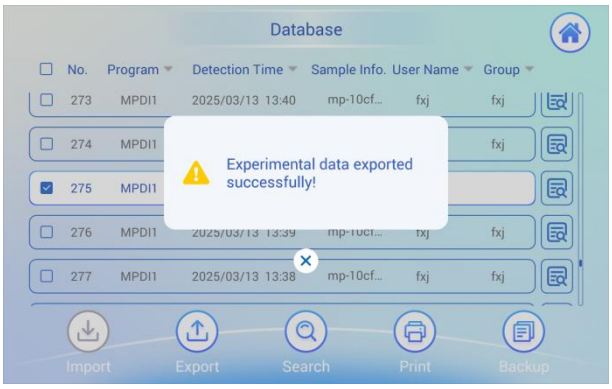
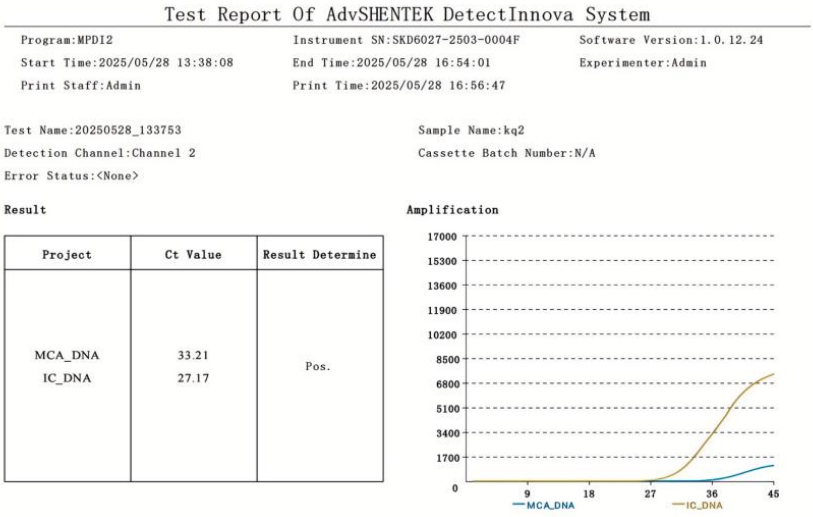


Fig. 4.41

4) Export Format

The exported report will be saved in PDF format, as shown in Fig. 4.42.



Test Report Of AdvSHENTEK DetectInnova System

Program:MPDI2 | Instrument SN:SKD6027-2503-0004F | Software Version:1.0.12.24
Start Time:2025/05/28 13:38:08 | End Time:2025/05/28 16:54:01 | Experimenter:Admin
Print Staff:Admin | Print Time:2025/05/28 16:56:47

Test Name:20250528_133753 | Sample Name:kq2
Detection Channel:Channel 2 | Cassette Batch Number:N/A
Error Status:<None>

Result

Project	Ct Value	Result Determine
MCA_DNA IC_DNA	33.21 27.17	Pos.

Amplification

.

Fig. 4.42

It is strongly recommended to assign a dedicated USB flash drive to each user account to ensure data integrity and traceability.

Note: The instrument is equipped with four USB flash drives (28GB storage capacity each) by default. For long-term data archiving, it is recommended to transfer files from the USB drives to a secure computer or external storage system.

For additional compatible flash drives, please contact the supplier.

Print: To print the selected file, follow the procedures below.

1) Initiate Printing

Select the target file and click the "**Print**" button. Please confirm the "**Print Settings**" as shown in Fig. 4.43.

Fig. 4.43

The system will prompt for user authentication by requesting an account name and password (see Fig. 4.44).

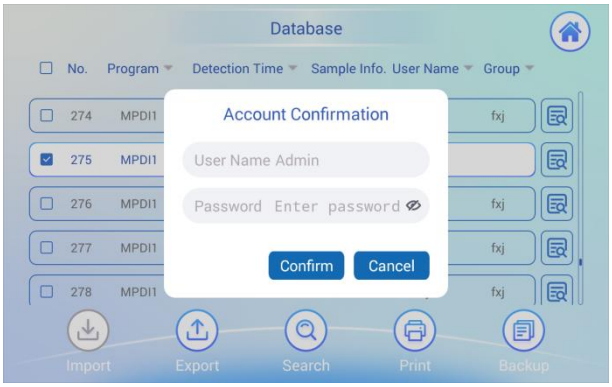


Fig. 4.44

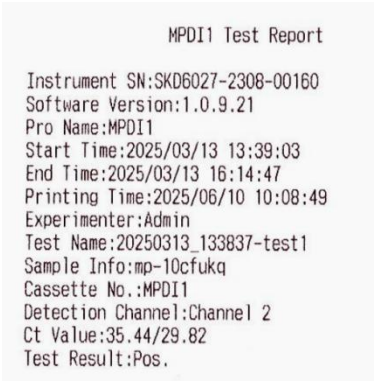
2) Execute Print Command

After inputting the required account and password, initiate the printing process. Once the printing process is complete, the following message will be displayed as shown in Fig. 4.45.

Fig. 4.45

3) Printed Output and Archival Recommendation

The thermal printer generates a simplified report, as shown in Fig. 4.46.



MPDI1 Test Report

Instrument SN:SKD6027-2308-00160
Software Version:1.0.9.21
Pro Name:MPDI1
Start Time:2025/03/13 13:39:03
End Time:2025/03/13 16:14:47
Printing Time:2025/06/10 10:08:49
Experimenter:Admin
Test Name:20250313_133837-test1
Sample Info:mp-10cfukq
Cassette No.:MPDI1
Detection Channel:Channel 2
Ct Value:35.44/29.82
Test Result:Pos.

Fig. 4.46

For compliance with data integrity and traceability requirements, it is strongly recommended to make a photocopy of the original printout and archive both the original and the copy within 24 hours of generation.

Backup: This function is restricted to the Administrator user account only. The data backup operation steps are described as below:

1) Insert the USB Drive

Insert a compatible USB flash drive to "**USB A port**" located on the back panel of the device as shown in Fig. 4.38.

2) Initiate backup

Only users with Administrator privileges are authorized to perform backup operations. To select all data for backup, use the scroll bar on the far right to navigate to the bottom of the file list. Click the checkbox next to "**No.**" in the upper left corner to

select all entries (see Fig. 4.47).

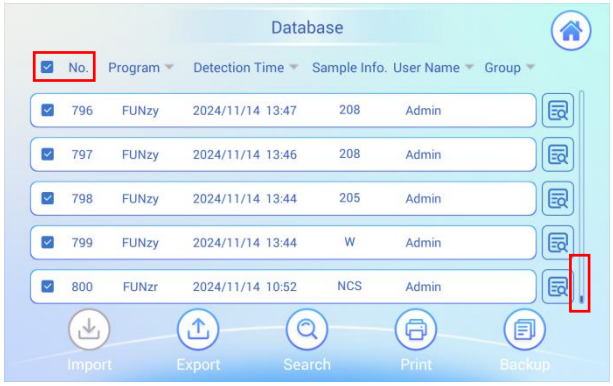


Fig. 4.47

Next, click the "**Backup**" button located at the bottom right of the screen (see Fig. 4.38). The system will prompt for user authentication, requiring the entry of a valid user name and password (see Fig. 4.48).

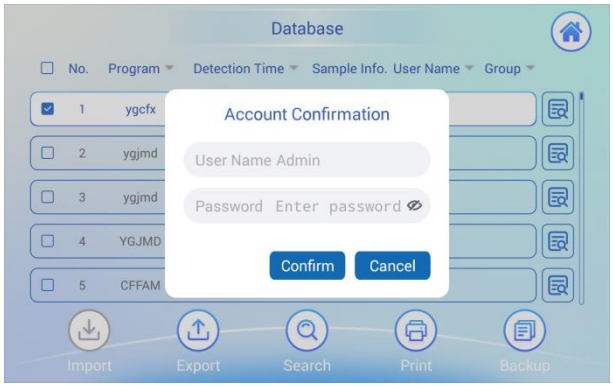


Fig. 4.48

3) Confirmation

After successful authentication, the backup process will be initiated. (See Fig. 4.49)

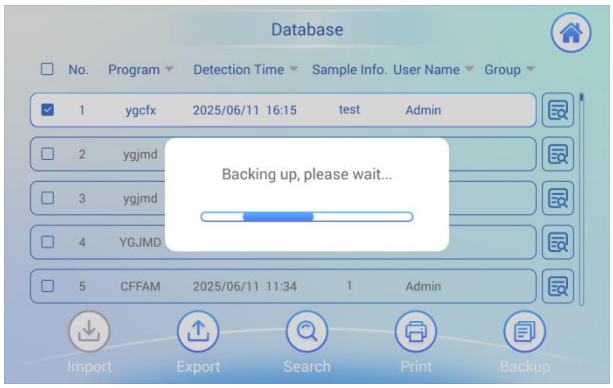


Fig. 4.49

Once completed, a confirmation message - "**Backup successful**" will appear (see Fig. 4.50).

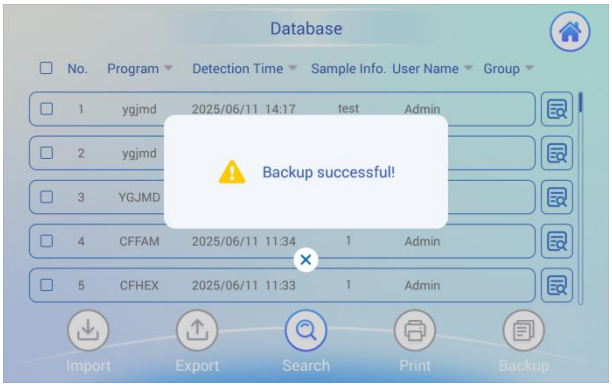


Fig. 4.50

4) Backup file format

Upon execution of the backup function, the system generates a database (DB) file containing all relevant instrument data.

Only the user account with authorized Administrator credentials are permitted to perform subsequent import operations using this backup file.

5) Frequency Recommendation

It is recommended to perform data backup after every 1,000 mycoplasma test runs to free up internal storage capacity (8 GB) and maintain optimal system performance.

Failure to perform regular backups may lead to excessive data accumulation, which could negatively impact the instrument's operational stability.

It is strongly recommended to assign a dedicated USB flash drive to each user account to ensure data integrity and traceability.

Note: The instrument is equipped with four USB flash drives (28GB storage capacity each) by default. For long-term data archiving, it is recommended to transfer files from the USB drives to a secure computer or external storage system.

For additional compatible flash drives, please contact the supplier.

4.8 Log Export and Backup

To check the log file, click '**Log**' on the main interface (Fig. 4.51) to access the log page, where you can view or export the logs.

Administrator, Manager and Operator accounts are authorized to export usage records permitted within their authorized access level.

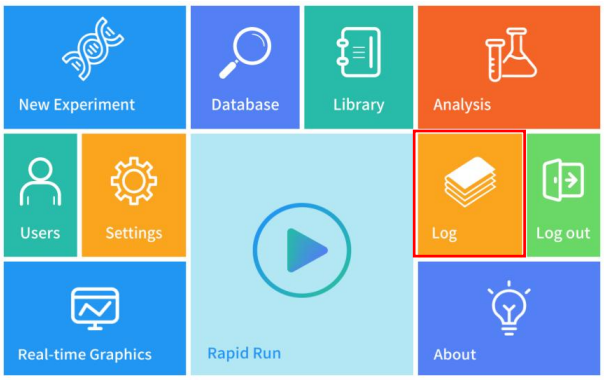


Fig. 4.51

Utilize the filtering and sorting functions to identify the desired log entries. Select specific logs by checking the corresponding checkbox ☐ as shown in Fig. 4.52.

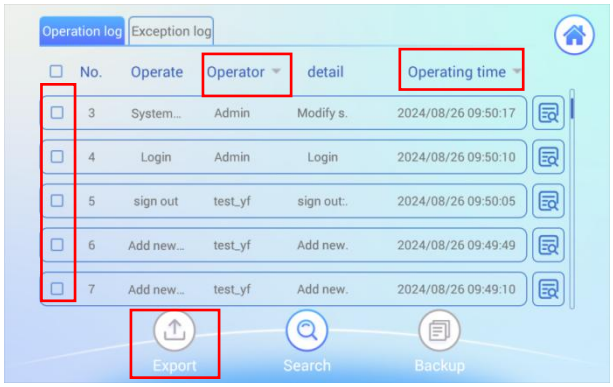


Fig. 4.52

Before initiating the export process, insert a compatible USB flash drive to "**USB A port**" located on the back panel of the device (see Fig. 4.38). Once the USB drive is properly connected, select the desired logs for export as shown in Fig 4.53.

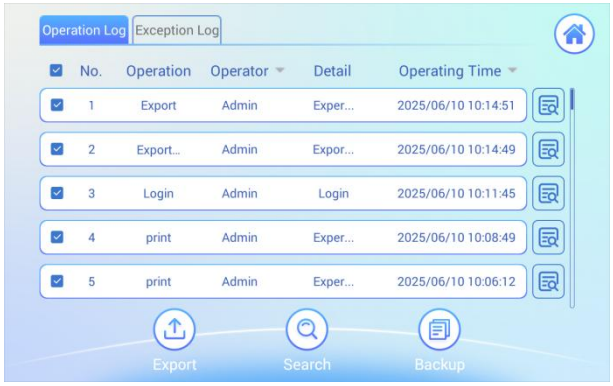


Fig. 4.53

After clicking "**Export**", a user authentication prompt will appear as shown in Fig. 4.54.

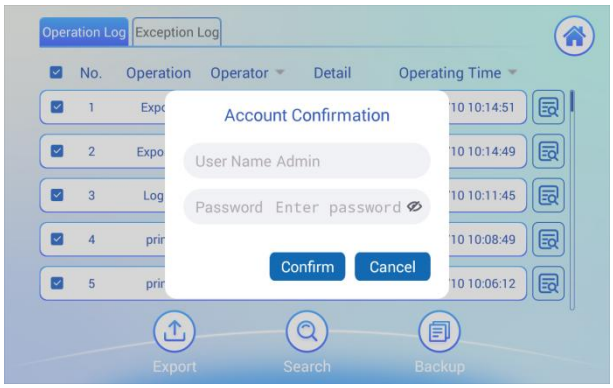


Fig. 4.54

Upon entering a valid username and password, the export function will be initiated as shown in Fig 4.55. Once completed, a confirmation message - "**Instrument log exported successfully!**" will appear (see Fig. 4.56).

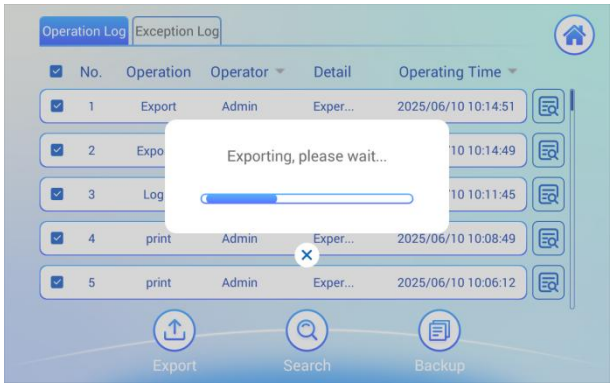


Fig. 4.55

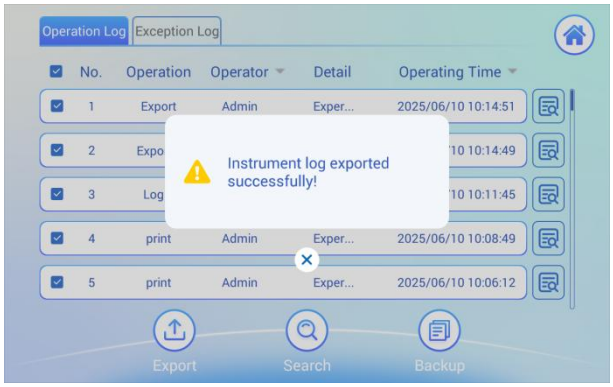


Fig. 4.56

The exported report is generated in the format as shown in Fig. 4.57.

AdvSHENTEK DetectInnova System

Operation Log

No.	Operation	Operator	Detail	Operating Time	Version
1	Login	Admin	Login	2025/06/04 10:22:53	1.0.11.23
2	Export	Admin	Instrument log exported successfully data:2025-06-03 09-50-49	2025/06/03 09:50:50	1.0.11.23
3	Export	Sql	Experimental data exported successfully data:2025-05-30 13-55-28	2025/05/30 13:55:42	1.0.11.23

Fig. 4.57

It is strongly recommended to assign a dedicated USB flash drive to each user account to ensure data integrity and traceability.

Note: The instrument is equipped with four USB flash drives (28GB storage capacity each) by default. For long-term data archiving, it is recommended to transfer files from the USB drives to a secure computer or external storage system.

For additional compatible flash drives, please contact the supplier.

Only the user account with Administrator privileges are authorized to perform log backup operations. The log backup process is intended to systematically archive system log data, thereby ensuring data integrity and enabling effective recovery in the event of system malfunction, data corruption, or loss.

For detailed procedural guidance, refer to the standardized workflow outlined in the Database Backup section.

5. Operation Guide

Click "**About**" on the main interface (see Fig. 5.1) to view information such as the software version, instrument model, instrument serial number, and the operation guide, as shown in Fig. 5.2.

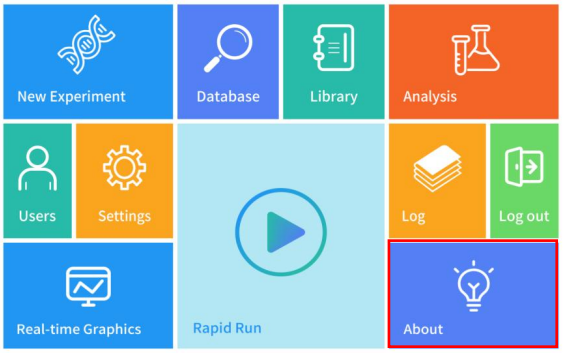


Fig. 5.1

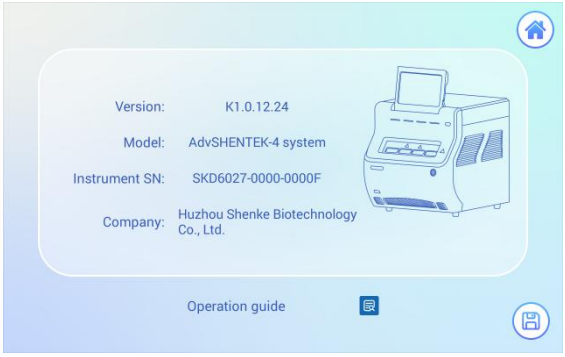


Fig. 5.2

Click the button (see Fig. 5.2) to access the quick operation guide animation as shown in Fig. 5.3.

Fig. 5.3

6. Precautions

Remove the cassette immediately after the test is completed, seal it in a biological waste bag, and place it in the designated place. Do not open the cover.

Do not use if the cassette is damp or the lid seal is damaged.

Each cassette is single-use only, and must not be reused.

If further inquiries, please contact our technical support (info@shentekbio.com).

Support & Contact

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