Product Manual for TVS Pro4 -Animal Pathogen Analyzers

Changzhou Trendi Medical Technology Co., Ltd

Catalogue

FCC Caution

§15.19 Labelling requirements.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

§15.105 Information to the user.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated withminimu m distance 20cm between the radiator & your body.

Annotation

The TMS Pro4 POCT Molecular Diagnosis Analyzer is a new equipment developed independently by Changzhou Trendi Medical Technology Co., Ltd. (hereinafter referred to as "the Company"), which employs constant temperature LAMP reaction spectroscopy detection.

We ensure that the TMS Pro4 POCT Molecular Diagnosis Analyzer you are using has undergone comprehensive testing and meets the requirements outlined in the instruction manual.

It is imperative that users adhere to the guidance and safety warnings provided in this user manual, as the Company will not be held responsible for any issues arising from failure to do so.

Regarding the built-in software: Any software associated with this product is provided to customers as a service. The software is essential for the operation of the instrument, and the Company retains ownership of its copyright while granting customers the right to use it.

Software modifications: To enhance operational performance and reliability, the Company reserves the right to modify the functionality or design of the software. All intellectual property rights related to the modified version belong to the Company.

Liability: The Company disclaims responsibility for any direct, indirect, or incidental losses resulting from compliance with instructions or incorrect use of the TMS Pro4 POCT Molecular Diagnosis Analyzer. Only authorized technical personnel or their representatives may inspect or provide any parts of the instrument. The Company shall not be held liable for any losses resulting from unauthorized disassembly or replacement of the instrument. Our responsibility is limited to repairing machines and replacing spare parts. We do not bear responsibility for interpreting experimental results or the consequences of applying these results. Please read the manual carefully before using the TMS Pro4 System to ensure optimal experimental outcomes.

1. Safety Instructions

1.1 Operation and Usage Requirements

Please carefully read the manual before conducting experiments with the TMS Pro4 POCT Molecular Diagnosis Analyzer to ensure compliance with safety guidelines.

The instrument's nameplate contains essential information such as the manufacturer's name, product name and model, equipment number, power input, service telephone number, and address. This information is marked on the instrument's packaging.

As this instrument involves both mechanical and electrical components, failure to adhere strictly to the operating manual may pose risks such as electric shock or physical injury.

Always adhere strictly to the safety instructions provided with the instrument.

Replacement parts and accessories required for the instrument must be obtained solely from the Company or its authorized agents.

Do not open the instrument's access door during operation.

The operating conditions of the instrument, according to the product's technical standards, include temperatures between 0 ℃ and 40 ℃, with relative humidity not exceeding 80%.

When handling toxic, corrosive, or infectious substances, always wear safety goggles and gloves.

Exercise caution when dealing with highly purified nucleic acids or any biological substances, following local safety protocols for handling and disposal to prevent laboratory contamination. In case of spills or leaks, disinfect immediately.

Damaged instruments must be returned to the manufacturer for repair, and the instrument's surface must be disinfected before repair.

1.2 Electrical Safety

The TMS Pro4 POCT Molecular Diagnosis Analyzer has a Class I electrical safety design protection level (IEC).

To prevent electric shock hazards, the instrument must be connected to a three-core grounded socket conforming to safety standards. Before connecting the instrument to the power cord, ensure that the AC power supply's voltage and frequency match those required by the instrument. Always ensure the power is off during power cord connections.

Avoid touching the power switch and power cord with wet hands.

Do not remove the power cord while the instrument is still powered on.

Avoid contact with the instrument's thermal surface and refrain from cleaning the instrument while it is powered on.

If the instrument will be disconnected for an extended period, ensure it is turned off.

2. Overview

2.1 Product name

The TMS Pro4 POCT Molecular Diagnosis Analyzer (EQ-MS400; YQ-MS400) is a portable constant temperature LAMP detector with four channels and eight detection fluxes.

2.2 Model number and version number

Model: EQ-MS400; YQ-MS400;

Version Number: EQ-MS400-001; YQ-MS400-001.

2.3 System parameters

Specification	**Value**
Machine Net Weight (g)	2000
Machine Size	250mm * 150mm * 80mm (length * width * height)
Indicator	TFT color monitor with touch screen, pixel 800X480
Detection Flux	8
Detection Wavelength	400nm to 800nm
Operating Ambient Temperature	0 ℃ to 40 ℃
Storage Temperature	-20 ℃ to 50 ℃
Working Humidity	<80% RH, no condensation
Operational Environment	Not suitable for use in explosive environments.
WIFI	2.4G, supports IEEE 802.11 b/g/n protocol
PDA	Bluetooth 5, Bluetooth mesh, and wifi, shared antenna
Input Voltage	176VAC to 245VAC, adapter output 12VDC 5A

2.4 Structural composition

The TMS Pro4 POCT Molecular Diagnosis Analyzer mainly consists of the control system, power system, photoelectric system, module components, housing components, and software components.

2.5 Product characteristics

Small volume, lightweight, simple shape, easy to carry.

Built-in HD capacitive screen PDA with touch screen operation for simple and fast operation.

Simple and intuitive software guidance for easy initiation of constant temperature rapid detection experiments.

2.6 Intended use

The product, based on constant temperature LAMP technology, is used with supporting microfluidic chips for qualitative inspection of target samples.

2.7 Application field

Includes but is not limited to basic scientific research, pathogen and microbial testing, genetic testing, etc.

2.8 Technical Services

The seller provides online training and technical support services to the buyer's customers.

2.9 Performance requirements

Appearance requirements:

The instrument should have a smooth and uniform color, free from edges, burrs, cracks, scratches, or other defects.

Screen-printed characters and marks should be correct and clear.

Mechanical components:

Fasteners should be securely connected without loosening, and moving parts should operate smoothly without any sticking.

2.10 Product Lifespan

The shelf life of the product is 5 years, determined based on failure data analysis of key components. Users are responsible for maintaining, repairing, and following product specifications. If the product can still maintain basic safety and effectiveness after maintenance, it can continue to be used normally.

3. Instructions for Instrument Installation and Use

The TMS Pro4 POCT Molecular Diagnosis Analyzer is installed and debugged by customers. Follow the steps below.

3.1 Transportation and storage

Transportation of the products shall adhere to the requirements of the order contract. Use the original packaging during transportation to prevent damage to the instrument.

Store the product in its packaging at an ambient temperature of -20 ℃ to 50 ℃, with relative humidity not exceeding 85%, and ensure that the environment is free from corrosive gases.

Pack the instrument horizontally in the carton and surround it with foam for buffering to minimize vibration effects during transportation.

Logistics vehicles should have rain and snow protection to prevent goods from getting wet. Instrument packaging boxes should be placed smoothly in the truck box without stacking, inversion, or tilting.

Upon arrival, designated personnel should receive and accept the goods. Unauthorized dismantling of the packing box and instruments is strictly prohibited.

The storage area for instruments should be clean, tidy, ventilated, and moisture-proof.

3.2 Unboxing

The product is packed in a carton filled with shock-absorbing foam. Upon unpacking, check for any damage to the received items.

If the outer packaging is damaged during transportation, do not use it and contact the seller immediately.

Cut the tape and remove the foam from the instrument.

Check if the provided accessories are complete according to the packing list (found in the instruction manual).

If the instrument or accessories are damaged or lost during transport, inform the freight company personnel and our customer service immediately.

3.3 List of items

Check if the items in the TMS Pro4 POCT Molecular Diagnosis Analyzer package match the following list:

Name	Quantity
The EQ-MS 400 / YQ-M S 400 host	1
DC power supply (12VDC / 3A)	1
Operating instruction	1
Factory inspection report	1

Contact the seller immediately if there are any missing or damaged items.

3.4 Instrument working environment

Place the TMS Pro4 POCT Molecular Diagnosis Analyzer on a horizontal test bench to ensure stability.

Operational Conditions:

Ambient temperature: 0 ℃ to 40 ℃ (if not maintained, use an air conditioner).

Humidity: Maintain humidity at 80% to prevent condensation.

Storage Conditions:

Ambient temperature: -20 ℃ to 50 ℃

Relative humidity: 85%

Avoid placing the instrument in areas with severe temperature changes, excessive humidity, high temperature, or direct sunlight, as it may affect performance.

Do not share the same power socket with other high-power devices to avoid voltage fluctuations.

Connect the adapter to the instrument and plug it into the power socket. Ensure the power supply voltage meets the instrument's requirements:

Voltage: Use the instrument's DC power supply with a voltage range of 176VAC to 245VAC.

The TMS Pro4 POCT Molecular Diagnosis Analyzer is easy to operate. Refer to the detailed procedures below for instructions.

3.5 Instrument connection mode

The power adapter of the TMS Pro4 POCT Molecular Diagnosis Analyzer is connected to the instrument on one end and to the socket on the other end, ensuring proper grounding. The power interface and USB port are located on the left side of the device (as shown in the figure).

Connect the power adapter to the designated interface, and plug the other end into a 220V AC power supply. Ensure that part of the power supply is effectively grounded, and position the power socket where operators can easily plug and unplug the power cord.

3.6 Instrument operation protection

Some samples processed by the TMS Pro4 POCT Molecular Diagnosis Analyzer may contain infectious agents, requiring careful handling in accordance with relevant safety regulations. Operators should wear safety glasses and two pairs of latex gloves, as well as laboratory attire. If sample processing requires a specific environment, it should be conducted accordingly.

The designated responsible person, such as the lab manager, must ensure that instrument operators receive proper training and avoid direct contact with infectious sources.

After operating the instrument, dispose of sample waste in compliance with local, national, provincial, and municipal sanitation and safety regulations. Infectious waste should be autoclaved before being transferred to the designated site.

3.7 Precautions

Do not open the chamber door during testing!

When performing detection, insert the power adapter into the power input port!

4. Instrument operation

4.1 Boot

After powering on, the boot screen will be displayed. Allow approximately 5 seconds for instrument initialization before transitioning to the main page. Refer to Figure 1 for the boot screen.

Figure 1: The boot screen

4.2 Main page

The main page provides options for New Detection, Historical Data, and System Settings. Refer to Figure 2 for the main control page.

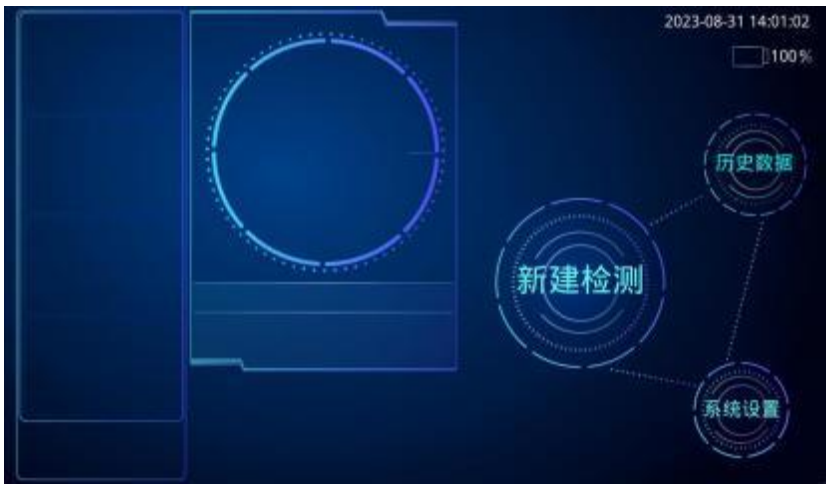

Figure 2: Main control page

The leftmost module is the task pane, displaying user-established tasks. The middle module is the work pane, where relevant information will be displayed. In the upper right corner, system time and instrument power are displayed.

4.3 New Detection

Click the "New Task" icon on the main control interface to access the detection task creation interface.

4.3.1 Creating a New Detection Task

Based on the detection requirements, users can click to select the corresponding test type tab. The selected tab will be highlighted in green and displayed in the upper left box. On the right side, users should indicate the quantity of chip reagent cards to be prepared for testing.

After selecting the detection type, click the "OK" button to complete the establishment of the detection task and enter the operation guide interface. If you wish to abandon the detection task, you can also click "Back" to cancel. Refer to Figure 3.

Figure 3: Detection task creation interface

4.3.2 Operation Guide Interface

The operation guide interface homepage directs the user to insert the test card into the specified chip channel.

If the user encounters an error in establishing the detection task, they can click the "Back" button to return to the previous interface and re-establish the task. Users can also click on "Change Channel" as needed to insert into other channel ports. Refer to Figure 4.

After following the guide, the screen will prompt successful operation and automatically switch to the main interface. Refer to Figure 5.

Figure 4: Operation guide interface (default start status)

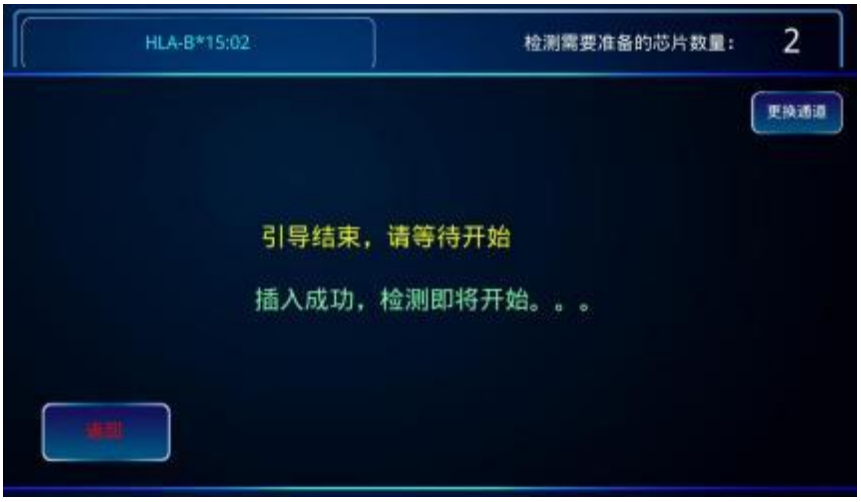

Figure 5: Operation guide interface (successful operation status)

4.3.3 Task Status Viewing

To view the current status of tasks, refer to the task pane located on the left side of the main interface. Within the task card, you can preview details such as the chip channel number, detection type, and task status, which includes:

Processing: Indicates that the task has commenced.

Done: Indicates that the task has been established but not initiated.

Clicking on a task card highlights it and displays additional test time information in the right work pane. When selecting a task card labeled "Detection," the work pane will switch to show the progress of the current task. A circular progress bar around the detection time indicates task progress, with a

rotating circle signifying that the task is in progress. Additionally, a progress bar below the task card will be visible (Figure 6).

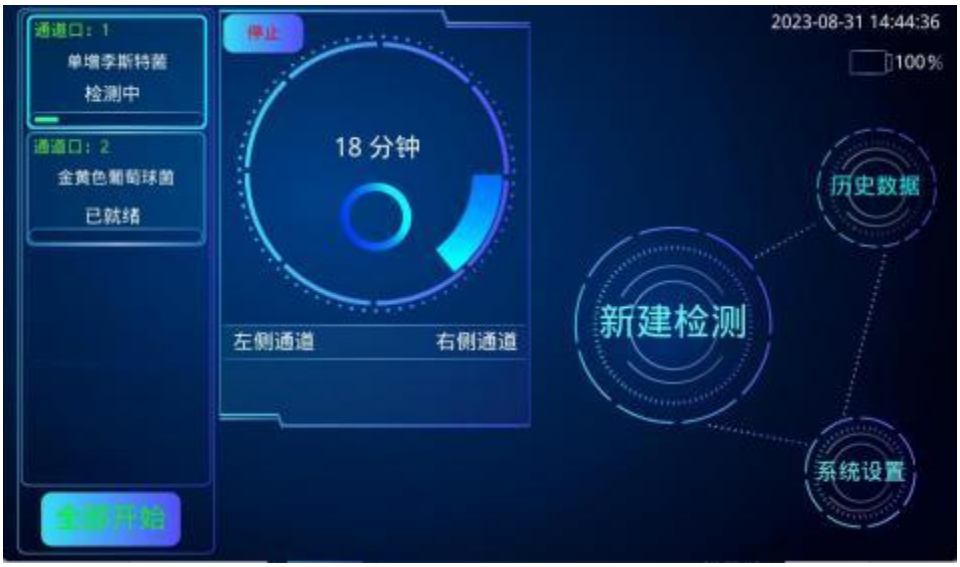

Figure 6: The Work Pane Corresponding to the "Detection" Task Card

4.3.4 Task Control

Users can initiate the highlighted task by clicking the "Start" button in the work pane or directly on the task window (Figure 7). To start all tasks labeled "Ready," use the "Start All" button located under the grid (Figure 7).

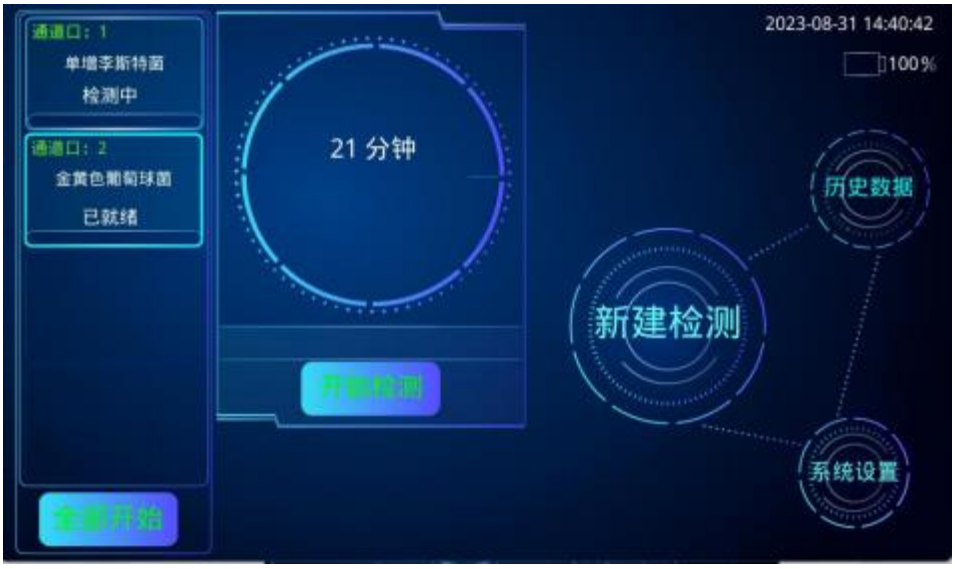

Figure 7: Task Status Displayed on the Main Interface

If a task needs to be stopped, users can click the "Stop" button on the upper left of the work pane to complete the cancellation operation. Alternatively, removing the chip reagent card from the corresponding channel port of the task and waiting for the system prompt box for 5 seconds will also confirm the cancellation of the task.

4.3.5 Viewing Task Results

Upon completion of a task, the corresponding test results will be displayed below the task card and work pane. Positive results are presented in red font, while negatives are shown in blue.
For single-flux detection units, the results of the left and right flux of the chip will be displayed separately under the "Left" and "Right" sections of the work pane, with the task card indicating left and right as well. See Figure 8 for an illustration of the results displayed. The results of multi-diagnostic detection are depicted in Figure 9.

Figure 8. Displayed Results

Figure 9. Results of the multi-throughput task at the main interface

4.4 System Settings

Navigate to "System Settings" on the main interface to access the settings interface (illustrated in Figure 10).

Figure 10: Setup Interface Graphic Menu

The "Gear Icon" located at the upper left corner facilitates system parameter adjustments, requiring administrator authorization for configuring heating time and temperature.

The "Text Graphic" situated in the upper right corner is for language settings. Currently, this model primarily supports Chinese and English languages.

The "Clock Drawing" at the lower left corner allows for system time adjustments.

The "WIFI Icon" in the lower right corner represents the WIFI connection interface, providing access to view the device's WIFI hotspot name and password.

4.5 Historical Data Interface

Select "Data" on the main interface to access the historical data viewing interface, as depicted in Figure 11.

The historical data interface showcases details of completed tasks, with the most recent task displayed at the top.

Figure 11: Historical Data Interface

Information includes automatically compiled test numbers based on the historical detection sequence, along with test type, test time, and test results. Users can navigate through the data using the "PageUp" and "PageDown" options and return to the main page by clicking "Back."

4.6 Anomaly Handling

When the following situations occur, the prompt box notifies the user:

4.6.1 Insufficient Remaining Chip Channel Ports for a New Detection Task, as illustrated in Figure 12.

Figure 12: Prompt box indicating insufficient remaining chip channel ports

In this scenario, users should follow the guidance provided in red letters to remove the chip reagent card from the channel slot.

4.6.2 Task not started, but the Test Card is Accidentally Removed or Not Inserted Properly, as depicted in Figure 13.

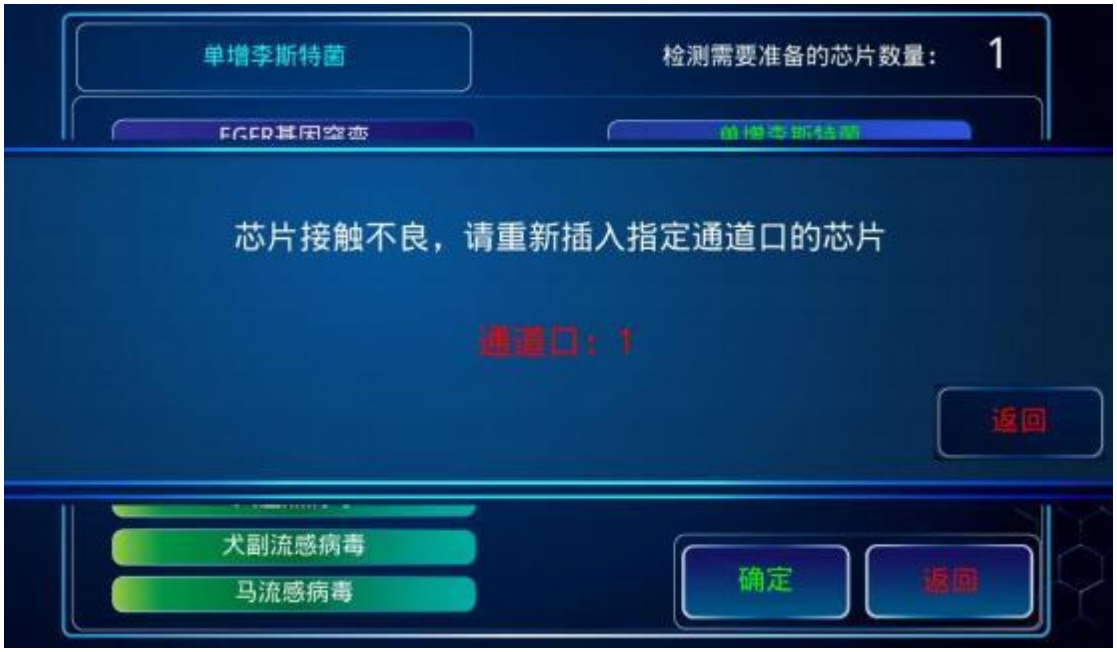

Figure 13: Notification box for undetected chip

Process Steps:

Reinsert the test card into the designated channel marked in red.

Click "Back" to confirm the prompt, which will automatically cancel the task corresponding to the channel.

4.6.3 Test Card Accidentally Pulled Out During Task Execution, as shown in Figure 14.

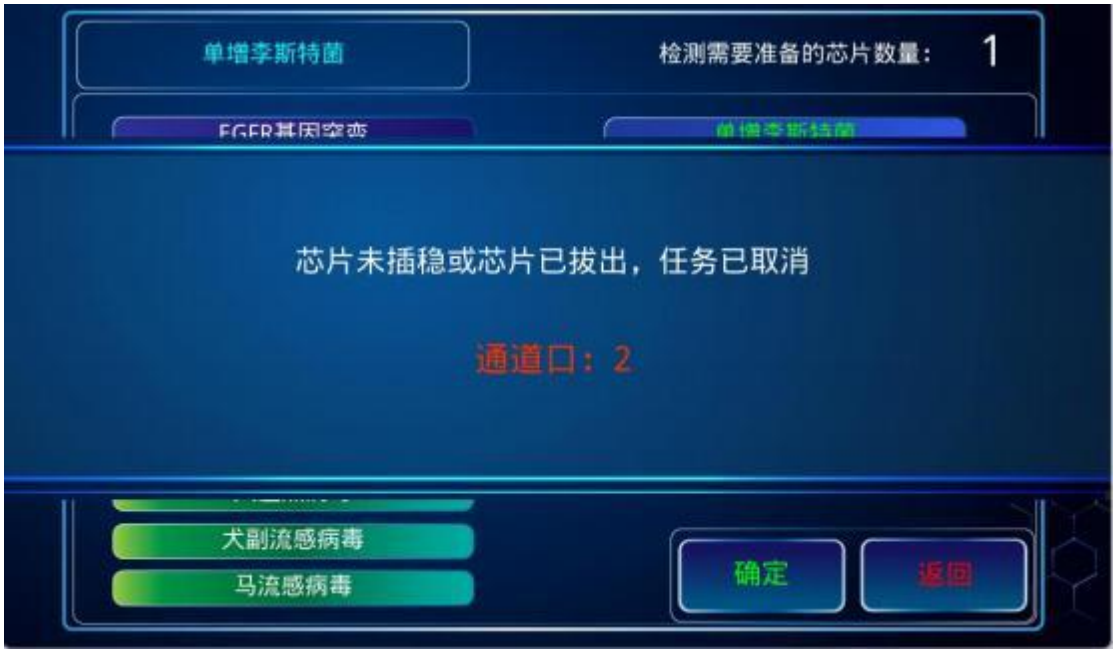

Figure 14: Prompt box for Special Case 3

In this case, users should click on the screen to confirm.

5. Instrument maintenance

5.1 Instrument cleaning

The surface of the instrument is cleaned.

The surface of the instrument should be scrubbed regularly with a soft cloth and a small amount of water, and dry the instrument after cleaning. If any reagent leaks in the instrument, wipe clean with a soft cloth and 75% alcohol.

5.2 Instrument protecting

Do not switch the instrument frequently.

Non-original maintenance personnel are prohibited to open the instrument without authorization.

5.3 Precautions

Service number: +86-519-88868582

6. Analysis and elimination of common faults

6.1 Common faults

Fault Phenomenon	Disposal Method
Can't boot	1. Check whether the power supply is connected normally; 2. Check whether the power socket is powered on; 3. Ensure the instrument switch is pressed down.

6.2 Maintenance records

Date	Issue	Resolution

7. Related Documents

Number	Name	Version Number	Remarks

8. Quality records

Number	Name	Version Number	Remarks

9. Version Update

Version Number	Added / Modified Clause Number	Revise Content	Date Changed	Author