Fully Automated Pathology Staining System

User Manual

PA-3600

REF W948

Guangzhou Wondfo Biotech Co., Ltd

No.8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China

Tel:(+86)400-830-8768

Website: en.wondfo.com

E-mail: sales@wondfo.com.cn

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Notice for Use

Thank you for choosing the Fully Automated Pathology Staining System (hereinafter referred to as the instrument or stainer) of Guangzhou Wondfo Biotech Co., Ltd. This product adopts the principle of specific binding of antigen and antibody to make the antibody-labeled chromogenic reagent (fluorescein, enzyme, metal ion, isotope) visualize a color through chemical reaction and then determine the antigens (polypeptides and proteins) in tissue cells. The localization, qualitative and relative quantitative researches on such antigens would be carried out. The product is used with our reagents from our series for sample processing before pathological analysis (deparaffinization, antigen retrieval, staining as well as fluorescence in situ hybridization (FISH) detection pretreatment and post-hybridization wash).

This manual is suitable for Fully Automated Pathology Staining System, which elaborately describes the instrument, including its installation, daily staining operation, maintenance and precautions. The operation steps with graphs are convenient for your use.

In order to remind the operator to avoid potential danger or instrument damage or wrong staining results, we have given the following safety warning signs depending on the hazard degree of operation:

⚠Warning	Indicating a potential hazard, and if the operation steps are not followed, a hazard will be caused to the operator and environment.
⚠Caution	Emphasizing the operating method to be followed to avoid possible hazard or instrument damage and potential wrong staining results.
⚠Notice	Emphasizing important information.

If any unexpected failure occurs when you are using the instrument, please refer to the appendix "*Chapter 9 Troubleshooting Guide*" to solve it, or refer to "*Chapter*

10 Contact Information" in this manual to call Wondfo for technical support service.

Anyone who may use, preserve, move and maintain the instrument should read this manual carefully. The best performance of the instrument can be ensured only if you completely follow the user manual published by the manufacturer.

Chapter 1 Basic Product Information

Product name: Fully Automated Pathology Staining System

PA-3600

REF W948

General introduction of the instrument:

The slide position is 3*12, and there are three groups in total, which can process a maximum of 36 slides.

The staining module is a component that can load a slide, and each staining module controls the temperature individually.

The solid cover diaphragm can be inserted into the staining module, and it can form a liquid cover film with slides after the angle is changed.

A slide is a standard microscope slide with a specimen attached to its surface for being processed by the instrument. The slide size applicable to all commercially available slides for immunohistochemical use.

The reagent rack is used to hold reagent bottles. There are a total of 40 placement locations to hold these bottles. The reagent bottles can be scanned by RFID reader to determine the reagent locations.

The wash basins are two black plastic components behind the reagent rack area, which serve as a wash station for Teflon™-coated reagent probes and are used to wash the probes when each new reagent is used in case of cross-contamination.

The buffer solution bottle is collected with 3.5 L buffer solution, which is available online.

The X-axis mechanism can move the Y-axis robot arm from left to right.

The Y-axis mechanism is a robot arm that extends from the front of mechanism to the rear, supporting the Z-axis head component. The Y-axis robot arm can move from right to left.

The Z-axis head component is located on the Y-axis robot arm and can move from front to back. The Z-axis head consists of two independent Z-axes:

Z1 is used to immobilize probes that draw reagents from the bottle and injects it into a chamber. This probe can also provide cleaning solution to the chamber online;

Z2 is used to immobilize probes that draw reagents and cleaning solution from a chamber.

1.1 Intended Use

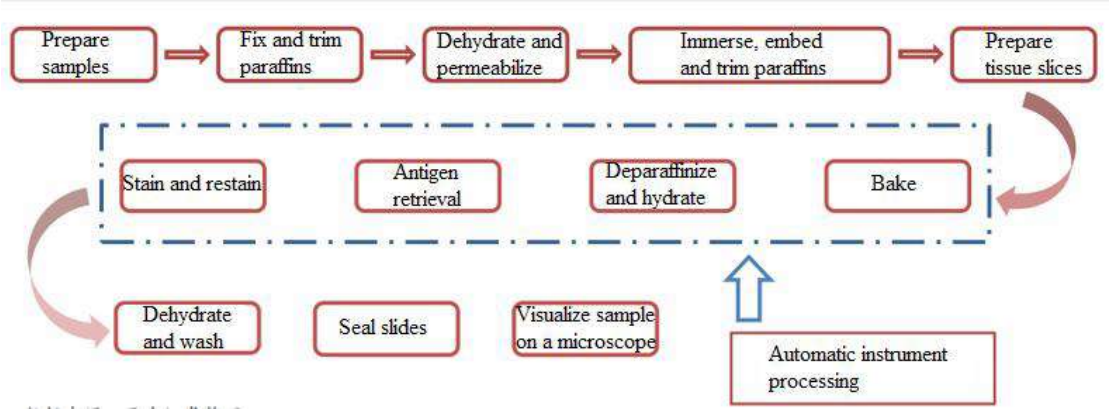
It is used for sample processing before pathological analysis (deparaffinization, antigen retrieval, staining as well as FISH detection pretreatment and post-hybridization wash).

Hospital pathology department/third-party pathology laboratory/scientific research unit, only trained professional pathologists or technical personnel to operate and use .

1.2 Working Principles

Instrument Automation Section: Users require to prepare slices and reagents needed for staining in advance and launch a start command to carry out the staining procedure after confirming that these have been completed. The stainer will be based on an established process to finish deparaffinization, antigen retrieval, staining, binding of antigen and antibody as well as FISH detection pretreatment, hybridization reaction and post-hybridization wash. In the process, after the waste liquid needle absorbs the waste liquid left over from the previous step, the sample addition needle adds pre-absorbed reagent to corresponding slide through the sample addition port of solid cover diaphragm. The staining module form a liquid cover film between the solid cover diaphragm and the slide surface after adding reagents when the angle of solid cover diaphragm has been changed, and the mixing and shaking steps are being conducted to make reagents more uniform by virtue of wave mixing technology. Each staining independently controls the staining temperature according to different reaction conditions. The solid cover diaphragm can effectively protect reagents from evaporating in case of dry slides. After the whole staining process ends, users only need to pull out the staining module to lift the solid cover diaphragm and remove the

slide, and move to the next step (turning blue again, dehydrating, sealing the slides, etc.).



1.3 System Accessories

After unpacking, please count and inspect accessories according to the following table. If you find any missing or damaged components, please contact Guangzhou Wondfo Biotech Co., Ltd. or your local sales representative in time. For detailed contact information, please refer to *Chapter 10 Contact Information* in this manual.

No.	Content	Configuration	Unit	Quantity	Image
1	Fully Automated Pathology Staining System	Standard	Set	1	/
2	Power Cable	Standard	Set	1	
3	Data Cable	Standard	Set	1	

4	Float Sensor	Standard	Set	2	
5	Tube Clamp	Standard	Set	2	
6	Reference Tissue Slide	Standard	N/A	1	
7	7mL Reagent Vial(with RFID tag)	Standard	N/A	20	
8	Waste Liquid Container Base	Standard	N/A	1	
9	Waste Liquid Container	Standard	N/A	2	

10	Waste Liquid Tube - Blue	Standard	N/A	1	
11	Waste Liquid Tube - Black	Standard	N/A	1	
12	Printer	Standard	Set	1	
13	Label	Standard	coil	1	
14	Ribbon	Standard	N/A	1	
15	Computer Host	Standard	Set	1	
16	Monitor	Standard	Set	1	
17	Accessories Packing	Optional	Copy	1	/

	List				
18	User Manual	Standard	Copy	1	/
19	Quick Operation Instruction for Use	Standard	Copy	1	/
20	Packing List	Standard	Copy	1	/
21	Quality Guarantee	Standard	Copy	1	/
22	Certificate of Approval	Standard	Copy	1	/
23	Warranty Card	Standard	Copy	1	/

1.4 Main Structure

1.4.1 Appearance of instrument

(1) Front view (top lid closed)

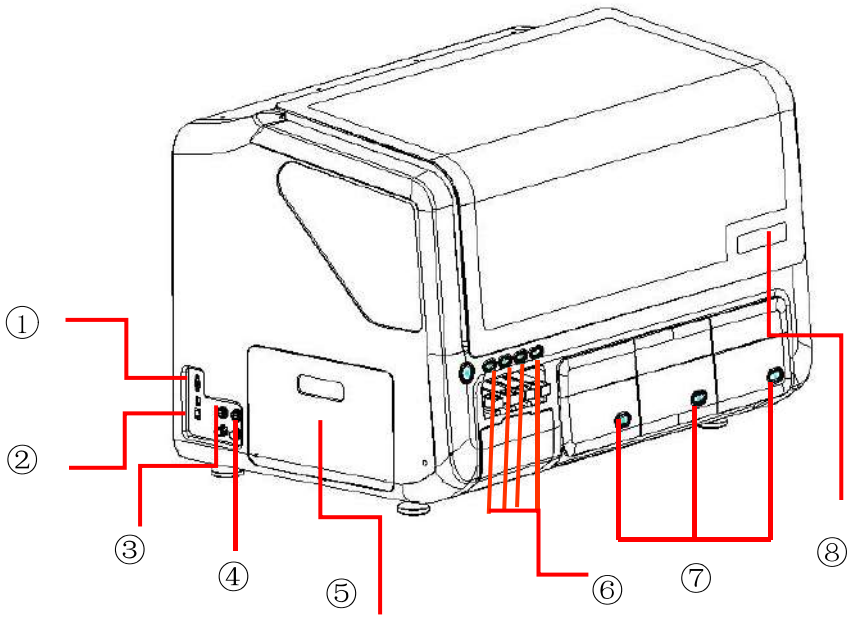


Figure 1-16 Front View

No.	Project	Function

①	Serial Port	Interface to connect serial port.
②	Ethernet Interface	It is used to connect computers, routers, switches and other devices to achieve data transmission
③	Liquid Level Alarm Interface of Waste Liquid Container	It is used to alert and monitor the filling of waste liquid in waste liquid container
④	Waste Liquid Pipeline Interface	It is used to connect the waste liquid pipeline and the waste liquid channel in the machine
⑤	Pump Repair Window	It is used to observe the running state of the pump and facilitate maintenance, replacement and disassembly
⑥	Reagent Rack Unlock Button	It is used to protect the test tube rack during operation and replace it at leisure
⑦	Push-pull Module Unlock Button	It is used to protect the status of the locked module during the operation of the instrument and pull out the module when it is idle
⑧	Countdown Display	Indicates the expected time when the test will end

(2) Side view (top lid flipped open)

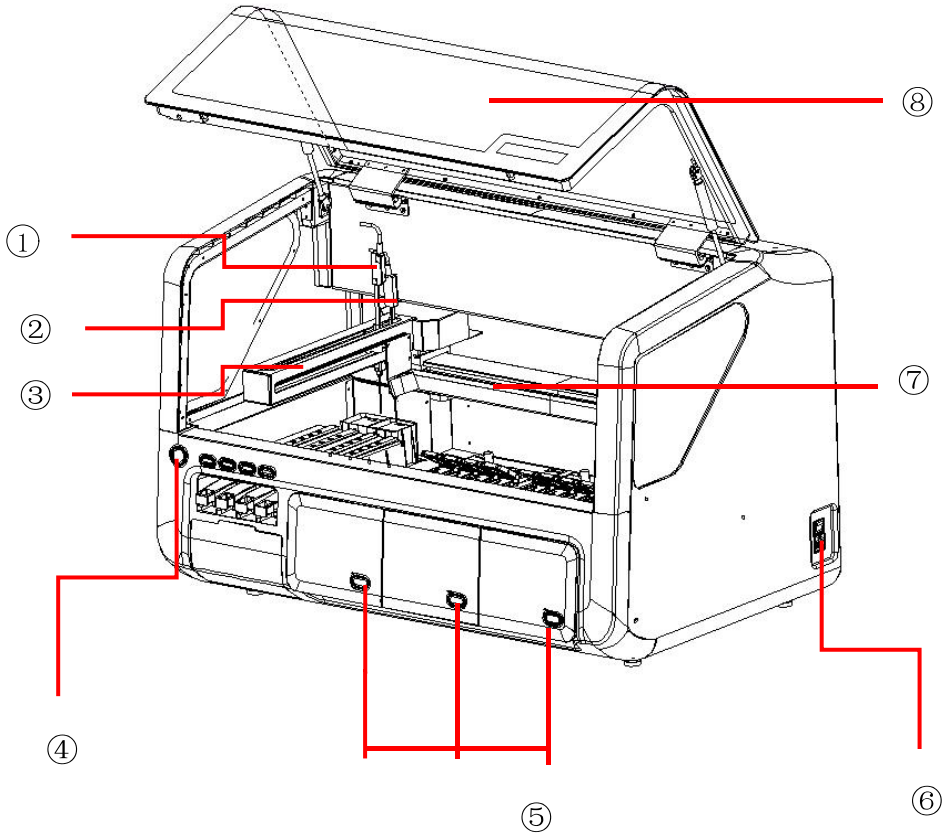


Figure 1-17 Side View

No.	Project	Function
①	Z1 Axis	The needle is moving vertically up and down
②	Z2 Axis	The liquid waste needle moves vertically up and down
③	Y Axis	The needle on the scrap mechanical arm moves forward and backward
④	Instrument Switch Button	Equipment on/off start control
⑤	Push-pull Module Unlock Button	Prompts the switch status of the drawer module
⑥	Main Power Switch	External power switches that control the entire device
⑦	X axis	The whole robot arm is guided by horizontal motion
⑧	Top lip	Facilitate the observation and maintenance of the internal module a

		nd protect the operator from the mo vement of the robot arm

(3) Schematic diagram for back panel

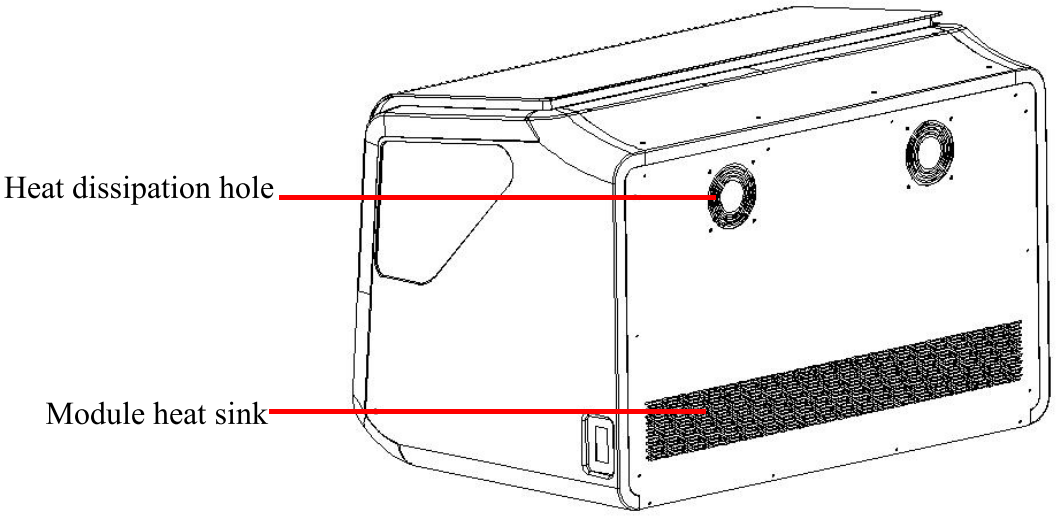


Figure 1-18 Back Panel

1.4.2 Structure and composition

It consists of antigen retrieval module, staining module and slide processing module. The staining module is composed of staining and controls; antigen retrieval module includes control system based on the principle of thermal repair and chemical repair; and slide processing module comprises slide processing platform (including robot arm and heating module), system control center and tube road system.

1.4.3 Operating software interface

The instrument display screen is divided into four areas, as shown in the following figure:

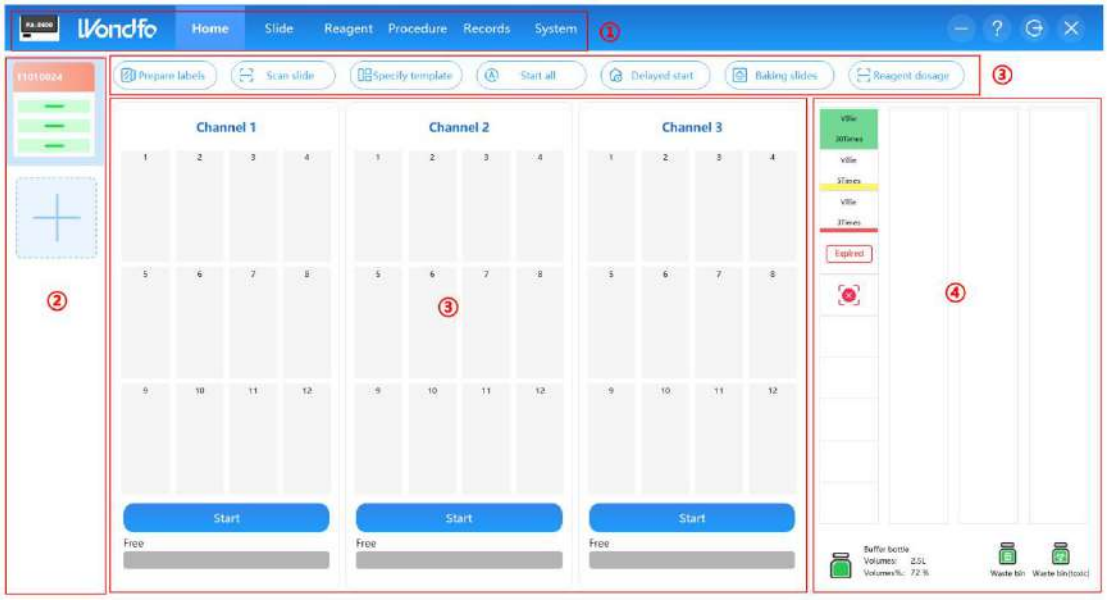


Figure 1-19 Main Interface

①Top navigation bar with navigation menu items for system function interface

②Instrument status area which shows the connection status

③Window display area and staining operation area

④Status display for accessories, reagent, buffer solution, waste liquid

1.5 Basic Parameters and Service Conditions

1.5.1 Main technical index

1.5.1.1 Staining module heating components

Each staining module is temperature-controlled independently on a single slide.

The temperature for staining module heating components is controlled between: 37 ℃~101 ℃.

The temperature accuracy is ±2 ℃, and its fluctuation is less than 0.5 ℃.

1.5.1.2 Added reagent volume

The added reagent volume is controlled between: 100 μL~500 μL.

The accuracy of added reagent volume is ≤3%, and its variable coefficient (the CV) is ≤5%.

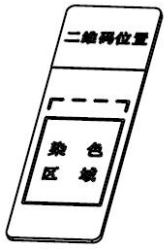
1.5.2 Instrument function

1. It is used for sample processing before pathological analysis, with fully automatic

procedures such as deparaffinization, antigen retrieval, staining and FISH detection pretreatment, and post-hybridization wash.

2. The Fully Automated Pathology Staining System has a total of 36 staining positions.
3. The Fully Automated Pathology Staining System has a total of 40 reagent positions.
4. It is equipped with slide QR code scanning system.
5. The software interface can display the buffer solution volume in real time.
6. It performs a function to sort and store the waste liquid.
7. It is equipped with patient information management system.
8. It is equipped with reagent information management system.

Specification	
Model No.	PA-3600
Instrument Dimensions	1050 *690* 736 mm (L*W*H)
Weight	126 kg
Noise Decibel	Working State ≤85 dB; Standby State ≤65 dB
Slides Loading Capacity	Maximum loading slides: 36 standard microscope slides (slide size: 25 mm * 75 mm * 1 mm); slide racks (12 slides) that have finished running can be loaded into slides again.
Reagent Loading Capacity	Maximum loading reagents: 40 kinds which are divided into 4 groups and are added freely.
Sample Type	Paraffin sections, cryosections, cytology specimens, puncture specimens and tissue chip
Stained region	The area where the reagent will be used on the slide.

	 20mm* 33mm
Operating System	
Operating Environment	Windows 10 64-bit operating system
Interface	one serial port and one Ethernet interface;
Print	support thermal wax printer

1.6 Cyber Security Instructions

1.6.1 Operating environment（Minimum software operating environment and configuration requirements）

(1) Hardware configuration:

Memory: 8GB DDR4, Frequency 2400 MHz;

Hard Disk: 512GB SSD M.2 2280 NVMe.

(2) Software environment: Windows 10 64-bit operating system

(3) Network conditions: support a wired network.

1.6.2 Software version

View the software version, **[System] - [Help] - [About]**, the information is as shown in the figure:

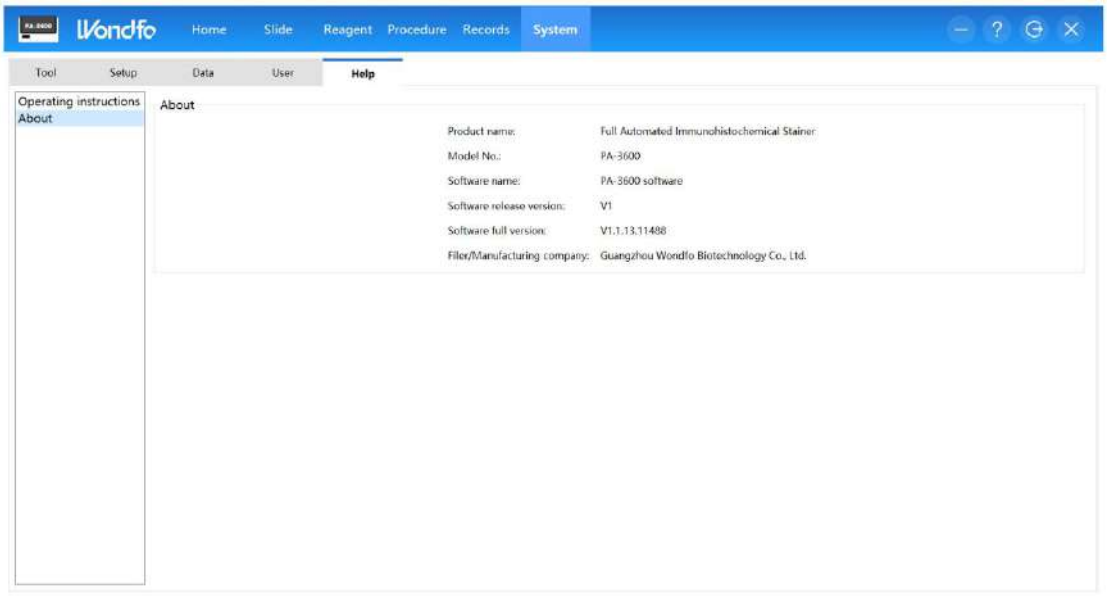


Figure 1-9 Software Version

- Software name: PA-3600 software
- Software model: PA-3600
- Software release version: V1
- Rules for naming full version of software: VA.B.C.D;

V represents the prefix of software version number, i.e., the abbreviation for Version;

A represents major version number, which means software version update for important enhancements;

B represents minor version number, which means software version update for general enhancements;

C represents version number about patching, which means software update for corrective actions;

D represents compilation version number.

1.6.3 Safe software

It is run on the Windows operating system and does not require relevant anti-virus software. If necessary, please contact Wondfo to solve the problem.

1.6.4 Data and instrument interface

1.6.4.1 Data interface

The data interface of the instrument includes a network port and a serial interface. The network port can connect the instrument to the computer, and the serial interface is used by manufacturer to debug the instrument but users cannot get access to it.

(1) The wired network is mainly transmitted by the protocol as specified by the manufacturer.

(2) The serial interface includes: transmission protocol: RS232, data format: a baud rate of 115200; but the parity check, RTS/CTS protocol, 8 bit of data and stop bit are not available.

1.6.4.2 LIS data connection

1. Internet connection

a) Click **[System] - [Setup] - [Server Settings]**.

b) Set communication protocol, automatic upload, network type, target computer IP, port, IP type, IP address, subnet mask and gateway.

c) Click **[OK]**

d) Set internet protocol version 4 (TCP/IPv4) for the computer network and set its IP address, subnet mask and gateway.

e) Use the TCP debugging assistant in the computer to check whether the LIS system is connected.

f) If it is a third-party LIS system, the server IP and port number can be directly filled in according to information provided by the third-party, and no settings is needed in the computer.

1.6.5 User access control mechanism

Click **[System] – [User]** to perform operations for user management.

(1) User type: general user, admin user;

(2) User identification: determine user authority in terms of defined user names after

booting up the computer, and disable and enable operating processes based on user authority when using the software;

(3) General users have the right to perform a staining procedure; the admins can also add or delete general users in addition to performing a staining procedure.

The specific authority is included as follows:

Grade	User	Duty	Authority Authentication Means	Password	Remark
1	General User	Perform daily staining procedure, view and manage historical data	General users with a maximum of 100 users	The password can be changed	General users don't have the authority to manage users.
2	admin	The admin who has the authority as same as general users, should also manage the user information.	admin	The default password is (123456), which can be modified.	The admin also has the authority as same as general users.

1.6.6 Software update

This software runs independently in the Windows operating system, please contact Wondfo to solve the software update problems.

1.6.7 Software application installation

Irrelevant software applications are forbidden to be installed in the computer in case of crashing or data loss. If you need to install software applications, please contact Wondfo to solve the software update problems.

Chapter 2 Instrument Installation

Please use this instrument under the environmental conditions as required by the instrument (see the section *1.5 Basic Parameters and Service Conditions*). The ambient temperature to use supporting reagents should be subject to the instructions.

2.1 Package

After receiving the instrument, if you found there are breakages on outer packaging or the instrument is obviously damaged, please contact the carrier in time and claim for compensation according to the degree of damage, and please contact your supplier at the same time. After confirming that the instrument is well packaged, please move to next steps to remove the packaging materials and install the instrument.

2.2 Unpacking

Carefully remove the instrument and accessories from the box, and preserve the packing material for future transport or storage.

Count the instrument accessories according to the packing list, and check whether the instrument and accessories are mechanically damaged. If there is any problem with the instrument and accessories, please restore the packaging and contact your supplier immediately.

When transporting the instrument, multiple people should stand on both sides of the instrument and support the instrument with both hands at the middle and rear bottom panels where labels HANDLE WITH CARE are attached. Direct force exerted on the front housing is not allowed in order to avoid damage to the instrument.

2.3 Installation Requirements

2.3.1 Space requirements

The instrument should be placed on a stable and clean indoor operating table, avoiding direct sunlight and dust. Do not place the instrument in a position where it is not convenient to disconnect it if necessary. The back panels should be kept at least

15 cm and the two sides should be at least 10 cm from the wall, so as to ensure the instrument to connect cables and pipes.

⚠Caution:

The instrument should be placed on a horizontal operating table. Do not place the instrument in a position that is prone to falling or in other positions causing collisions, and do not place heavy objects on the instrument.

2.3.2 Environmental requirements

Normal working environment conditions

Ambient temperature: 18 ℃～30 ℃;

Relative humidity: 20% to 70% (non-condensing);

Altitude: less than 2,000 meters;

Rated voltage: AC100 V~240 V;

Input power: 900 VA;

Frequency: 50 Hz/60 Hz;

Lighting conditions: avoid direct exposure to strong light;

Use environment: the instrument should be used in an environment with good ground connection, which requires avoiding dust, volatile acid gas, vibration and strong electromagnetic interference.

2.3.3 Power requirements

The instrument requiresAC100 V~240 V, rated input power 900 VA. Do not place the instrument near centrifuges, ultrasonic wave apparatus, X-ray machines, magnetic resonance imaging and other places that emit strong electromagnetic waves.

⚠Warning:

A well-grounded power socket on a separate circuit must be used, and the neutral-to-ground voltage of power socket is not higher than 0.5 V.

2.3.4 Precautions for installation and debugging

(1) Please select a suitable installation site based on requirements in environment, power and space.

(2) The connection between the cable and the instrument must be safe, firm and in good contact. After confirming that the connection is correct, it can be turned on for use.

(3) Non-professional maintenance personnel is prohibited from opening the case in case of damage to the internal structure.

(4) Frequent power outages can seriously degrade instrument performance and reliability, and users should address this issue before using the instrument, such as by installing an uninterruptible power supply (UPS).

(5) Please do not damage the power cord, and hold the plug and pull it gently when unplugging.

(6) Please do not hit the instrument with force.

(7) If the local ambient temperature is below zero, please place the instrument at room temperature for 24 hours after receiving it before debugging.

(8) Instrument installation must be carried out by after-sales service personnel authorized by Wondfo, and users are not allowed to install without permission to avoid damaging the instrument.

2.4 Cable Connection

Figure 2-1 Power Cable Connection

Figure 2-2 Data Cable Connection

Connect the power cords and communication cables of a computer host, monitor, and printer.

Ensure that the power switch on the back panel of the instrument is in a state of turn-off (O), take out the power cord to plug one end into the power switch and plug the other end into a socket or power strip. The power cable connection is shown in Figure 2-1.

Take out the network cable and plug both ends into the Ethernet ports at the back of left panel of instrument and at the computer host respectively. The network cable connection is shown in Figure 2-2.

⚠Warning:

Before connecting the power cord, it is required to ensure that the power supply meets the requirements of instrument.

2.5 Installation of keyboard and mouse

(1) Carefully take out a keyboard, mouse pad and mouse from their packages.

(2) Carefully insert the keyboard cable plug into any socket with  marked on computer host.

(3) Carefully insert the mouse cable plug into any socket with  marked on computer host.

(4) The keyboard and mouse can be placed wherever you find it convenient to use.

2.6 Printer installation

(1) Carefully take out the printer from its package.

(2) Carefully insert the printer cable plug into a USB socket of the computer.

(3) The printer can be placed wherever you find it convenient to use.

(4) For specific installation and use of printer, please refer to the user manual of printer.

2.7 Connections of waste liquid pipeline and float sensor

The waste liquid pipeline and float sensor shall be connected according to Figure 2-3. The pipes are divided into two groups, including innocuous waste liquid pipe (blue) and hazardous waste liquid pipe (black). No. 2 and 3 are connected from innocuous waste liquid bottle, and No. 5 and 6 are from hazardous waste liquid bottle. It is necessary to ensure that the pipes of both innocuous and hazardous waste liquid, and float sensors are connected with the waste liquid containers correspondingly.

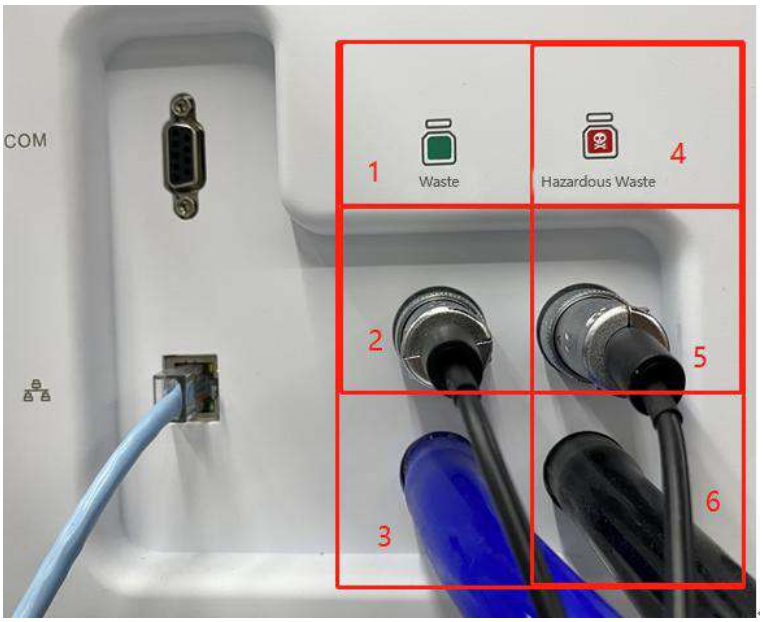


Figure 2-3 Connections of waste liquid pipes and float sensor

1. Identification for innocuous waste liquid bottle
2. Liquid level monitoring interface for innocuous waste liquid bottle
3. Pipe connected to innocuous waste liquid bottle (blue pipe)
4. Identification for hazardous waste liquid bottle
5. Liquid level monitoring interface for hazardous waste liquid bottle
6. Pipe connected to hazardous waste liquid bottle (black pipe)

Chapter 3 Instrument Operating Instructions

This chapter explains the most basic operations for you by introducing a complete staining practice in detail. Reading relevant information will help you quickly learn how to use this instrument.

3.1 Preparation Before Starting Up

Before each startup, an operator should carry out inspections in accordance with the following steps, checking that:

(1) The cleaning needle and reagent needle are not bent or damaged.

(2) There is no obstacle within range where the robot arm is traveling.

(3) The instrument power cord, network cable, communication cable, pipes, float sensor, etc. are properly connected, and the pipes are not bent.

(4) The keyboard, mouse, printer and other instrument are connected reliably.

In case of any instrument errors, please refer to *Chapter 9 Troubleshooting Guide* for settlement, or refer to *Chapter 8 Repair, Transportation and Destruction* to contact Wondfo for technical support.

3.2 Startup

Before a startup, please check whether the instrument is in a state which meets the startup requirements according to *3.1 Preparations before starting up*.

Please turn on the main power switch on the right side of the instrument, and then press the startup button on the left side of front panel of host computer to start up the instrument. The host machine will perform automatic initialization, and each module will automatically reset. After the initialization is completed, please start up the computer, and enter an account and password to log in. After confirming that the host computer is normally connected, you can start to perform the operations.

Prepare slides to be stained.

Reagents are contained in instrument reagent bottles and placed in reagent racks.

For operations, see *3.6.1 Installing or replenishing reagents*.

Correctly install a solid cover diaphragm on a slide. For operations, see *6.1.3 Instructions for installing or replacing solid cover diaphragm*.

The buffer solution container contains enough buffer solution to complete the run. It is recommended to fill at least 1/2 bottle of buffer solution before each run.

Ensure that the waste liquid container is empty or has enough volume to collect the waste liquid discharged during the run of the instrument.

Please start up the computer, and you need to log in with an admin account in the login interface. The login interface is shown in Figure 3-1.

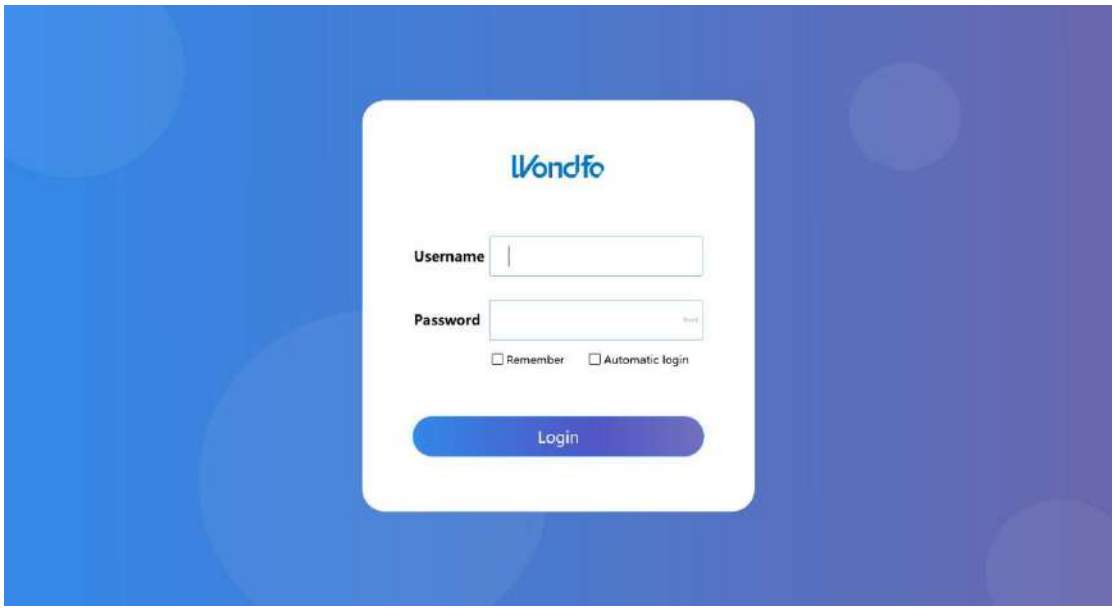


Figure 3-1 Login Interface Window

When the system is installed for the first time, a technical support engineer will provide you with the account password. You can also add, delete and modify accounts based on the actual situation. For details, please refer to *Chapter 4 System Management*.

Click **[Login]** to enter the main interface, as shown in the figure:

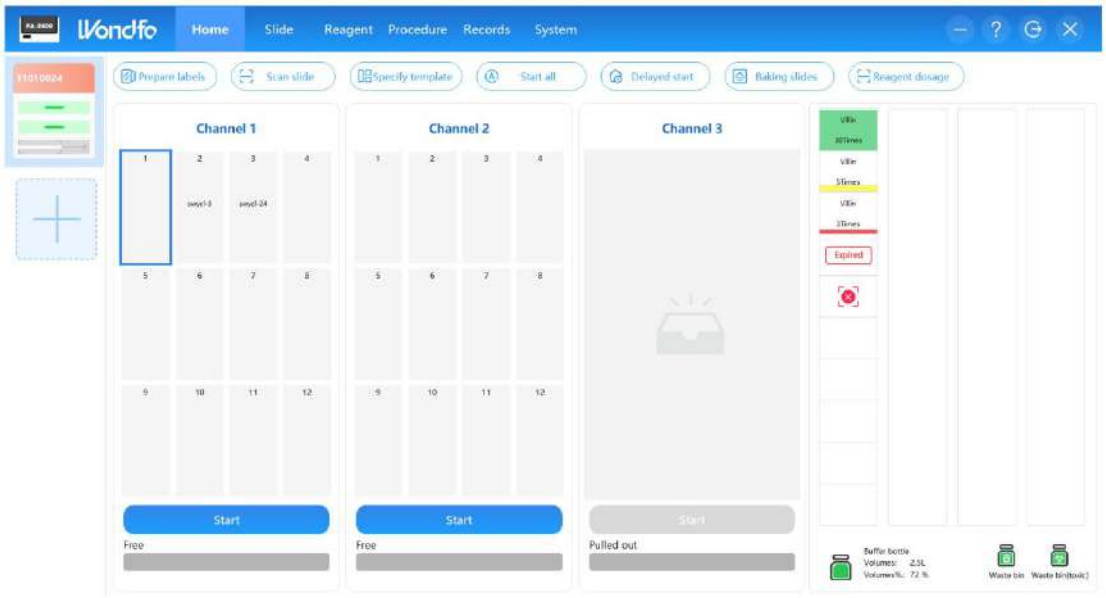


Figure 3-2 Main Interface

All basic functions are easily accessible from home screen. The slides displayed on the screen corresponds to the positions of 36 slices. To perform an operation, please click:

Prepare slides: print labels for slides. Each label has a QR code printed on it to identify the slide.

Scan slides: scan the QR code labeled on slides.

Specify slides: manually specify information for a slide.

Specify templates: manually specify a template for a slide.

Start now: start all slide groups at once.

Delayed start: perform the delayed start after the labeled slides are loaded, reagents are matched and the end time is set.

Baking slides: bake slides after selecting slides as needed.

Exit: close the application.

3.3 Instrument Connection

The computer ports can be connected to 5 sets of the instrument. In left main

interface, click  to add instrument automatically or manually in order to connect computer to instruments. In an instrument status area of left main interface, information about all connected instruments is displayed in a list, including instrument name and IP address. Click the list to switch instruments and enter an operation panel of the corresponding instrument. Figure 3-3.

⚠ Note: After the computer is powered on, it will connect to instrument that was successfully connected last time by default. If you need to add new instrument, you can enter the instrument management interface to add it.

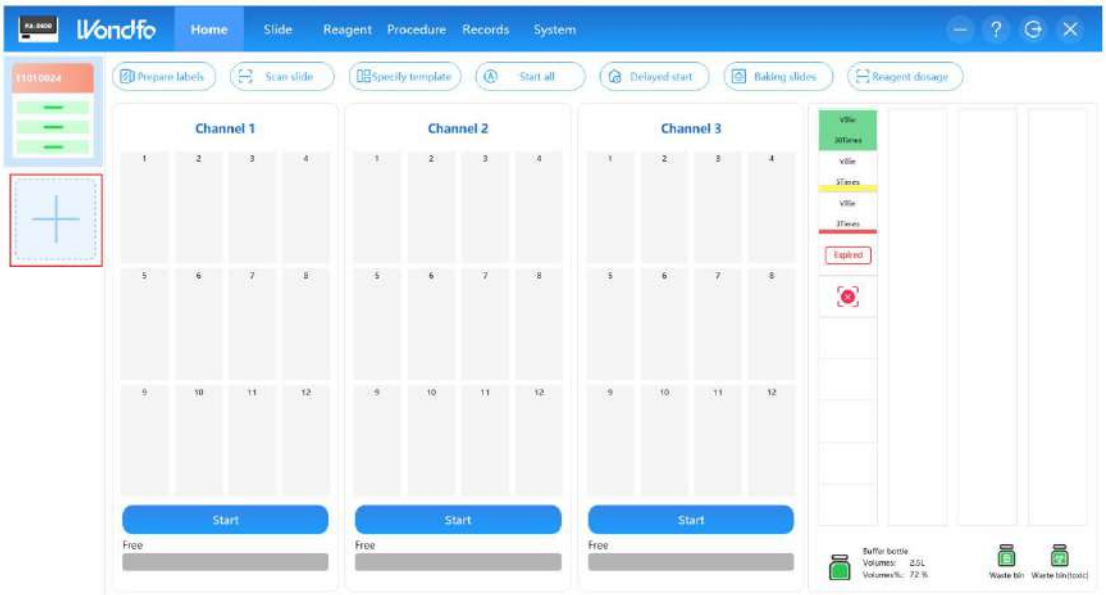


Figure 3-3 Adding Instrument

If a connection fails, it will prompt “The instrument cannot be found, please reset the instrument information”. If it is successful, the instrument connection status will be displayed in the instrument status area on left main interface.

3.4 Preparing slides

3.4.1 Add slide

After logging in an account, you will first enter the main interface. Click **[Prepare labels]** to jump to **[Slide Management]** interface, click **[Add]** to add slides, click **[Select case]**, then the system will automatically return to case information, select the staining item that the patient needs, and click **[OK]** after selection.

Add/edit/delete/copy/print slide label information when you need it.

Add: Add information about a new slide; click **[Add]** and a pop-up window will be available to adding it;

Edit: Based on slides selected in the list, click **[Edit]** and a pop-up window will be available to editing and modifying the slide information. (Only one selected slide can be edited at a time);

Delete: The slide information can be deleted (only slides whose status is shown as new slide can be deleted);

Copy: Create a new slide and copy information of corresponding slide;

Print: Click **[Print]** to print slides as selected, and multiple choices are available;

Set printed: Click **[Set printed]** to mark selected slide status as printed;

Statistics: Click **[Statistics]** and a pop-up window of **[Slide Statistics]** is available to obtaining slide data.

Next, add a template from a template selection list:

Select a template from a list which includes available templates, and click **[Add]** to add a template from selected templates. For more template information, see *4.2 Template Management*.

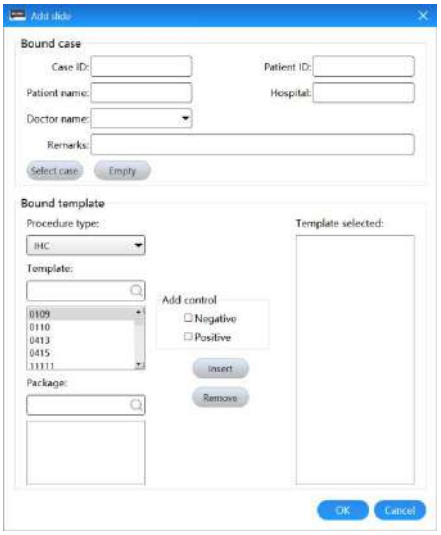


Figure 3-4 Add slides Figure 3-5 Add cases

A positive and/or negative control is required to be added from selected templates, selecting a template before selecting a check box (positive and/or negative) being added at the same time, and click **[Insert]**. This template will also add a positive and/or negative control.

Among optional packages, select a custom package and click **[Insert]** to add a template of entire package from selected templates. All templates (including positive and negative controls) that are put into the package will be added.

In case that you need to remove a selected template, please select the template from a list of "Selected Templates" on the right side, and click **[Remove]**.

If you need information about associated cases, click **[Select Case]** and a pop-up window for associated cases will be available. If you need to cancel an associated case, click **[Empty]** to clear current associated case information. If you need to maintain case information, click **[Case]** to browse, add, edit, copy and search case information.

3.4.2 Printing slide labels

Print labels from a slide management list, click **[Slide]**,

The main interface will display all slide labels, each on a separate line, including slide ID, case ID, No., template, patient name, date, and other information in a label.

⚠ Notice:

Case ID, serial number, hospital name and description are printed on a label by default. If you want to change this setting, please refer to **[System] - [Label settings]** to set the format.

3.4.2.1 Printing information

When printing labels from slide manager, please select a check box in front of labels to be printed, and then click [**Print**]. The user can click checkbox in the table header to select all tabs of current page. For more information on adjusting print

settings and label formats, please refer to *Chapter 4 System Management*.

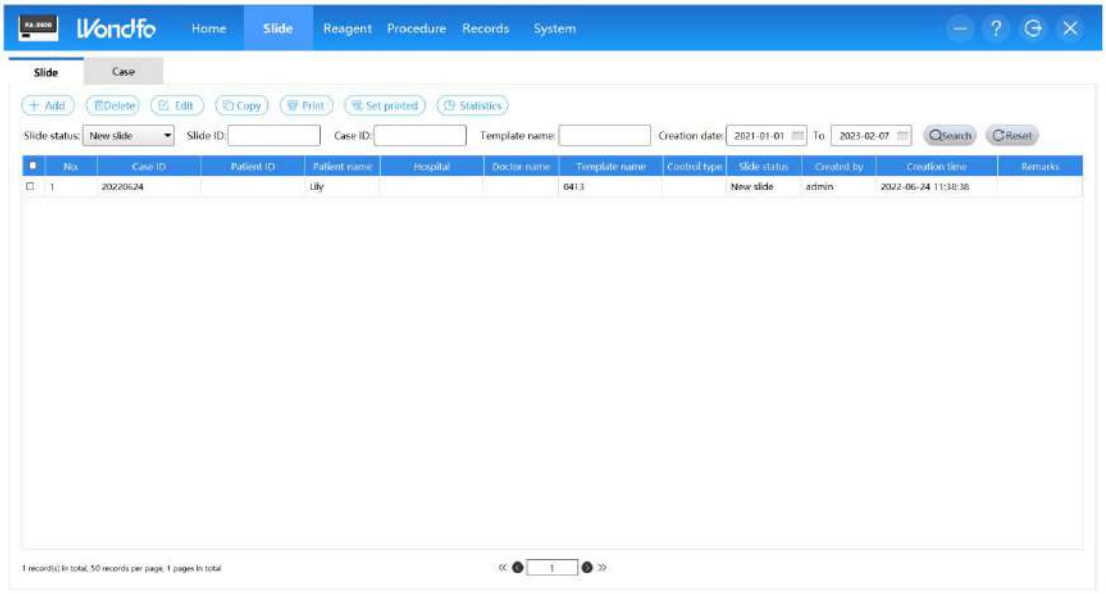


Figure 3-6 Displaying Slide Printing List

3.4.2.2 Modifying/Deleting information

In case that you need to delete or modify labels in slide manager, please select the check box and click **[Delete]/[Edit]**.

3.4.3 Labeling and loading slide

Remove a printed label from a printer and attach it to a slide, pull out push-pull assembly of slide position, and carefully insert the slide. Put the slide in the middle and push it against a bottom plate until it is firmly clamped, then push the staining module back.

⚠Notice:

Please check whether a label bar code is attached properly. A bar code must be flat, centered and its corners cannot be tilted up, otherwise it will easily cause failure or missed scanning and wrong scanning, which will affect your use.

3.5 Scanning Slides

After completing above steps, click **[Scan Slide]** in the software interface, and the instrument scanner will scan labeled slides in 36 modules to determine slide information at corresponding positions. If you need to scan a slide at a specific

position, you can click and drag slide images on the main screen to scan a set of specific slides, and then click **[Scan Slide]** to scan slide information at a specific position.

After the instrument scans slides, the slide information that obtained is displayed on a panel of slide rack, and the system automatically calculates a list of reagents required for slides which are recognized successfully. A pop-up window prompts: "Missing reagents required for the staining procedure were detected,please replenish the following reagents:", as shown in Figure 3-7. For details on reagent installation, see *3.6 Reagent Installation*.

Figure 3-7 List of Reagents that Need to Be Replenished

3.5.1 Specifying slides

If there is no readable label attached to a slide, or if the instrument fails to scan the slide, you can specify corresponding slide information for the slide position:

Select a slide position to be specified, click **[Specify slide]** to specify selected slide information to the corresponding slide position. One slide position can only be specified its own slide information.

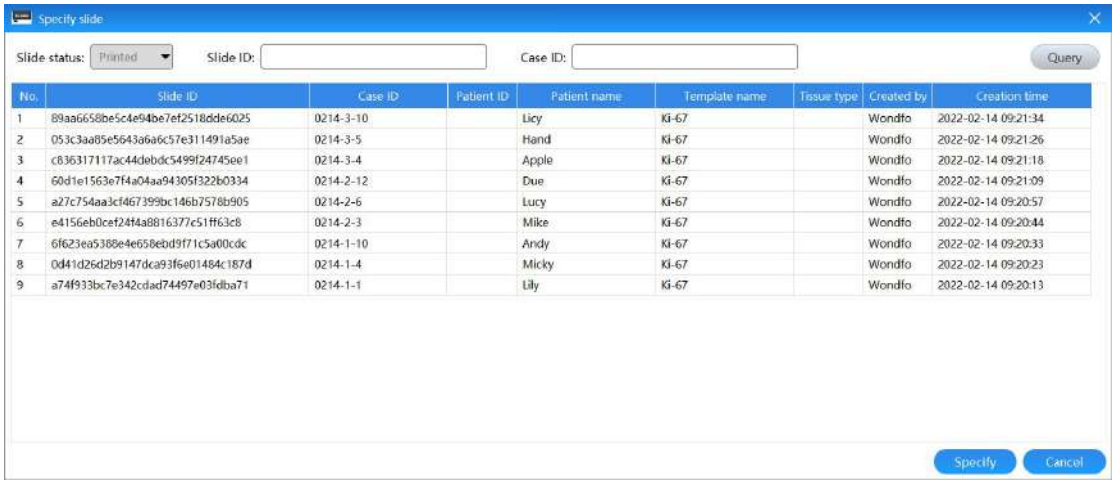


Figure 3-8 Specifying Slides

In case that you need to clear slide information as specified, please click the right mouse button to “Clear”.

⚠Notice:

The slide can only be specified if the slide information is in a state of “Printed”.

3.5.2 Specifying templates

If there is no readable label on the slide, or the slide information is not set, but you want to quickly perform slide staining, you can specify the template information to be executed for the slide position:

Select a slide position to be specified, and click **[Specify template]** to specify selected template information to a corresponding slide position. One template can specify multiple slide positions.

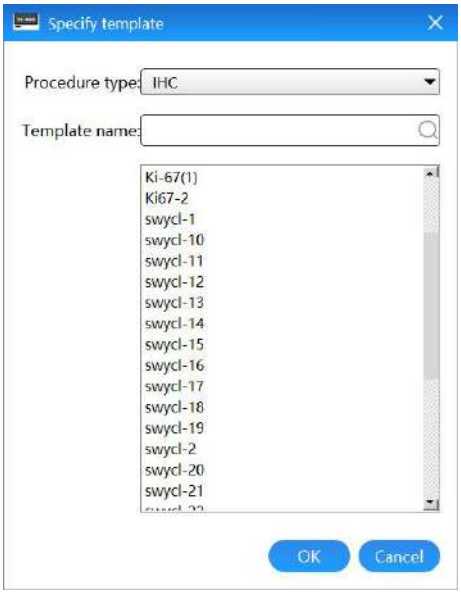
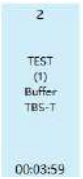


Figure 3-9 Specifying Templates

3.5.3 Slide status description

Slide Status Description	Diagram	Remark	Slide Status Description	Diagram	Remark
No slides		Display slide position number with white background	A slide kit is not in place.		
Scanned and identified		Display slide position number, template name with white background	Slides are running		Display slide position number, template name, step number, reagent name and time
Slides are not compatible with the system.		Fail to display icon with white background	Slides run successfully		
Being selected		Display serial number with blue frame	Slides run unsuccessfully		

3.6 Reagent Installation

The instrument has 40 reagent positions and can support a maximum of 40 different reagents in a round of staining procedure. After the instrument scans slides, the slide information that obtained is displayed on a panel of slide rack, and the system automatically calculates a list of reagents required for slides which are recognized successfully. After reagent racks are installed, the system automatically scans all reagents in the RFID reader and reads RFID tag information. The Link ID in RFID is a unique ID number programmed into each bottle. It can be used to track individual reagent bottles in different runs. For more RFID settings, please refer to *Chapter 4 System Management* in this manual.

3.6.1 Installing or replenishing reagents

(1) After preparing reagents, unscrew the caps of reagent bottles and hold them properly between the side walls in a correct manner, and place reagent racks into slots, making sure that reagent racks are installed in the correct direction and seated flat in the instrument. The instrument automatically scans the reagent RFID until the end. For details on installing reagents, see *6.1.4 Instructions for installing or replacing reagents*.

(2) After completing an automatic reagent scan, the instrument will automatically read and display RFID tag information including reagent abbreviation, remainder and remaining times, as shown in Figure 3-10.

If you need to add or modify reagent information, or manage reagent bottles, see *3.6.2 Reagent Management* for details.

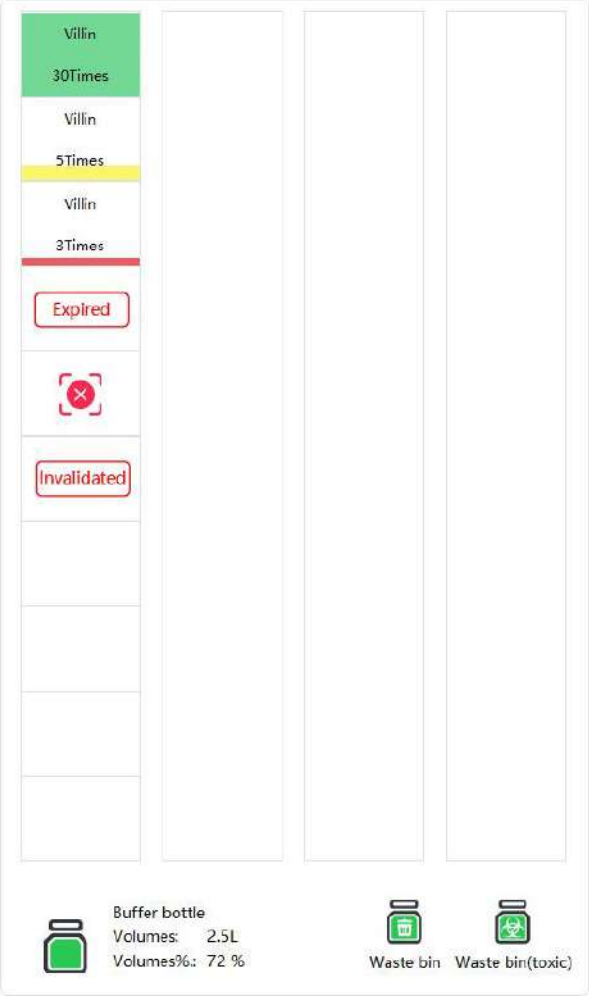
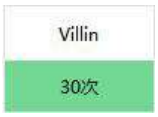
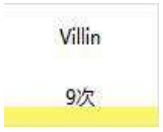


Figure 3-10 Reagent Positions

After the automatic scanning of reagents has been completed, a list on the right side should display reagent names and remaining usage times of reagent. The background color is displayed according to a status of remaining reagent. The specific situation can be judged based on a color that appears. After the situation is settled, the instrument will automatically scan all required reagents or all 40 positions of reagent racks.

After completing a scan, the system will display current status of reagents:

Reagent Status Description	Diagram	Remark	Reagent Status Description	Diagram	Remark

Normal reagent volume		Green progress bar 20%-100%	Reagent scan error		
Low reagent volume		Yellow progress bar 10%-20%	A reagent kit is not in place.		The entire reagent kit is blank, which means it is pulled out.
Reagent volume is nearly empty		Red progress bar 0-10%	Reagent has expired		Reagent has expired
Reagent has been invalidated		The priming volumes remaining and volumes remaining of reagent bottle are both 0.	No reagents		Blank
Buffer solution bottle		Green: sufficient volumes remaining Yellow: warning of volumes remaining Red: insufficient volumes remaining	waste liquid container		Innocuous Green: The waste liquid container is not full and can be used. Red: The waste liquid container is full and needs to be replaced and disposed of in time.
waste liquid container		Hazardous Greed: The waste liquid container is not full and can be used. Red: The waste liquid container is full and needs to be replaced and disposed of in time.			

⚠Notice:

Make sure that there are no air bubbles on the liquid surface of the reagent bottle to avoid liquid detection and sample addition errors.

3.6.2 Reagent management

In the main interface, click **[Reagent] - [Add]** and a pop-up window to add reagent is available, fill in reagent information according to the following figure, including reagent ID, reagent type, reagent name, etc., and click **[OK]** to complete the procedure to add reagents.

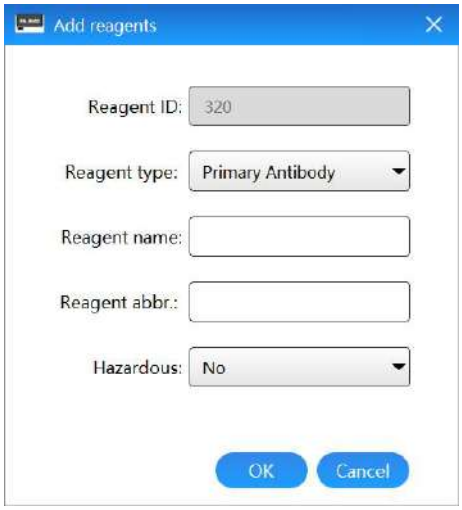


Figure 3-11 Adding Reagents

⚠Notice:

1. The reagent name needs to be unique and cannot be the same as existing reagent names.

2. The administrator can add, edit, delete, copy and view reagents.

3. General users are unable to add, edit, delete or copy reagents, but can only view the information.

The newly added reagent should be visible in a reagent list, including reagent serial number, reagent ID, reagent type, reagent name, reagent abbreviation, hazardous property and other information.

Edit: Edit and modify the information of selected reagent;

Delete: Reagent information can be deleted (reagents that come with the system cannot be deleted);

Copy: Select a reagent you need to copy and make a new reagent;

Click Search button to screen corresponding reagents based on search conditions such as reagent name, reagent type and other keywords, and display them on the list.

3.6.3 Reagent bottle management

Click **[Reagent] - [Bottle]** on the main interface to view detailed information and usage of reagent bottles.

Details: View details of reagent bottles;

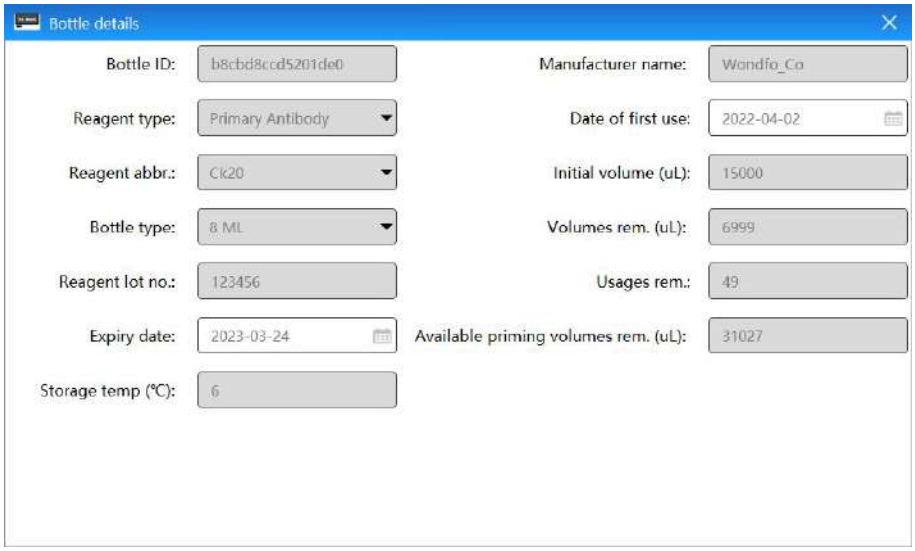


Figure 3-12 Details of Reagent Bottles

Report: View usage details of reagent in a selected bottle;

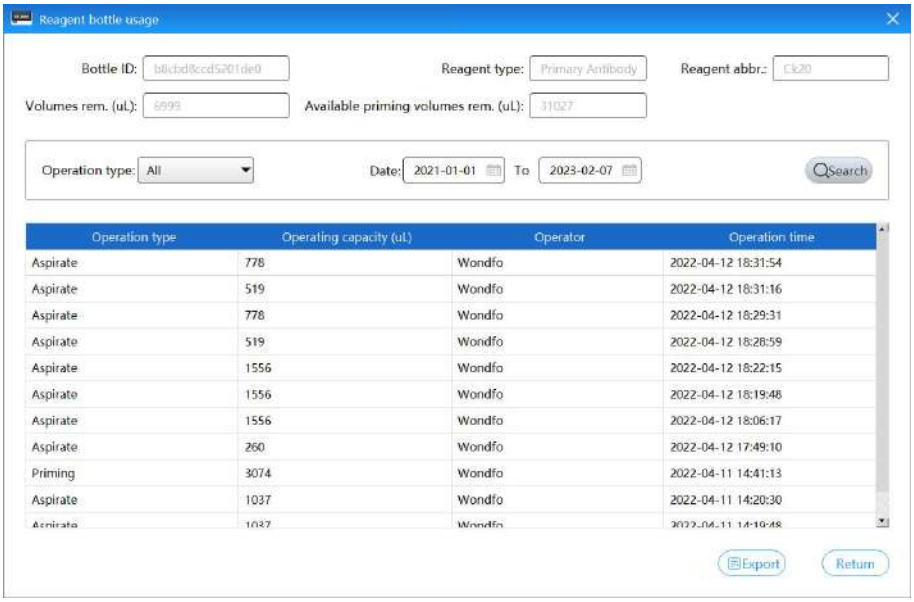


Figure 3-13 Usage of Reagent Bottle

Search: Screen information corresponding to a reagent bottle and display it on the list.

3.7 Executive Program

3.7.1 A single stain module runs independently

If you need to run a separate program for one of the staining modules, you can ensure that the safety door of instrument is closed. After the reagent installation is confirmed, click **[Start]** button of the corresponding group, and the system will first check whether reagent racks and buffer solution are sufficient for this staining procedure. If they are insufficient, the program will prompt you to add reagents, see 3.5.1 for details; if they are sufficient, then start a staining procedure for the single staining module.

⚠Notice:

1. Before starting a staining procedure, please verify that all caps have been removed from reagent bottles.

2. Before starting a staining procedure, please verify that all solid cover diaphragms have been properly placed.

3.7.2 Starting all

If you need to run the entire staining module programs immediately, you can ensure that the safety door of instrument is closed. After the reagent installation is confirmed, click **[Start all]** button, and the system will first check whether reagent racks and buffer solution are sufficient for this staining procedure. If they are insufficient, the program will prompt you to add reagents, see 3.5.1 for details; if they are sufficient, then start a staining procedure for all slides.

3.7.3 Delayed start

If a delayed start is required, click **[Delayed start]** button, and it will first check whether the reagent on a reagent rack and buffer solution are sufficient for this staining procedure. If the reagent is insufficient, the program will prompt you to add reagents, see 3.6.1 for details; if it is sufficient, then enter the time you want the run to end in the figure below. Click **[OK]**, and the system will calculate delay time and start the countdown. When the time reaches 00:00:00 from the beginning, the system will automatically start a staining procedure.

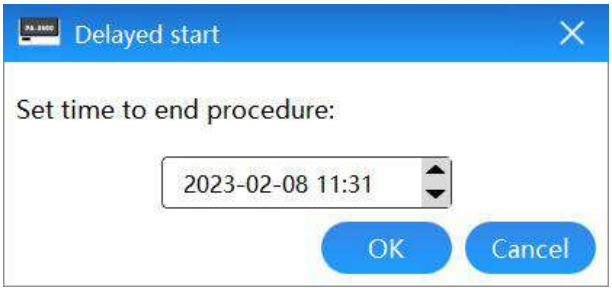


Figure 3-14 Delayed Start

⚠Notice:

If you need to run the program overnight, you can use a delayed start to prevent slides from drying out.

3.8 Baking Slides

3.8.1 Automatically baking slides

If you need to automatically bake the slides before each staining procedure is running, you can set it in **[System] - [Setup] - [Bake settings]**. For details, see

4.1.1.1.

3.8.2 Manually operated baking slides

If you need to bake the slides manually, you can click **[Baking slides]** on the main interface. You can check the group that need to be baked, set the baking time and temperature in the following figure, then click **[OK]** to bake the slides. During the baking process, the countdown display is based on the set time, and when the countdown ends, the baking slide is completed.

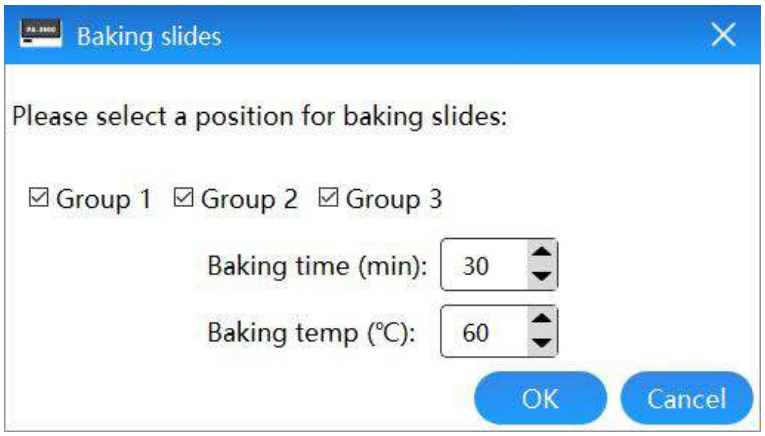


Figure 3-15 Baking Slides

3.9 Replenishing Buffer Solution and Cleaning Waste Liquid Bottles

3.9.1 Replenishing buffer solution and emptying waste liquid container

Before starting the run, you should make sure that there is sufficient buffer solution in a barrel and that the two waste liquid containers are not full. If the buffer solution remaining is insufficient or if the waste liquid containers are full, which are in a state of alarm, such problems need to be solved. For details on replenishing buffer solution and emptying waste liquid containers, see 6.1.5.

3.9.2 Prompts for buffer solution dosage

After clicking **[Start]**, **[Delayed Start]** or **[Start all]**, the system will judge the buffer solution volume. If the volume is low, it will prompt: “The Buffer is running low, please replenish it in time!”; if the volume is nearly empty, it will prompt: “The Buffer is nearly empty, please replenish it immediately!”.

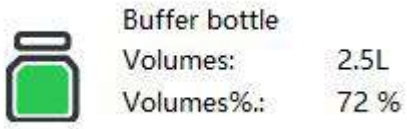


Figure 3-16 Displaying Buffer Solution Volumes

3.9.3 Staining process

When the instrument is running, the user can track the progress on the main interface. The slide image will display all 36 sections, template records, time and the current step. Three groups of slides respectively display a step for the staining program that being run, progress bar and running progress percentage.

Figure 3-17 Status Bar that Showing Staining Progress

During the staining process, the instrument locks the slides in the staining modules. When the instrument is running, you should give up a run without attempts to pull out the slide racks. The method is to click [Stop] icon below the staining modules on the system status screen, then unlock the corresponding group, and finally pull out the slide rack.

3.10 Basic Maintenance After Staining

The staining process will be displayed a success after it is completed, and be marked as **[Finish]**.

The instrument will automatically store all data after each staining is completed. Users can generate reports through content query introduced in this chapter, including slide report, reagent usage report, staining operation report and running events report. click **[Records] - [Records]** on the menu bar to enter the historical data interface, as shown in the figure.

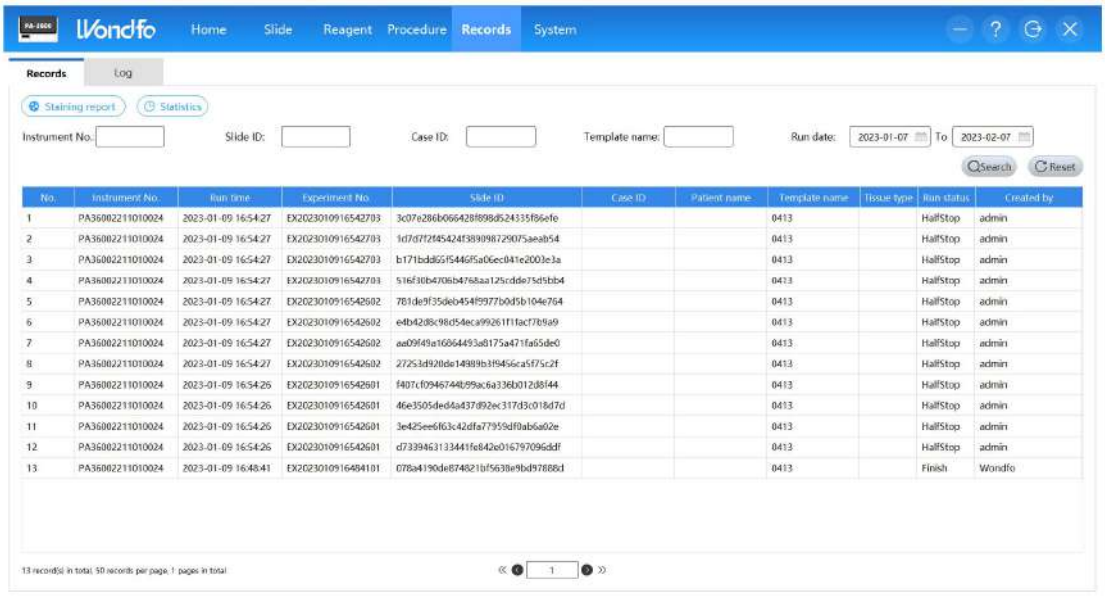


Figure 3-18 Results for Historical Data

Open the main interface, click **[Records]** on the menu bar, and click [Log] to enter the log database interface.

3.10.1 Finding log information

(1) Enter search condition: “operator”, “log description”, “log date”;

(2) And click **[Search]**, the system will automatically search and display the search results interface.

3.10.2 Exporting log data

An external storage device is inserted into any USB port of the host computer. You can click **[Export]** on the log interface, and select the path toward the external storage device, then the log data can be exported to the storage device.

3.10.3 Finding patients’ diagnostic information

Open the main interface, click **[Records]** on the menu bar, and click **[Diagnosis]** to enter the “Diagnostic Information” interface.

(1) Enter search conditions: “operator”, “instrument No.”, “error code”, “date of diagnosis”.

(2) Click **[Search]**, the system will automatically search and display the search result interface.

3.10.4 Exporting diagnostic data

In the diagnostic database interface, you can insert an external storage device into the external device port of the system, and then click **[Export]** to export the diagnostic data to the storage device.

⚠Notice:

1. When the instrument is running, please do not try to run other application software in background, or do not try to log in or out of the window system or switch users because such operations may cause the instrument to be disconnected.

2. After taking out the slide, you can insert a clean paper towel into the module slot to soak up residual waste liquid and then take it out, and use an alcohol pad to simply clean the module and wipe off any remaining buffer solution on the surface of the module and the slide position.

3.11 Exit

After completing the above steps, click  to exit the software, click **[OK]** to confirm the exit, and close the instrument and computer.

The process of shutting down the system may take a few minutes, and until the application is completely closed, you can press and hold the power button of the instrument on the lower right side to power it off.

⚠Notice:

1. Please do not turn off the instrument and computer when the instrument is running, otherwise it may cause data loss.

2. Please ensure that the software is safely exited before shutting down the computer.

3. After finishing the staining procedure, please clean up residues on solid cover diaphragms as required in Chapter 6.

3.12 Continuous Load

The user add new slides during staining run. Users are allowed to load more slides or to accept additional slides after completing a staining run.

⚠Notice:

1. Adding new slides during staining runs will significantly increase the total run time for

remaining slides.

2. New slides cannot be added to a running group.

3.13 Stopping the Running

If you find that a staining item is set incorrectly, or the instrument has an unexpected failure and needs to stop staining urgently, you can click **[Stop]** button, and the system will stop working and abandon all ongoing items.

⚠Warning:

When you select **[Stop]** button to end the operation as the instrument has an unexpected failure, please refer to the *Troubleshooting Guide* for instrument accessories to deal with it, or refer to *Chapter 8 Repair, Transportation and Destruction* in this manual to contact Wondfo for technical support.

Chapter 4 System Management

Before an instrument is delivered, all settings have been completed. For the convenience of users, many of its parameters can be reset by users according to their actual needs. The user can set parameters individually and customize its working mode and display mode through the function of **[System]** provided by the instrument.

4.1 System Management

The user can set the instrument system as follows:

4.1.1 Tools

4.1.1.1 Baking slides

In the main interface, click **[System] - [Setup] - [Bake settings]** to execute settings for baking slides, and select the baking temperature (℃) and baking time (minutes). According to actual needs, users can design to bake slides before staining, then click **[Save]** after setting.

If you check baking before staining, the system will automatically bake slides before each run of the staining procedure.

4.1.1.2 RFID management

In the main interface of the instrument, click **[System] - [Tool] - [RFID]** to edit reagent RFID tags.

Write information in an RFID tag: Click the **[Write]** button to write the data edited on the reagent bottle information panel on the right into a reagent bottle RFID tag based on the selected reagent position.

Read RFID tag information: Click the **[Read]** button to read a reagent bottle RFID tag based on the selected reagent position, and display the read-out information on a reagent bottle information panel on the right.

Write information in RFID tags in batches: Click the **[Bulk write]** button to write in batches the data edited on a reagent bottle information panel on the right into the reagent bottle RFID tags based on the selected reagent kit.

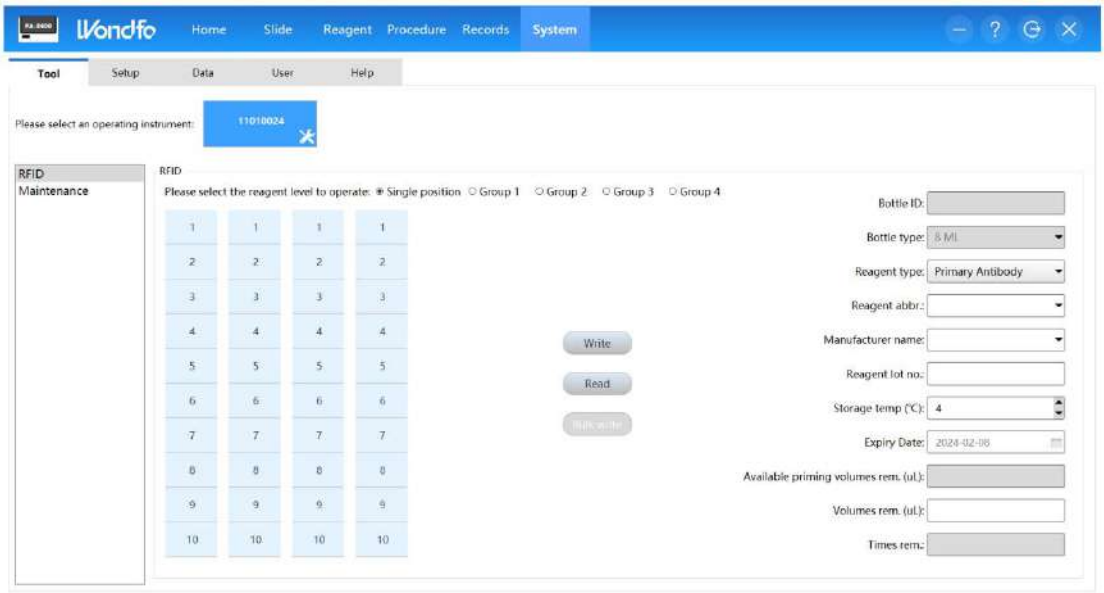


Figure 4-1 Editing RFID Information

⚠ Notice:

1. Before editing the RFID tag, make sure that a reagent that a user needs to edit is in the reagent list, otherwise a reagent needs to be added first.
2. General users and administrators can only set reagent RFID tags for reagent types such as “Primary Antibody, Probe, Other”, and other types cannot be set. If you need to set types other than that of “Primary Antibody, Probe, Other”, please contact the manufacturer for maintenance.
3. Brand-new RFID tags will only contain a randomly generated tag ID.

4.1.1.3 Instrument maintenance

Click **[System] - [Tool] - [Maintenance]** to enter the instrument maintenance interface. Before you can perform maintenance on instrument, you need to select the instrument first (if the instrument is running a staining procedure, all buttons will not be clickable).

(1) Robot arm reset

Click **[Robot arm reset]**, the system will start the program, and the robot arm will return to the initial position.

(2) Pipeline system

Entering the pipeline system maintenance interface, a user can select operations such as resetting, priming, and cleaning of the syringe pump.

Click **[Syringe pump reset]**, the system will start the program, and the syringe pump will return to the initial position.

For more details about management system maintenance, see *Chapter 5 Utilization of Functions*.

(3) Staining modules

Click **[Cover plate reset]**, the system will start the program, and the staining module cover will return to the original position.

Click **[Module cleaning]**, the system will start the program to clean the staining module.

(4) Compete machine

Click **[Reset complete machine]**, the system will start the program, and the instrument will be initialized.

4.1.1.4 Data maintenance

Data backup: Open the main interface, click **[System] - [Data] - [Data maintenance]** on the menu bar, select a backup path, click **[Backup]**, and then the system will automatically perform the backup, during which other operations will not be allowed.

Data recovery: Open the main interface, click **[System] - [Data] - [Data maintenance]** on the menu bar, click **[Restore]**, select the recovery file, click **[OK]**, and perform data recovery in the system according to the selected file.

⚠ Warning:

It is forbidden to restore irrelevant data from the outside in the computer, which will occupy the hard disk space and affect the storage of product test data.

4.1.1.5 Import and export

If there are multiple computer operations and it is required to migrate the data for

requiring uniform reagents, programs, templates and package information, then you can perform import/export operations.

Import: Open the main interface, click **[System] - [Data] - [Import/Export]** on the menu bar, click **[Import]**, select a file to be imported, and click **[OK]** to import the selected file into the system.

Export: Open the main interface, click **[System] - [Data] - [Import/Export]** on the menu bar, click **[Export]**, select an export path to save, and click **[OK]** to export reagents, programs, templates and package information available in the system.

⚠ Notice:

It is forbidden to import irrelevant data from the outside in the computer, which will occupy the hard disk space and affect the storage of product test data.

4.1.2 Settings

4.1.2.1 Instrument management

In the main interface of the instrument, click **[System] - [Setup] - [Instrument]** to automatically or manually add instrument to complete the connection between the computer and the instrument. In instrument management, you can add instrument and browse connected instrument information.

4.1.2.2 Label management

Click **[System] - [Setup] - [Label settings]** in the main interface, and a label setting window will pop up to set the label format.

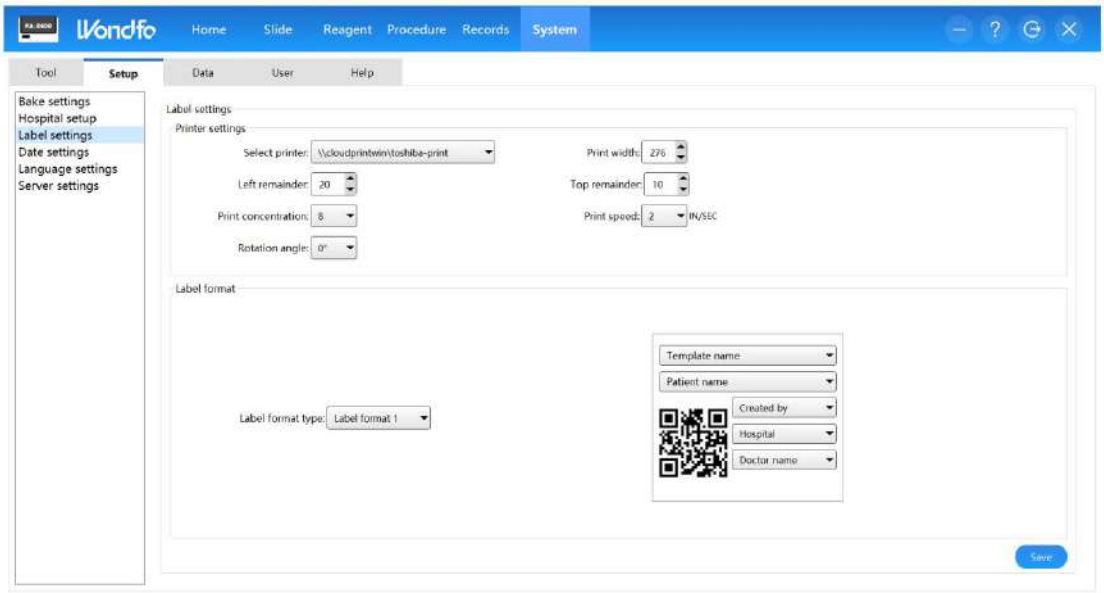


Figure 4-2 Label Format Settings

4.1.2.3 Date settings

(1) In the **[System] - [Setup]** menu, click **[Date settings]** to enter the date and time setting interface;

(2) Select a date format: YYYY-MM-DD, YYYY/MM/DD, MM-DD-YYYY, MM/DD/YYYY, DD-MM-YYYY, DD/MM/YYYY, the default format is YYYY-MM-DD.

(3) Click **[Save]** to save the settings. After saving the settings, restart the system to take effect.

4.1.2.4 Server settings

In the main interface of the instrument, click **[System] - [Setup] - [Server settings]** to set the LIS server. For more information, see *1.6.4 Data and Instrument Interface*.

4.1.3 User management

General users cannot access to user management so it is not displayed for them. Only the administrator(s) and factory engineers have the operation authority and see the displaying interface.

The administrator(s) can modify the password through the **[User] - [Admin]**

interface.

General users can add, delete and modify passwords through the **[User] - [General user]** interface. A maximum of 100 users are allowed to set in the system. User permissions are detailed in *1.6.5 User access control mechanism*.

Add: add a new user;

Change password: change the user password;

Delete: delete user being selected

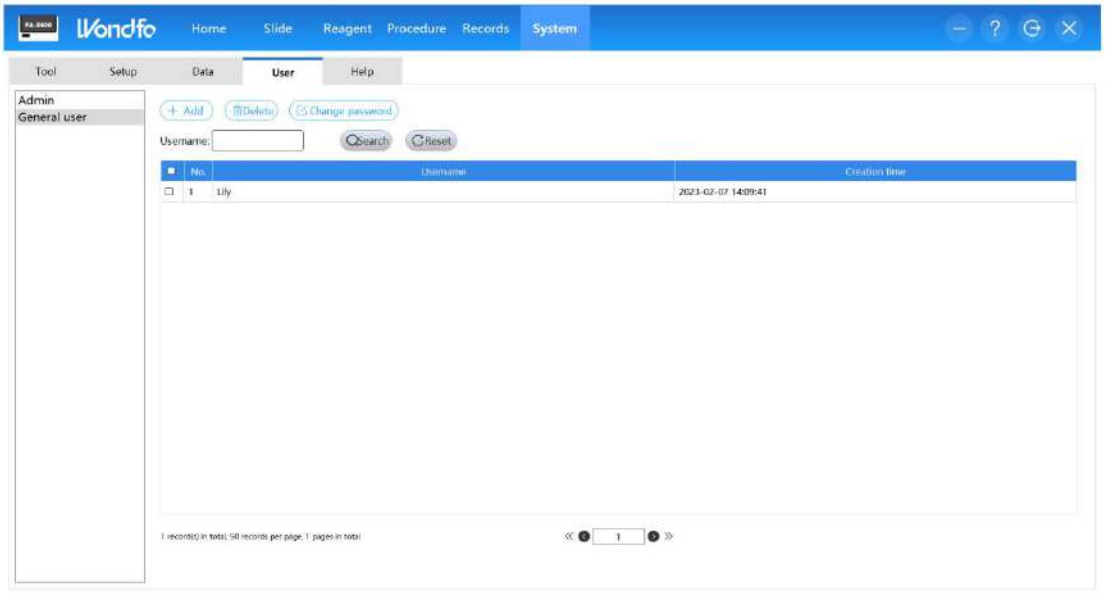


Figure 4-3 User Management

4.1.4 Help center

Through the **[Help]** interface, you can view the operation instructions of the instrument, including the user manual and operation video; click **[About]** to view detailed information about the manufacturer. For information about software version, see *1.6.2 Software version*.

4.2 Template Management

4.2.1 Template management

The operator can click **[Template]** in the main interface, and perform the custom modification. Users can access different types of templates in this interface.

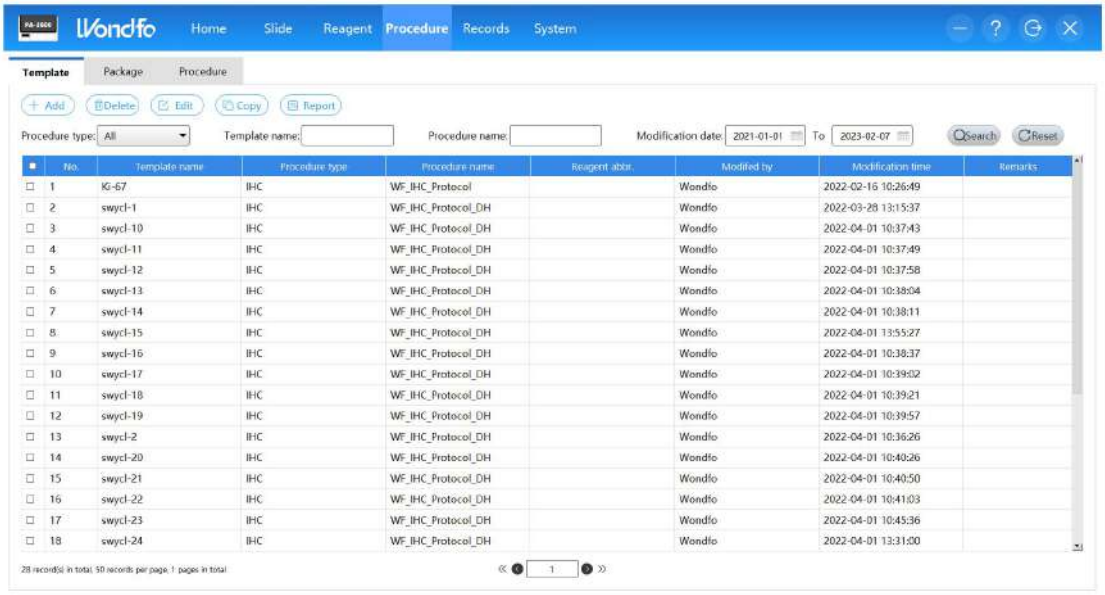


Figure 4-4 Template Management

⚠Notice:

Users who are not professional technicians are not suggested to use this function.

Before adding templates, you should make sure that the programs and primary antibody reagents that need to be added are in the optional list, otherwise, you need to add new programs or new reagents first.

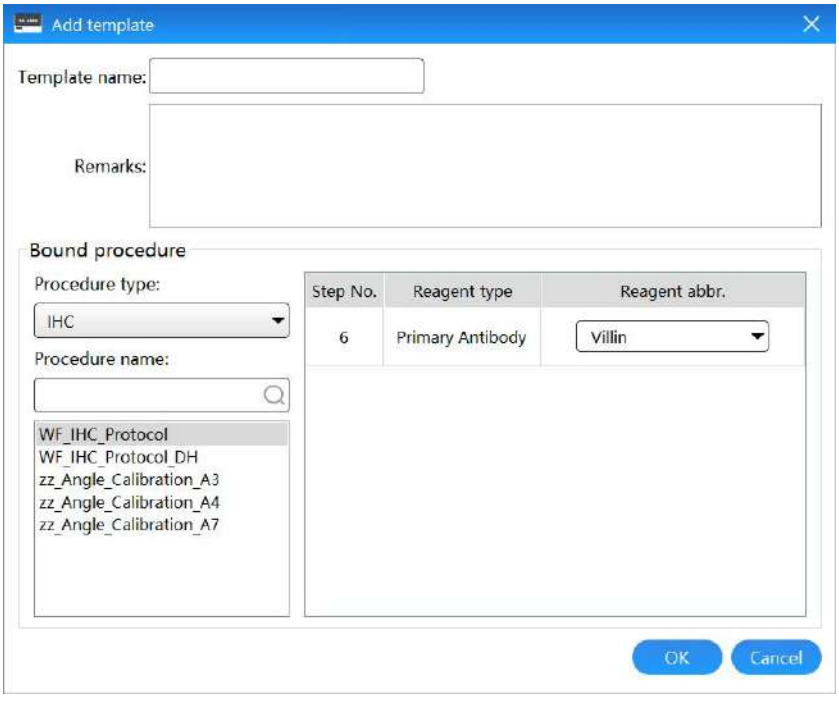


Figure 4-5 Add Template

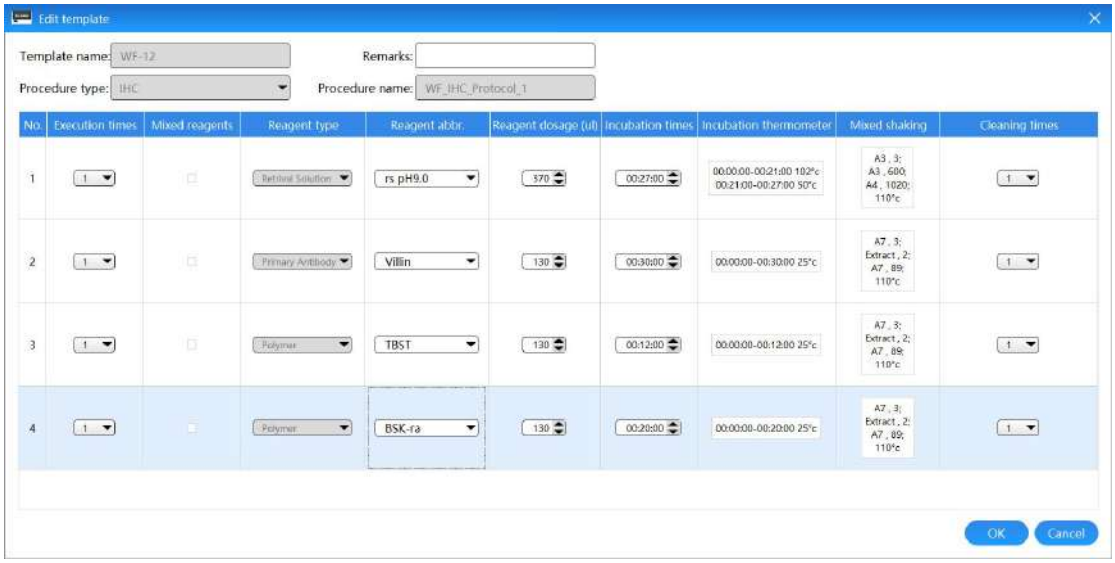


Figure 4-6 Edit Template

Click **[Add]** to open a window for adding a template. Each template type has one selected for generating all templates of that type. Select a program type and a program name, fill in a template name and remarks, and click **[OK]** to add a new template, or click **[Cancel]** to cancel the newly added one.

Click **[Edit]**, and the custom modifications will be executed. If you want to change the operating information, click **[OK]** to edit it.

For copying a template, you can select a template to be copied, and click **[Copy]** to make it a new template, or click **[Cancel]** to cancel the copy.

Click the **[Search]** button to screen the corresponding templates based on search conditions such as template name, program type, program name, modification date and other keywords, and display them in the list.

In case of deleting a newly created template, please select a template to be deleted, and click **[Delete]**, among which templates that come with the system cannot be deleted.

4.2.2 Package management

Users can click **[Add]** in “Package Management” to create a package. For example, click **[Add]**, enter the package name and program type, and click **[Insert]** to

complete adding a new package. After the user creates a new package, he or she can directly select a commonly used package in “Slide Management” and “Add Slides”.

Add: add a new package, as shown in Figure 4-7; users can customize common packages and select multiple templates to form a new package.

Edit: customize and modify a package being selected;

Delete: delete a package being selected;

Copy: select a package to be copied and copy it to make it a new package;

Search: screen the corresponding package based on search conditions and display them in the list.

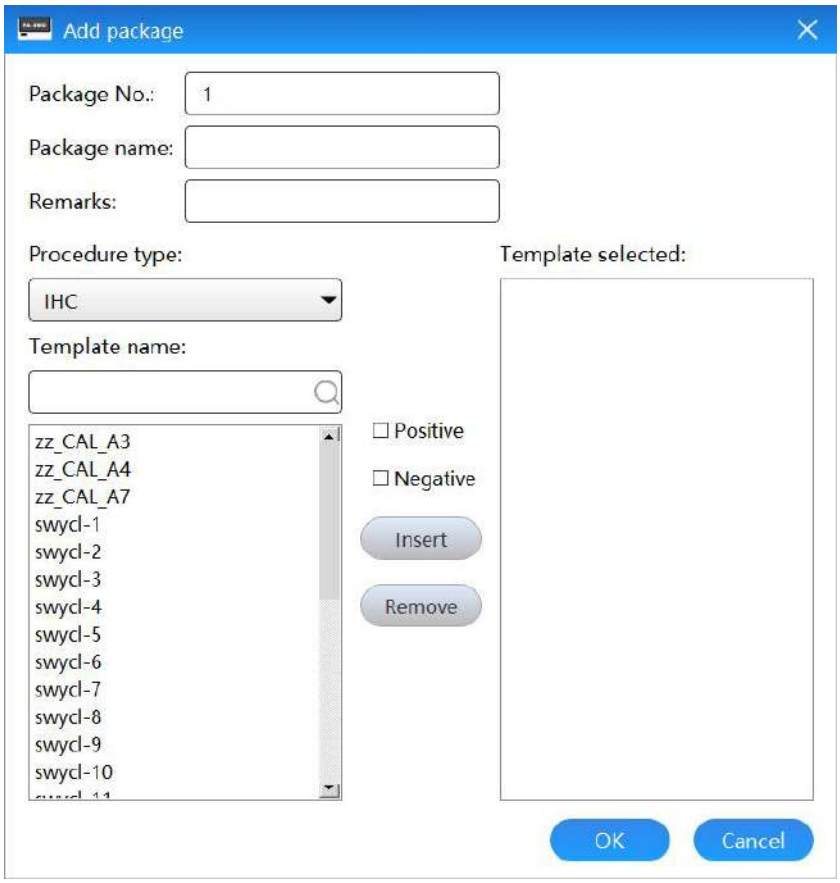


Figure 4-7 Add Package

⚠Notice:

1. Each template name must have a unique name.

2. If a newly added package name is the same as that one in the list, it will prompt: The

package name already exists, please re-enter!

4.2.3 Program management

In the main interface, click **[Program],** and the custom modification will be executed. Users can access different types of programs in this interface.

Add: add a new program;

Edit: customize and modify a program being selected;

Delete: delete a program being selected (the programs that come with the system cannot be deleted);

Copy: select a program to be copied and copy it to make it a new program;

Search: screen the corresponding program based on search conditions and display it in the list.

4.2.3.1 Adding new programs

If you need to add a new program, select a program type from the list and click **[Add]**, and enter a name to an area of "Program Name". Click **[Save]** to finish adding a new program.

4.2.3.2 Editing programs

If you want to modify an existing program in the system, select a program from the list and click **[Edit].**

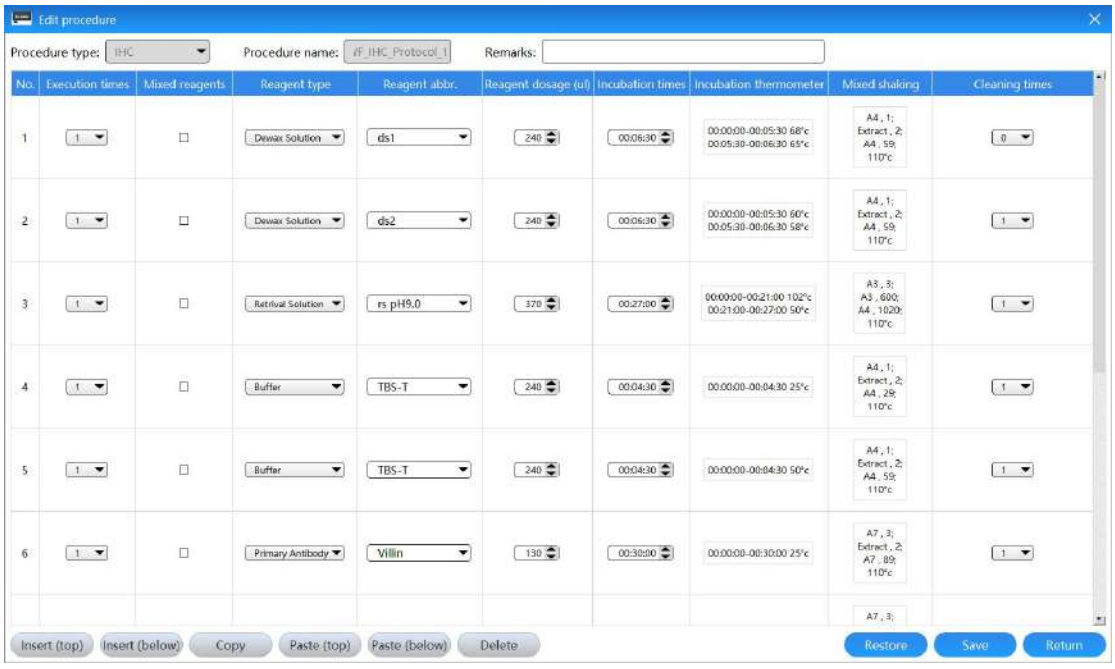


Figure 4-8 Edit Program

Edit the incubation temperature table including templates for time and temperature, and then click **[OK]** to complete modifications based on time (hours, minutes, seconds) and temperatures.

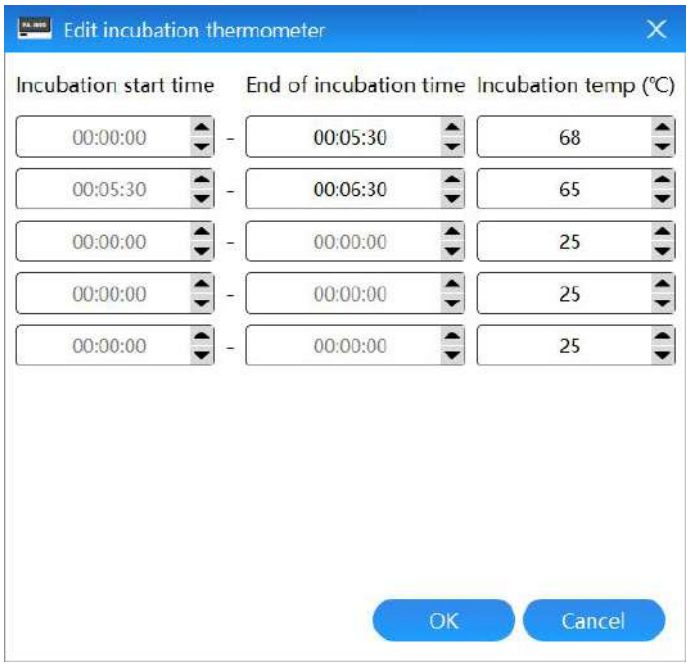


Figure 4-9 Edit Incubation Temperature Table

View and edit the mixing and shaking parameters; in case of an initial mixing and shaking procedure, you should fill in the position and frequency of initial mixing and shaking, select the upper position of cover plate and lower position of cover plate, fill in the residence time and critical temperature, and click **[OK]** to complete customized settings for mixing and shaking parameters.

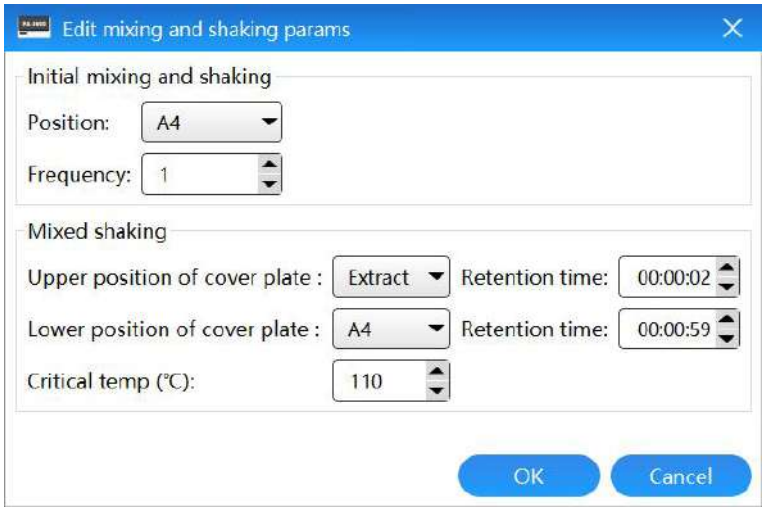


Figure 4-10 Edit Mixing and Shaking Parameters

Chapter 5 Utilization of Functions

This chapter describes various service functions provided by the instrument. By using them, you will find it easier and more convenient to use the instrument.

5.1 Maintenance

The maintenance program provides a more comprehensive and effective measures on instrument to avoid cross-contamination through a series of cleaning operations, and prevents the risk of residues that may exist under the long-term working conditions of the instrument. Necessary maintenance operations are suggested to be performed on the instrument according to your actual situations.

5.1.1 Priming

Every time the system is turned on, it will automatically perform a priming operation to remove gas from the liquid pipeline. When you use the system for the first time or turn it on again, you should perform 2-3 priming operations to make the liquid (cleaning solution) fully primed in the liquid pipeline.

5.1.2 Cleaning

If necessary, you can perform a cleaning operation perform according to your actual operating conditions, and the instrument will suck a buffer solution to clean the entire liquid pipeline and sampling needle mechanism of the instrument. Click **[System] - [Maintenance]** in the main interface, place the cleaning solution in the buffer solution vessel by following the system prompts, click **[OK]** and the instrument will execute the automatic pipeline cleaning command until the end of the operation.

5.2 Liquid Level Detection

The system provides liquid level detection functions such as reagent,waste liquid and buffer solution. The liquid level detection operation is to confirm whether the liquid level detection function of the sample needle is good. When the conditions of the liquid (reagent, buffer solution, waste liquid, etc.) are normal and if the reagent

needle cannot detect the liquid level at the suction position, the color status of the reagent displayed on the reagent position is red, prompting that the operator needs to replenish or replace the reagent. For more prompts about reagents and liquid volumes, see the slide status description and reagent status description in Chapter 3.

If the liquid level detection function is abnormal, please refer to *Chapter 10 Contact Information* to contact Wondfo.

Chapter 6 Maintenance

In order to ensure the reliable performance, good working condition and life of the system, please operate and regularly maintain the system in strict accordance with the requirements of this user manual. Only by understanding the maintenance and repair knowledge in this chapter to carry out daily and regular maintenance carefully, can the instrument be in good working condition for a long time, obtain reliable measurement results and reduce the frequency of instrument failure.

The system provides maintenance instructions and regular maintenance. Through the maintenance instructions, various maintenance operations can be performed on the instrument.

This chapter describes the methods and steps of preventive maintenance. If you need more relevant information, please contact our customer service department.

⚠ Notice:

1. It is strongly recommended that the instrument should be powered off when cleaning or maintenance is performed. (except for cleaning the suction probe)
2. Some of reagents used in immunohistochemistry and in situ hybridization are hazardous, so you should ensure that you have completed training in this procedure before proceeding:

   a) Wear latex or nitrile gloves, safety glasses and other suitable protective clothing before touching reagents or cleaning instrument.

   b) All relevant laboratory procedures and government regulations should be followed in the use and handling of reagents and concentrates.

6.1 Routine Maintenance

6.1.1 Cleaning the outer surface

Frequently touched places such as instrument panels and operation screens are prone to accumulating dust or other contaminants. In order to keep the working environment clean and reduce biological risks, exposed parts such as the case of host machine, slide position and reagent rack should be cleaned in a timely manner. It

should also be decontaminated and sterilized before repackaging and shipping.

Wipe its outer surface with a clean gauze, deionized water and a neutral detergent including bleach (0.5%), isopropyl alcohol (70%) or ethanol (70%).

⚠Warning:

Please do not use corrosive acids, alkalis and strong volatile organic solvents (such as acetone, ether, chloroform, etc.) to scrub the surface of the instrument to prevent damage to the outer surface, the screen and other devices.

⚠Warning:

Please do not use strong bleach and other chemical detergents for cleaning, and do not spray it with disinfectants or clean any internal parts and surfaces to prevent damage to internal components of the instrument.

⚠Notice:

1. If hazardous substances leak on the surface or enter the inside of the instrument, appropriate disinfection should be taken;

2. Do not use cleaning agents or disinfectants that chemically react with instrument parts or materials contained in the instrument and pose a danger;

3. If you have your doubts about the compatibility of disinfectants or cleaning agents with instrument parts or materials contained in the instrument, you should consult the manufacturer or its agent.

Please ensure that the instrument is in a powered-off state before performing the maintenance. The specific operation steps are as follows:

(1) Open the top lid.

(2) Use gauze dipped in neutral detergent to gently wipe the case of host machine, slide position, reagent rack and other parts.

(3) Push and pull the staining module on the slide position, and wipe the slide position with gauze dipped in a small amount of alcohol. If necessary, use a cotton

swab dipped in a small amount of alcohol to wipe the dirt on the staining module.

(4) Pull out the reagent rack, remove reagents on the rack and refrigerate them.

(5) Wipe the QR code scanner with clean gauze to confirm that there are no traces or dust left on the glass.

(6) Use gauze dipped in a small amount of alcohol to wipe the reagent rack, and if necessary, use a cotton swab dipped in a small amount of alcohol to wipe the dirt.

(7) Put the reagent rack back into the reagent area.

(8) Close the top lid.

6.1.2 Replacing the fuse

The fuse is installed in the fuse box next to the power switch on the right side of the instrument. The fuse can be easily replaced if you take a slender hard object and put it into the card box to lift the cover.

Note: The fuse specification and model specified by the instrument: 15 A 250 V, 5*20 mm glass quick-break footless fuse.

⚠Warning:

A fuse of the specified specification must be used.

6.1.3 Instructions for installing or replacing solid cover diaphragm

The operator needs to properly install the solid cover diaphragm before starting each staining procedure or after cleaning the solid cover diaphragm. The method is to insert its head into a slot of the staining module, and gently push it forward to the end. When you hear a “click”, it means that the solid cover diaphragm has been inserted in place.

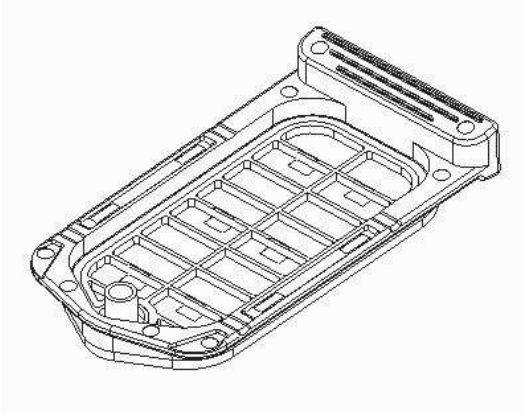


Figure 6-1 Solid Cover Diaphragm

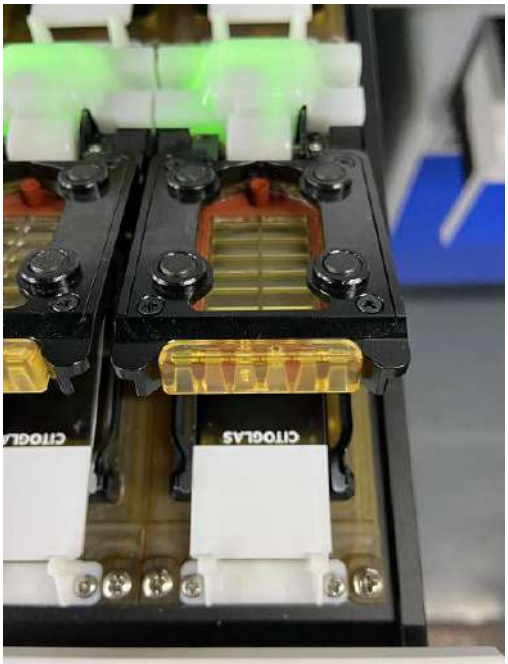


Figure 6-2 Installation for Solid Cover Diaphragm

6.1.4 Instructions for installing or replacing reagents

Before starting the staining procedure, please place the prepared reagent in the reagent rack, uncover the reagent bottle and fasten it between two clamping side walls. And when you confirm that all reagent bottles have been completely fixed on the reagent rack before you push the reagent rack into the rack slot and hear a “click”, the reagent rack indicator light turns blue and then green, indicating that the reagent rack has been placed correctly.

⚠Notice:

1. Only Wondfo reagent bottles are compatible with the PA -3600 stainer.

2. You can only press the button to unlock and pull out the reagent rack to replenish the reagent after the reagent rack indicator light turns green.

Figure 6-3 Uncover the reagent bottle and fasten it between two clamping side walls

Figure 6-4 Properly install the reagent rack

6.1.5 Instructions for replenishing buffer solution and emptying waste liquid containers

The buffer solution container has a maximum capacity of 3.5 L.

1. Prepare the buffer solution
2. Unscrew the buffer solution container cap
3. Fill the container with buffer solution and screw the cap.

The waste liquid container has a maximum capacity of 10 L.

1. Unscrew the container cap and empty the waste liquid container. The waste liquid should be disposed of according to local regulations.
2. Screw the container cap and reconnect the waste line.

⚠Notice:

Please do not touch buffer solutions, reagents and waste liquid with bare hands and always wear gloves when handling.

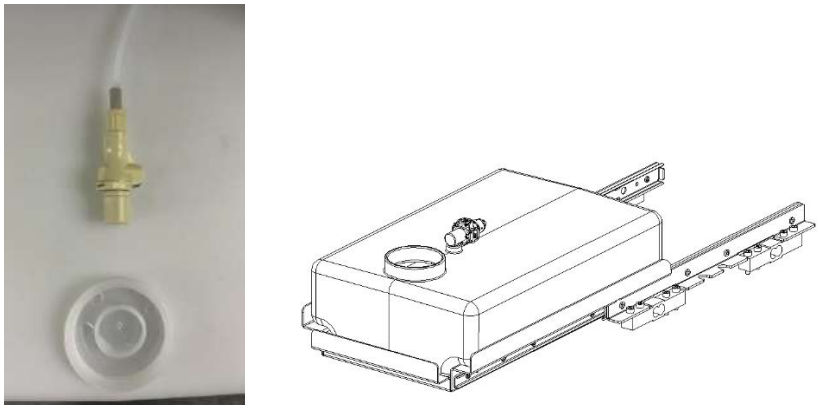


Figure 6-5 Buffer solution barrel

6.2 Daily Maintenance

✓ Clean the module after each staining, paying special attention to the area around the heating module:

1) Wipe and absorb residual liquid with a soft paper towel.
2) Remove the solid cover diaphragm from the sliding device for cleaning.
3) Clean salt deposits in the sliding device.
4) Clean around the heating module and make it dry.
5) Clean the surface of the panel from salt deposits or broken slides.

✓ Wash and dry the solid cover diaphragm

1) Soak the solid cover diaphragm in 84 disinfectant (active ingredient: 1% sodium hypochlorite) for 15-20 minutes, but not more than 30 minutes. The soaking time is appropriately adjusted depending on the cleanliness of solid cover diaphragm.
2) Rinse it with plenty of water for several times to make sure there is no bleach residue on the solid cover diaphragm as it may affect the staining result.
3) Dry the solid cover diaphragm or use a dry paper towel to wipe the surface for next use.
4) It is recommended to wipe the surface of it with an alcohol swab before next staining.

✓ Inspect the solid cover diaphragm for wear or damage

1) The user should check whether the solid cover diaphragm is damaged during the cleaning process.
2) Replace any solid cover diaphragm which is surface-damaged (or scratched).

⚠Notice:

Before use, please observe whether there are obvious scratches on the surface of the solid cover diaphragm and whether there is degumming at the injection port.

If it is cleaned after each staining, the solid cover diaphragm may be used for

more than 100 times.

✓ Check the outside of the sample/reagent needle for dirt and crystals. You can use a cotton swab dipped in a small amount of alcohol to gently wipe the outer surface, especially the tip of the needle, until the outer surface of the needle is clean and free of dirt, and then wipe off the alcohol on the needle with gauze dipped in deionized water.

⚠Notice:

When wiping, do not push or pull the needle bar forcibly, so as not to bend the reagent/sample needle and affect the normal staining.

Clean the workbench and keep the surroundings clean and ventilated.

6.3 Weekly and Monthly Maintenance

1. Wash the module with clean water and mild detergent; regular cleaning (weekly) is required to prevent the accumulation of dirt.
2. Regularly inspect the solid cover diaphragm (at least monthly) for cracks, water leaks, and aging gaskets.
3. Check the module and machine for loose screws. (monthly).
4. Inspect the tubing/hoses for damage or accumulation of actual waste (monthly).

6.4 Annual Maintenance

Preventive maintenance must be carried out once a year. Due to the high requirements of annual preventive maintenance work, it should be carried out by an engineer authorized by the company. Please contact the customer service department in our company before annual maintenance.

6.5 Maintenance for Instrument Not Used for a Long Time or Before Transportation

If the instrument is suspended for more than two consecutive weeks or needs to be packed and transported, the following steps should be performed:

(1) Take out the remaining reagents from the reagent rack, cover the reagent bottle caps, and store them in the refrigerator at 2~8 °C to prevent the reagents from being deteriorated and invalidated.

(2) Empty the buffer solution barrel, add pure water to it, use the priming function to rinse the pipeline repeatedly and then empty the pipeline and buffer solution barrel.

(3) Perform the [Shutdown] operation of the stainer to cut off the power of the instrument.

(4) Remove the solid cover diaphragm and clean up salt deposits and debris near it and the heater.

(5) Wash the power cord with a clean cloth dipped in neutral detergent, dry it in a cool place, and pack it in a plastic bag.

(6) Place the instrument and the parts packed with plastic bags in the packaging box.

(7) In case the instrument has not been used for a long time and it needs to be reinstalled, connected and used again, it is necessary to contact the Wondfo customer service center for on-site service to confirm and calibrate it to ensure that the instrument meets the test and use requirements.

Chapter 7 Warnings, Precautions, and Symbol

To use this instrument safely and effectively, please be sure to read the following precautions carefully first. Using the instrument in a manner not specified by the manufacturer may impair the protective function in the system, resulting in personal injury or damage to the instrument.

7.1 Safety Precautions

7.1.1 Preventing electric shock

After the instrument is powered on, non-authorized maintenance personnel should never open the instrument case.

If liquid (generally refers to liquid substances) enters the inside of the instrument or the instrument leaks liquid, please turn off the power immediately and contact our customer service department or the distributor in your area in time. Improper use of liquid (generally referred to liquid substances) may create an electric shock and cause damage to the instrument.

7.1.2 Mechanical hazard protection

(1) During the operation, the robot arm and other moving parts will move without warning and the speed of movement may cause injury. Please do not attempt to open the instrument lid during operation.

(2) When the instrument is running, please do not get close to the sample needle and reagent needle to avoid being stabbed.

(3) When the instrument is running, please do not get close to the robot arm and other moving parts to avoid being injured.

(4) When the instrument is running, please do not place objects within the moving range of the moving parts to prevent damage to the instrument.

(5) Operators must be trained in safe operating procedures before operating the instrument.

7.1.3 Protection from biochemical hazards

(1) Some of reagents used in immunohistochemistry and in situ hybridization are hazardous and you should ensure that you are adequately trained in this procedure. All relevant laboratory procedures and government regulations should be followed in the use and handling of reagents.

(2) Use the sample correctly, otherwise there is a risk of infection.

(3) Do not touch buffer solutions, reagents and waste liquid with bare hands and always wear gloves when handling.

(4) Once your hands or clothing come into contact with the reagent, the reagent must be rinsed thoroughly with soap and water immediately.

(5) If the reagent accidentally gets into your eyes, please rinse it immediately with plenty of water and consult a doctor for further treatment.

7.1.4 Waste liquid treatment

The disposal of reagents, buffer solutions, waste liquids, waste samples and other substances should follow the corresponding biomedical waste management regulations and discharge standards, and those substances should be placed in medical trash cans for centralized processing. It is forbidden to discard them at will. Please observe local discharge regulations and consult the relevant reagent manufacturer.

7.1.5 Prevention of fire and explosion

The instrument has heating modules and heated surfaces, and there may be an ignition hazard if flammable materials are placed nearby:

Please do not use flammable hazardous materials around the instrument and do not place flammable materials on any hot surface of the instrument.

7.1.6 Use environment restrictions

Please pay attention to the scope of use declared by this instrument and do not use it beyond the scope.

(1) The instrument must be installed in the installation environment and

conditions specified in this manual. Installation and use of this instrument outside the specified conditions may give unreliable results and may result in damage to the instrument.

(2) If you need to change the state of the instrument, please contact the user service department in our company or the distributor in your area.

7.1.7 Other restrictions

(1) For in vitro diagnostic (IVD) use only.

(2) Please do not expose the instrument to high humidity or direct sunlight, and do not freeze.

(3) The supporting reagents are for one-time use only, please do not reuse.

(4) Please keep the reagent rack and slide position clean and dry.

(5) Please do not operate with a mobile phone at the same time to avoid electromagnetic wave interference.

(6) Please do not touch the slide staining device and its surrounding area. These areas may be very hot and may cause severe burns. It is required to wait for the slide staining device and its surrounding area to cool after the operation is stopped.

7.2 Other Precautions

(1) Except for reagents provided by the manufacturer and general primary antibody reagents, please do not put other items into the reagent rack of the instrument.

(2) Please do not disassemble the instrument without the written authorization of Wondfo or its sales representative.

(3) Please use the instrument in the environmental conditions specified in this manual. If the conditions of use are exceeded, the instrument may not operate normally, which may affect staining results, damage the parts and threaten the safety of users.

(4) If the instrument is out of use due to maintenance, processing or damage

during transportation, please call customer service.

(5) When handling potentially infectious substances, protective measures such as gloves and masks should be used.

(6) The staining results are only for reference, and the results should be interpreted by professional medical personnel. It is recommended that doctors also consider clinical examination results or other test results for clinical diagnosis.

(7) This instrument can only be operated and used by personnel trained and authorized by the manufacturer.

(8) This instrument is intended to be used in industrial places. For other environments, please evaluate the electromagnetic compatibility according to the following table.

⚠Notice:

1. It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
2. It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
3. The Fully Automated Pathology Staining System (Model No.: PA-3600)complies with the emission and immunity requirements described in Part 2-6 of the IEC 61326 series.
4. Suggest the user evaluating the electromagnetic environment prior to operation of the device.

⚠Warning:

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

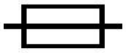
Please strictly comply with the requirements specified in this manual for daily use and maintenance.

7.3 Symbol Description

The following symbols are visible in the instructions for users, package insert, or

labels, related components and accessories.

Symbol	Description	Symbol	Description
Wondfo	Trademark		Warning danger
	Biological hazard		Hot surface
	Fragile		Do not stack
	This way up		Do not roll
	Keep dry		Keep away from sunlight
	Temperature limit		Consult instructions for use
UDI	Unique device identifier		Manufacturer
REF	Catalogue number		Date of manufacture
#	Model number	IVD	In vitro diagnostic medical device
SN	Serial number		Caution
	Device not for self-testing		Device not for near-patient testing

CE	CE marking		Importer
	This WEEE flag indicates that this device is classified as an obsolete electrical or electronic device under the EU WEEE directive	EC REP	Authorized Representative in the European Community/European Union
~	Alternating current		Fuse
Buffer Container	Buffer Solution Barrel		Stacking limit by number
	Waste Liquid Bottle (Innocuous)		Waste Liquid Bottle (Hazardous)

7.4 Contraindications

Not applicable.

7.5 Recommended Use Period

10 years. (The specific use period depends on the situation. The wear and tear of the stainer varies with different usage conditions.)

7.6 Warranty Period

The warranty information is subject to the sales contract. Generally, the product is guaranteed for 12 months from the date of delivery to the user. During the warranty period, all products can enjoy free after-sales service. However, if the products need maintenance due to the following reasons, our company will implement charging maintenance service:

1) Man-made damage；

2) Improper use；

3) The grid voltage is beyond the specified range of the product；

4) irresistible natural disasters；

5) Replace or use parts that are not approved by our company or be repaired by personnel not authorized by our company；

6) Other failures not caused by the product itself；

After the warranty period expires, our company will continue to provide paid maintenance services.

Chapter 8 Repair, Transportation and Destruction

For repair, transportation and destruction services, please call: 800-999-4268, 400-888-5268

Except for replacing instrument consumables or cleaning regularly, the instrument generally does not require special maintenance. For detailed maintenance procedures, please refer to *Chapter 6 Maintenance*.

8.1 Repair

If there is an instrument malfunction, please call our customer representative at 800-830-2094 for consultation. If the instrument does need repair, our technical service staff will be at your door in the shortest possible time.

8.2 Transportation

The packaged instrument can be transported by general tools. On the way, attention should be paid to preventing the instrument from moisture, sunlight and shock. The specific transport requirements are as specified in the order contract.

The transport environment of the instrument is less than 2000 m above sea level, ambient temperature of -40~55 ℃, relative humidity of 20%~70% (non-condensing). Please transport the instrument under the environmental conditions to avoid instrument damage or electric shock hazards. During transportation, it must be protected from severe shock, rain or exposure to sunlight. Please do not change the packaging at will during transportation to avoid damage to the instrument.

The instrument is marked with transport marks, as shown in the figure below. Please transport the instrument based on the marks to prevent damage to it.

⚠Notice:

If the instrument needs to be moved again after installation or needs to be repackaged and

transported, please contact the Wondfo Customer Service Center.

8.3 Storage

The packaged instrument should be stored in an environment with temperature of -40 ℃～55 ℃, relative humidity ≤85% (non-condensing), altitude of less than 2000 m, no corrosive gas and good ventilation.

8.4 Destruction

The Fully Automated Pathology Staining System accessories and the packaging has to be disposed correctly at the end of usage. Disposal of used analyzer should be in accordance with local ordinances and regulations.

8.5 Return

Should a malfunction occur, please contact the sales representative via 800-999-4268 or 400-888-5268. If it was determined that the instrument should be returned, a return authorization number will be assigned and a replacement instrument will be sent to you by Guangzhou Wondfo Biotech Co., Ltd. The return authorization number is printed on the packaging of the replacement instrument. The user is expected to utilize the packaging of the replacement instrument to return the malfunctioning instrument. Please send the instrument back to Guangzhou Wondfo Biotech Co., Ltd. as soon as possible following the receipt of the replacement instrument.

Chapter 9 Troubleshooting Guide

As it is a precision instrument, please operate and maintain it in strict accordance with the requirements in this manual so that its long-term and reliable operation can be ensured. The instrument should be placed in a room with a suitable temperature and a dry environment, on a stable and clean indoor operating table, protected from direct sunlight and dust and performed regular maintenance operations.

In the event of an error, there will be an alarm message at the bottom of the main interface, as shown in Figure 9-1.

Figure 9-1 Alarm Prompts

When there is any failure that affects the normal operation of the instrument, please handle it according to the solutions indicated in the alarm list in the main interface.

Notes: If the customer still cannot eliminate the fault according to the above solutions, please contact the after-sales service staff of Wondfo in time, and do not disassemble the instrument and replace the relevant parts without authorization in case of danger.

Common Troubleshooting Table

Phenomenon	Cause	Solution
The instrument cannot be turned on.	Power failure	Check the power plug
	Poor contact between instrument and power cord	Unplug the power cord and rewire the instrument
	The power switch is not turned on.	Turn on the power switch

Display error	Electrostatic effect	1. Ground the instrument to discharge static electricity
		2. Reboot
	Circuit failure	Please call Wondfo Customer Service Center
Alarm message: The temperature of the staining module is abnormal.	Staining module failure	Please call Wondfo Customer Service Center
Errors in read-out reagent information	Errors in information transmission and analysis	Please call Wondfo Customer Service Center
The QR code for loading slide cannot be identified.	Scan code component failure	Please call Wondfo Customer Service Center

Notes: If the customer still cannot eliminate the fault according to the above solutions, please contact the after-sales service staff of Wondfo in time, and do not disassemble the instrument and replace the relevant parts without authorization in case of danger.

Chapter 10 Contact information

Guangzhou Wondfo Biotech Co., Ltd. declares that the warranty will only be guaranteed under the condition that the user completely follows the instructions specified by the manufacturer. Otherwise, Wondfo will not be responsible for any guarantee of indirect or consequential damages arising from the incorrect use. The pictures in this manual are for reference only, please refer to the actual situation for details.

We have customer service team with extensive industry experience. If you have questions, suggestions or comments, please feel free to contact us.

For technical support , please call: 800-999-4268, 400-888-5268

Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City,

Huangpu District, 510663 Guangzhou, P.R.China

Tel: (+86) 400-830-8768

E-mail: sales@wondfo.com.cn

Website: en.wondfo.com

EC REP

Qarad EC-REP BV

Pas 257,2440 Geel,Belgium

Appendix 1 Introduction to Program Principles

Immunohistochemistry (IHC)

The instrument supporting reagents apply the antigen-antibody reaction, a basic principle of immunology, i.e., the specific binding of antigen and antibody, to make the antibody-labeled chromogenic reagent (fluorescein, enzyme, metal ion, isotope) visualize a color through chemical reaction and then determine the antigens (polypeptides and proteins) in tissue cells. The localization, qualitative and relative quantitative researches on such antigens would be carried out.

Fluorescence in Situ Hybridization (FISH)

The instrument supporting reagents apply histochemical and molecular biology techniques to directly detect and locate a specific target DNA or RNA on tissue sections through hybridization of nucleotide fragments (probes) of known sequences which is directly or indirectly labeled by fluorescein.

Appendix 2 Bibliography

1. Chinese Medical Association. Pathology volume of clinical technical operation specification[M]. People's Military Medical Press.2004.
2. Bingquan Wu, Yanfang Liu. Immunohistochemical pathological diagnosis (2nd edition) [M]. Beijing Science and Technology Press. 2013.
3. Jianfang He, Anjia Han, Qiuliang Wu. Practical immunohistochemical pathological diagnosis [M]. Science Press. 2018.

Appendix 3 Order List

The following accessories are recommended in the use of Wondfo instrument.

⚠Warning:

The accessories supplied by Wondfo Company must be used. Other types of accessories may damage the analyzer and affect the performance and safety of the instrument.

Order List

No.	Content
1	Power Cable
2	Data Cable
3	Float Sensor
4	Tube Clamp
5	Printer
6	Reference Tissue Slide
7	7mL Reagent Vial(with RFID tag)
8	Waste Liquid Container Base
9	Waste Liquid Container
10	Waste Liquid Tube - Blue
11	Waste Liquid Tube - Black
12	Label
13	Ribbon
14	Computer Host
15	Monitor
16	Solid Cover Diaphragm

Material Required but Not Provided

Name	Trademark	Specification
PA-Immunochromogenic Reagent	Wondfo	100 tests/box
PA-Sample Release Reagent	Wondfo	100 tests/box
PA-Wash Buffer	Wondfo	1L/ bottle
PA-Retrieval Solution(pH9.0)	Wondfo	100 tests/box
PA-Retrieval Solution(pH6.0)	Wondfo	100 tests/box
PA-Bluing Reagent	Wondfo	100 tests/box
PA-Enhancer(Linker)	Wondfo	100 tests/box

For other languages: DE/ FR/ IT /ES/ PT
Scan the QR code or copy the Link to view or download
https://en.wondfo.com/Pathology-Platform.html