

S80 Fully Automated Urine Sediment Analyzer



User Manual

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FOREWORD

This manual is used for the installation, commissioning, operation, use and maintenance of the S80 Fully Automated Urine Sediment Analyzer. If the version updated, it will not be notified.

This equipment complies with the emission and immunity requirements described in GB / T 18268.1-2010 and GB / T 18268.26-2010.

This equipment has been designed and tested to CISPR 11 Class A equipment which is defined in GB 4824. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

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

If the equipment is not used according to the manufacturer's method, it may damage the protection provided by the equipment.

Contents

1.1 Overview.....	错误!未定义书签。
1.2 Scope of Application.....	错误!未定义书签。
1.3 Contraindication	错误!未定义书签。
1.4 Main Structure Composition	错误!未定义书签。
2 Instrument Installation	错误!未定义书签。
2.1 Accessories List.....	错误!未定义书签。
2.2 Packaging	6
2.3 Installation	错误!未定义书签。
2.4 Cleaning System Installation.....	错误!未定义书签。
2.5 Dealing for Nonuse for S80.....	错误!未定义书签。
2.6 Pasting Bar Code on Test Tube.....	错误!未定义书签。
2.7 Boot Sequence.....	错误!未定义书签。
3 Menu System.....	错误!未定义书签。
3.1 Working	错误!未定义书签。
3.1.1 Operation Test	错误!未定义书签。
3.1.2 Alarm	错误!未定义书签。
3.1.3 User	错误!未定义书签。
3.2 Filing	错误!未定义书签。
3.2.1 Sample/Elements Overview	错误!未定义书签。
3.2.2 Sample Information Modifying.....	错误!未定义书签。
3.2.3 Sample Selection	错误!未定义书签。
3.2.4 Elements Information Modifying.....	错误!未定义书签。
3.2.5 Sample backup.....	错误!未定义书签。
3.2.6 Image Thumbnail.....	错误!未定义书签。
3.2.7 Image Editing	错误!未定义书签。
3.3 Setting.....	错误!未定义书签。
3.3.1 Routine	错误!未定义书签。
3.3.2 Maintenance.....	错误!未定义书签。
3.4 Others.....	错误!未定义书签。
4 Operation.....	错误!未定义书签。
5 Quality Control	错误!未定义书签。
5.1 Quality Control	错误!未定义书签。
5.2 Quality Control Serum Management.....	错误!未定义书签。
5.3 View History Data	错误!未定义书签。
6 Maintenance Methods for Product	错误!未定义书签。
7 Errors and Handling.....	错误!未定义书签。
8 Performance Anlysis	错误!未定义书签。
9 Support.....	错误!未定义书签。
9.1 Maintenance Statement.....	错误!未定义书签。
9.2 Order Information	错误!未定义书签。
10 Product Performance, Specification and Storage Condition	错误!未定义书签。

11 Sybol Description	错误!未定义书签。
12 Replace Fuse of Power Socket	错误!未定义书签。
13 Transport Condition and Method	错误!未定义书签。
14 Product Feature	错误!未定义书签。
15 Caution, Warning and Note	错误!未定义书签。
16 Product Information	错误!未定义书签。

Introduction

Thank you for choosing S80 Fully Automated Urine Sediment Analyzer, manufactured by COBIO Smart Healthcare Technology Co., Ltd in China. We hope that you will be satisfied with the device.

1.1 Overview

S80 is easy and efficient to operation. The operator injects distilled water into the instrument's cleaning liquid bucket, put the counting chamber bar into the counting chamber rotating disc, and put the test tube containing the sample into the test tube rack, and then put the test tube rack on the feeding platform. Then the rest of work can be left to S80. S80 can automatically push the test tube to the sampling position, and then the injection needle is inserted into the test tube. After several suction and spitting movements, the sample is fully mixed. S80 only needs 2 ml of urine sample to get accurate test results. However, only 0.2ml was injected into the one-time counting chamber through the injection needle. After completing injection, the injection needle will be moved into a special cleaning barrel at the back of the instrument. The internal and external walls of the injection needle will be thoroughly cleaned with distilled water to avoid cross interference between urine samples.

Counting chambers containing urine samples were fed into the built-in centrifuge, centrifuging for 10 seconds at a rate of 2,000 revolutions per minute. The visible elements distributed in the sample are deposited to the bottom of the counting chamber, which is the side of the microscope.

After centrifugation, a built-in camera, through a built-in microscope, collects images at different points in the count image collection area. All collected images are processed through a high-quality image processing software to detect visible elements in urine.

The results and images can be stored in the hard drive of the S80's computer host, with a standard storage capacity of 25,000 records.

1.2 Scope of Application

S80 can automatically checks for visible elements in urine: Red blood corpuscle (RBC), White blood corpuscle (WBC), and cylinderuria (PAT/HYA).

1.3 Contraindication

None

1.4 Main Structure Composition

S80 is mainly composed of hydraulic system, optical system, mechanical system, circuit control system, analysis and processing software, input and output equipment.

2 Instrument Installation

2.1 Accessories List

Power cord	2pcs
RS232	1pc
USB cable	1pc
1394 wire (1394 special for camera) or network cable (special for webcam)	1pc
VGA cable	1pc
Fuse (T6.3AL250V)	2pcs
Fuse (T3.15AL250V)	3pcs
Liquid waste barrel	1pc
Cleaning fluid barrel	1pc
Feeding disk	1pc
Catheter ϕ 6	1pc
Catheter ϕ 8	2pcs
Rotating disk	1pc
Former rail	1pc
Rear rail	1pc
Feeding module	1pc
Counting chamber bar (contain 50 visible elements counting chamber)	12pcs
Test tube + Test tube cap	100pcs
Test tube rack	10pcs
Product Manual	1pc
Computer host	1pc

2.2 Packaging

Preparations



Biohazard risk

This instrument is likely to be infectious and pathogenic during use. Please discard it as biological waste according to local regulations.

Caution

- Inspect parts are intact comparing to the accessories list before the instrument installed. If the package is incomplete or damaged, please contact your distributor immediately, otherwise, continue to read the following operation.
- Don't place the instrument in direct sunlight, because of the strong sunlight may interfere with the instrument of optical sensors.

S80 is packed with foam model and wooden case in transportation. Before installation, clean the table of the instrument to be placed, and need a solid and stable table of 100 x 200 cm that can support the equipment of 100 kg. Refer to the packing list above for the detailed number of parts

involved. Please pay attention to the shipping mark on the box when opening the package. Cut off the tape to keep the wooden box intact. It is suggested to keep wooden box, foam box, self-tapping screw and fastening screw for internal fixation of instrument for future transportation.

Instrument placement space: the minimum installation distance needed to be set aside from walls or other devices is shown below.

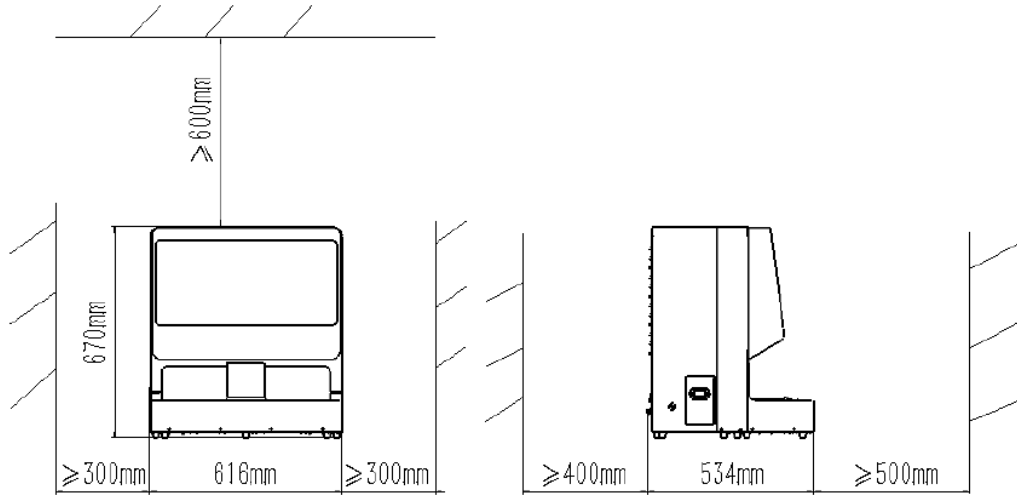


Figure 2-1

Caution:

- Because the backside of Instrument need to connect the pipe, wire, etc., also need to put cleaning fluid barrel and liquid waste barrel, so it should be convenient for people to come in and out when the instrument put.

Input and Output introductions

1. Introduction for interface panel, as shown below:

- 1——1394 camera exclusive interface, connect the computer host
- 2——USB control interface for the liquid waste, connect the liquid waste barrel
- 3——Function reserved interface, forbidden
- 4——VGA interface on the display screen of the instrument host, connected to the computer host
- 5——RS232 control interface for the lower computer, connected to the computer host
- 6——USB control interface for cleaning fluid, connected to the cleaning fluid barrel
- 7——USB control interface for the touch screen, connected to the computer host
- 8——Power switch of the instrument host
- 9——The power interface of the instrument host, connected with the power supply of external network
- 16——Connection bridge reserved interface, use when connected with dry chemical machine
- 17——Network camera professional interface, connected to computer host

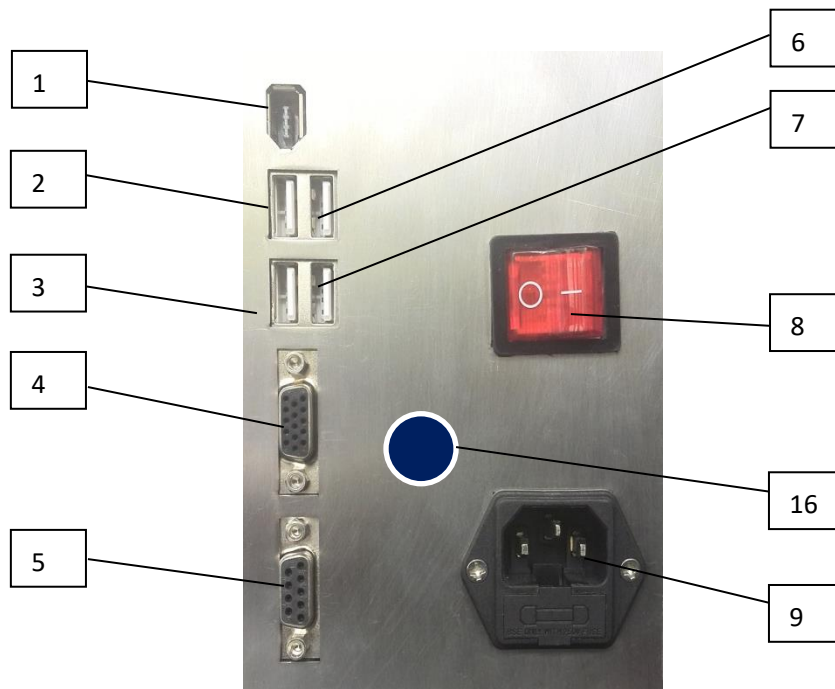


Figure 2-2

After the wire is inserted, it is shown in the following figure:



Figure 2-3

2. Piping joint description, as shown in the figure below:

- 10—Quick connection of cleaning fluid pipe, connected to the cleaning liquid barrel
- 11—Quick connection of liquid waste, connected to the liquid waste barrel
- 12—Quick connection of liquid waste, connected to the liquid waste barrel



Figure 2-4

Figure 2-5

3. Instructions of the emergency stop button and the waste materials box, as shown below:

13—Stop button: Press the emergency stop button to stop all mechanical actions of the instrument host in case of the instrument failure such as collision.

14—Waste materials box, is the collection device for waste counting chamber. Please clean up the waste counting chamber when it is full or not used for a long time.

15—Handle of waste materials box: Hold the handle and gently pull outward to remove the waste materials box.

16—Barcode scanning port: When scanning the bar code on the sample tube, LED light is emitted. Don't look directly into the light, which can cause damage to the eyes.

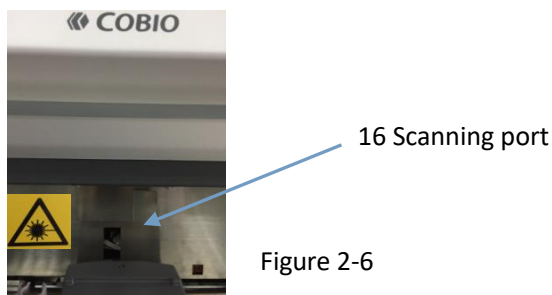


Figure 2-6

2.3 Installation

1. At least two persons are required to hold the bottom and place it smoothly on the workbench.
2. Remove protective objects for safety during transportation and remove the M5x60 inner hexagon cylinder head screw used for instrument fixation during transportation. It is recommended that they be kept for use the next time the instrument is moved.
3. Take out the counting chamber former rail from the waste materials box and install it on the position of injection sample where right side of the centrifuge.
4. Take out the counting chamber rear rail from the waste materials box and install it on the position closed to microscope where left side of the centrifuge.
5. Install the counting chamber disk on the axle closed to the counting chamber former rail.
6. Put the counting chamber bar into the counting chamber rotating disk, and then cover the feed disk and lock the butterfly bolt.

7. Connect the feedstock module with the communication conductor of the main machine.
8. Aim the positioning pin hole and the buckle of the feedstock module at the pin and the buckle of the host, and then push in, and the sound of "click" is heard, that is installed in place.
9. Connect the computer with the main machine.
10. Connect power to the main machine and computer host respectively. Earth protection must be proved when power is connected.
11. Please restart the instrument after each installation or upgrade procedure.

Precaution

- **It is very important that tearing down the plastic ribbon which fixed sampling module and fixing screw before starting up. When the power is turned on, the instrument is initialized, including the motion check of each elements. If the ribbon and fixing screw are not removed, the instrument may be damaged.**
- **ac voltage range 100-240 - v, the scope of this instrument can automatically adjust the power supply voltage. Do not exceed this power supply range.**
- **Non-professional personnel shall not open the instrument rear panel.**

2.4 Cleaning System Installation

1. Connect the two thick catheters to the inside of the liquid waste barrel through the jack on the liquid waste barrel lid. Leave the two thick catheters 10cm long in the liquid waste barrel and the other end connected to the equipment main machine.
2. Connect the liquid waste barrel sensor to the No. 2 liquid waste USB control interface of the device main machine by USB cable, see figure 2-2.
3. Pour distilled water into the cleaning fluid barrel.
4. Insert the thin catheter into the cleaning fluid barrel through the lock buckle on the cover of the cleaning fluid barrel. One end of the thin catheter is inserted into the bottom of the barrel and the other end is connected to the device main machine. The No.10 cleaning fluid catheter is jointed to the quick connector, inserted tightly, see figure 2-4 is.
5. Connect the cleaning fluid barrel sensor to the No.6 cleaning fluid USB control interface of the device main machine by USB cable, see figure 2-2.
6. Put the two barrels closed the device main machine.

Note:

Put the liquid waste barrel under the water level of the instrument. According to the principle of gravity, the remaining liquid in the instrument can be introduced downward into the container without suction. Put it on the ground, the suction pump suck up the liquid waste depending on the principle of siphon, so the catheter of liquid waste bottle should not be too long. So pay special attention to the fact that the tube continues down.

2.5 Dealing for Nonuse for S80

When S80 is not in use, there is no special processing arrangement. Just follow the following steps to store it:



Warning

- **Because urine is a fluid from people, there may be contagious and the biological risk. Trained people are treated according to local regulations.**
 - **Handle carefully with the counting chamber and the urine containers which were used.**
 - **When operating S80, pay attention to wear rubber gloves and other protective clothing.**
1. Clean the instrument with disinfectant, close the S80 and PC host, and then disconnect the line.
 2. Discard the used counting chambers in the waste materials box.
 3. Empty all the liquid in both barrels and clean them, pack them after drying, and keep the lids open.
 4. Fix the sampling module by set screws.
 5. Clean S80 carefully and remove all removable elements. Package after drying in the same state as before. If you want the instrument to return to normal operation, please refer to steps in section 2.3 for instrument installation.

2.6 Pasting Bar Code on Test Tube

The S80's built-in bar code scanner automatically identifies the barcode attached to the test tube of the urine sample being tested. S80 can identify the type of bar code: one dimensional code including code39\Codabar\code128\UPC\EAN, etc. two dimensional code including QR Code\Data Martix, etc.

The barcode should be pasted in the middle of the test tube, as shown below, between two red horizontal lines.

Note: if the pasting position of the barcode is beyond the red horizontal line, it may cause the S80 built-in bar code scanner to be unable to identify properly. In addition, the bar-coded side must be placed on the open side of the test tube rack, otherwise the S80 built-in bar code scanner will not be recognized.



Figure 2-6

2.7 Boot Sequence

1. Turn on the power switch behind the S80.
2. Turn on the power switch of S80 matching computer.
3. Double-click the S80 software icon to start the program and wait for instrument initialization.
4. After the S80 initialization window is closed, sample detection can be conducted.

3 Menu System

3.1 Working

During normal inspection, the working page is shown in the following figure:

The screenshot shows the COBIO software interface with a table titled '作业列表 (8)'. The table has columns for '时间' (Time), '试管架' (Tube Rack), '试管' (Tube), '编号' (ID), and '状态' (Status). The status column uses colored circles: green for '完成' (Completed), red for '报警' (Alarm), and yellow for '离心' (Centrifugation).

时间	试管架	试管	编号	状态
2013-12-25 09:24:05	1	1	10000	完成
2013-12-25 09:24:08	1	2	10001	完成
2013-12-25 09:25:04	2	3	100	完成
2013-12-25 09:25:07	2	4	101	完成
2013-12-25 09:25:12	2	5	102	完成
2013-12-25 10:16:42	1	1	200	完成
2013-12-25 10:16:45	1	2	201	报警
2013-12-25 10:16:50	1	3	202	离心

Figure 3-1

Top bar icon:

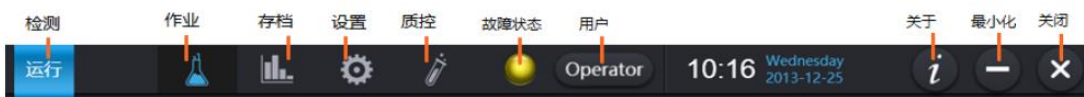


Figure 3-2

3.1.1 Operation Test

After the red indicator light on the feeding platform is off, put the tube rack on the feeding platform and click the "run" menu on the top. There are different ways of testing according to different situations.



Figure 3-3

Automatic: Use for batch automatic inspection for a large number of samples. The equipment will continue to work, continuously complete automatic sampling and sampling inspection, and automatically output results (can be viewed on the archive page), without manual intervention.

Manual: you can specify the sample size for a test and the number of tests passed.

Quality control: quality control for checking the availability of instrument. Prepare the quality control product, the low-value quality control product is first, the high-value quality control product is second, then start the quality control inspection. Status shows success indicates availability and failure indicates unavailability.

You can set the start number before starting the instrument, as shown in the figure below.

Note: you can indicate different meanings by setting different starting Numbers, such as the number starting from 5000, the number of hospitalized patients, and the number starting from 8000, the patients who have participated in the physical examination.



Figure 3-4

In the automatic detection process, the run menu has the option of "emergency".

Emergency: In the process of automatic inspection, if you encounter an emergency sample, you can use the "emergency" function to insert the emergency sample into the test sequence. Before the emergency starts, the test tube rack currently under examination should be completed. The emergency sample, the test tube rack was used as the unit.

Upon completion of the emergency, the instrument will return to the automatic examination mode and continue to examine the remaining samples.

3.1.2 Alarm

System failure states (both software and hardware) are indicated in different colors. [see top bar icon: Figure 3-2, failure status]

Green indicates system normal, yellow indicates warning, red indicates error.

Click the status light to see the details when red and yellow appear.

3.1.3 User

Indicate the current user, namely the instrument operator, [see top bar icon: Figure 3-2-User], click to view user information, change password and switch users.(User's other related operations can be seen in the top bar icon: Figure 3-2 Settings -> Maintenance sub-page)



Figure 3-5

After the sample is tested, it will be archived automatically. You can go to the archive page to view it.

3.2 Filing

3.2.1 Sample/Elements Overview

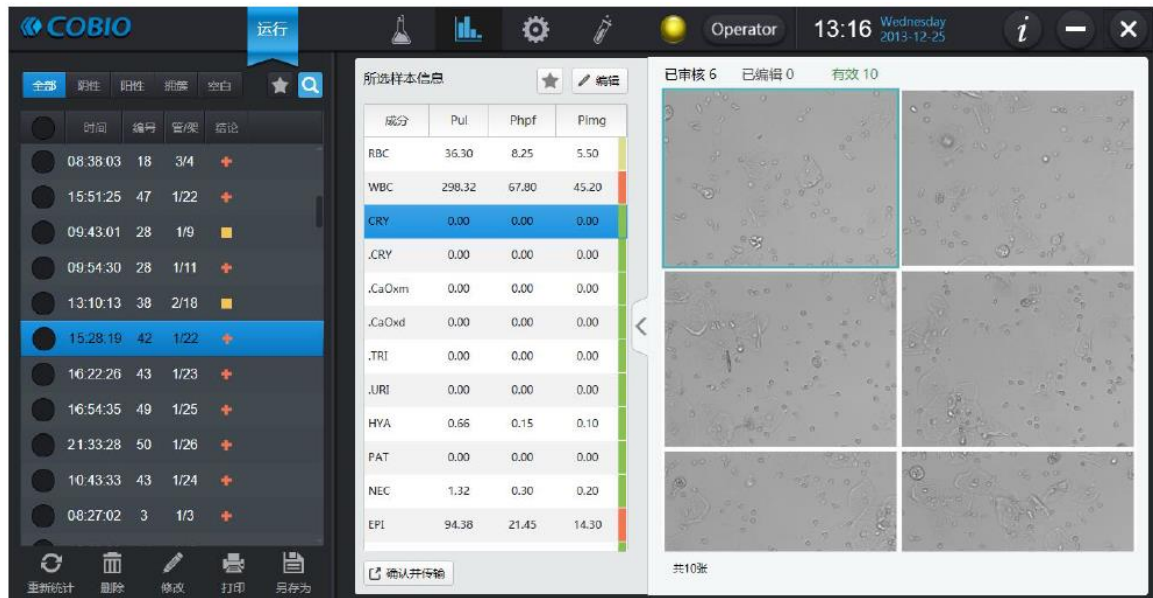


Figure 3-6

The archive page is divided into two parts: the left (dark background) is the tested sample, and the right (light background) is the selected sample information: composition table and image.

The conclusions of the sample are various: Negative(—), Positive(+), Mass(■), Blank(□).

Note: Negative means that all the element/cells in the sample are negative.

Positivity refers to the presence at least one positivity among the many element/cells in the sample.

Mass means that the sample has too many element/cells to be properly analyzed by the system and needs to be manually reviewed.

Blank means that the image of the sample is blank, which is usually due to the lack of liquid extraction by the instrument.



If the sample belongs to the quality control sample, there are only two conclusions: Pass(✓), Failure(⊘).

Pass means the elements/cell content determined by the instrument conforming to the content range of quality control requirements, that is, in control.

Failure refers to the loss of control when the elements/cell content determined by the instrument exceeds or falls below the quality control requirements.

Note:

- It can hide or show some column of the sample list and composition list, see the top bar icon: Figure 3-2 Settings - > Routine/show subpages.

The operation at the bottom of the sample list (except modification) can be applied to multiple samples at one time by checking the circular selection box to the left of the list item:  --> 

The [confirm and transmit] at the bottom of the elements list transmits the information to LIS. A tick mark in the sample list LIS indicates that the sample information has been transmitted to LIS.(note: transmission is related to LIS system of a specific hospital, which needs to be realized separately.)

From the thumbnail list on the right, you can see the original image and its information. See Figure 3-9.

3.2.2 Sample Information Modifying


Compared with the manual microscopic examination, a few samples with differences can be modified manually.

Click the "modify" button below the sample list to modify the information of the selected sample, as shown below.



Figure 3-7

Press the [restore] button to restore to the initial test conclusion.(see section 3.2.1 for the meaning of the conclusion)

After modification, there will be a modification mark (pencil) next to the conclusion, indicating that some sample conclusions have been manually modified .

3.2.3 Sample Selection

A selection button at the top of the sample list can be used to screen samples that meet certain criteria.

Negative, positive, mass, blank only filter the samples in the current sample list. Favorites and lookups can change the list.



Lookup: Click this button to specify the selection criteria.



Figure 3-8

The date can be specified either as a day or as a time period.

Multiple conditions, the "and" relationship: if a number (or bar code) is specified, indicates the date of the screening, and the number (or bar code) is a sample of a value.

3.2.4 Elements Information Modifying

In the elements statistics results section, select a elements and click the [edit] button at the top right of the list to modify the content or qualitative results of the elements. When modified, the list item background is highlighted. Press the [restore] button to restore the elements results automatically recognized by the device.

3.2.5 Sample backup

The [save as] button at the bottom of the elements list can be used to store a copy of the sample. The copy is saved in the form of a web page. For relevant Settings for storing copies, see the top bar icon: Figure 3-2 Settings -> routine subpage.

3.2.6 Image Thumbnail

On the far right is the list of thumbnail images of the sample. Double-click the mouse or long press a thumbnail to see the high clear image and its elements distribution. Some images can be left out of the composition statistics (see image editing section), and the thumbnail will appear gray-white if not in the statistics. The left side of the graph is involved in the statistics, and the right side is not involved in the statistics)

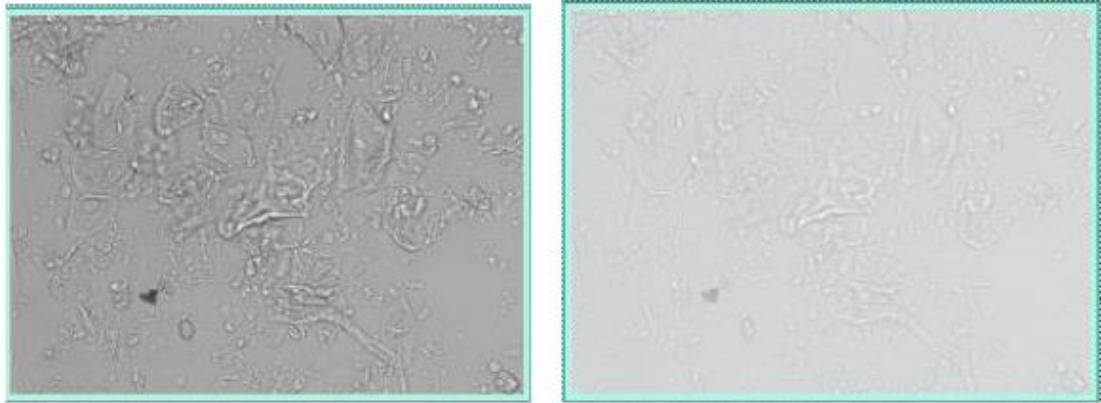


Figure 3-9

3.2.7 Image Editing

Default display and Settings, as shown in the following figure:

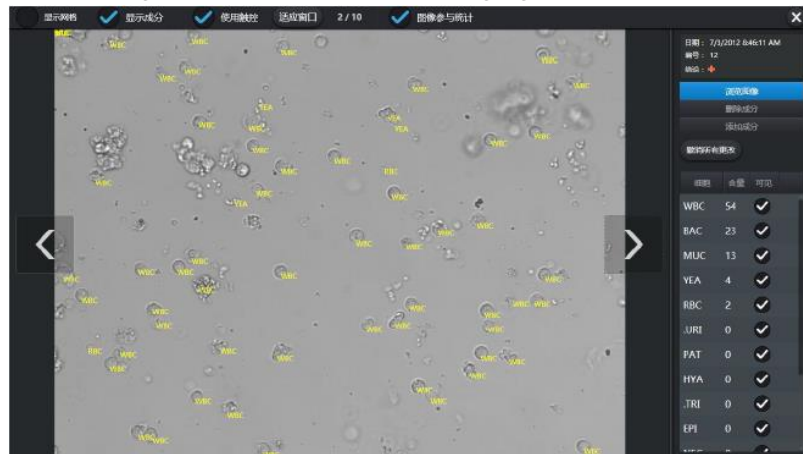


Figure 3-10

Top:

Grid display switch and **elements display** switch used to control grid and elements display or hiding.

Note: The "visible" column of the contents list in the lower right corner allows certain element to be displayed or hidden.

Image participation statistical switch: if the image's composition distribution and content are in line with the actual situation and can reflect the disease condition, check. Otherwise, if the image has large blank or dark areas and the composition distribution and content are not objective, do not check.

Right side:

The upper part is the basic information of the sample (including this image), the lower part is the content information of this image, and the middle part is the operation related to composition editing.

Browse images: At this point, the image can be viewed front and back through the navigation buttons on both sides of the image. If the "touch" switch on the top of the window is checked, you can use your fingers to drag the image to switch the image. You can use two fingers to zoom the image.

After zooming, you can use one finger to move the image. At last, click the "fit window" button at the top to make the image fit the window size. If the "touch control" switch is not checked, you can use the mouse wheel to zoom the image. After zooming, you can press the left button to drag the image, and click the "fit window" button or the left button to click the image to make the image adapt to the size of the window.

Delete elements: At this point, you can remove an element by clicking it with your finger or mouse. (The finger or mouse depends on the top switch)

Add elements: at this point, select the added elements type in the drop-down list (the drop-down list is immediately below the [add elements] button) and click on the image to add to the image.

Undo all changes: restore the original elements statistics.

Note: If more elements are added or deleted, mouse operation is recommended. Mouse is more accurate and faster than finger.

After finishing operation, click the top right corner to close and return to the archive page.

3.3 Setting

3.3.1 Routine



Figure 3-11

The output part, Automatic Sending and Automatic Printing means that every time a sample is tested, the sample is sent to LIS or printed out. Selectively send or print based on setting according to the conclusion type. The sample conclusion type is shown in section 3.2.1. Inclusion of only positive elements means that only those elements/cells that are positive in the sample are sent or printed.

Startup screen keyboard of the display section: Whether to display the system soft keyboard when you need to input text.

Note: the options in the setting page cannot be changed during detection.

3.3.2 Maintenance



Figure 3-12

User list is that records all users using the system.

Automatic clearing, used to clear historical data on computer disks to make room. (**Note:** This will only clear the default archive, not a copy of the sample stored.)

The name of the laboratory will appear on the copy or printed report to indicate the source.

3.4 Others



Figure 3-13

1. The dark background is today, and the blue background is the date you choose
2. Click the title at the top of the calendar control to switch to the year/month selection panel.
Click the title again to switch to the year/decade (ten years) selection panel
3. Click on the bottom of [today] and it will jump to today

Spinner Control:

Press and hold the mouse button or long press the + and - on both sides to rapidly increase and decrease the value.

4 Operation

1. Open the door of S80 equipment under the shutdown state.

2. Turn and remove the butterfly screw on the upper disc, and remove the disc at the same time.
3. Before inserting the turntable, please shake the counting chamber bar up and down to facilitate the smooth falling of the counting chamber plate. Insert the counter chamber bar into the slot corresponding to the rotary disk. Note that the limit bar on both sides of the counter chamber bar should be aligned with the card slot on the turntable and inserted in place.

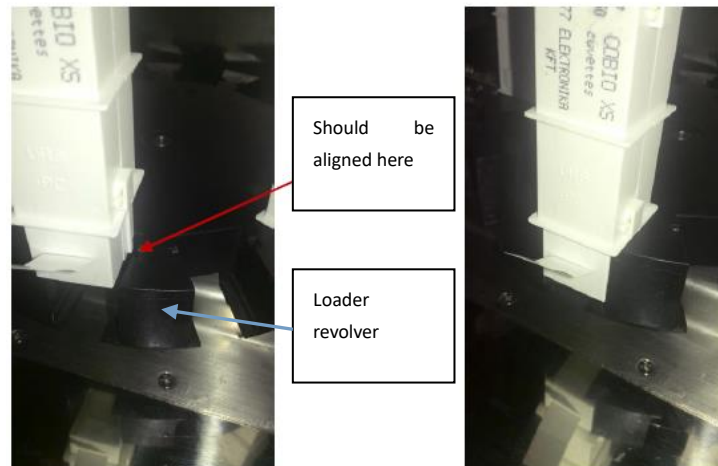


Figure 4-1

4. Put your hand on the counter chamber bar and pull out the sealing strip on it, as shown in the figure below. Be careful not to bring the counting chamber tank out of the slot position when tearing the sealing strip. Otherwise, it will affect the normal rotation of the rotating disk and cause the chuck fault.



Figure 4-2

5. Repeat steps 1-4 to fill the entire rotating disk, and a total of 12 counting chamber bar can be installed at one time.
6. Cover the disc and tighten the butterfly screw. See the figure below.



Figure 4-3

7. After loading the counting chamber, close the door of S80.
8. Turn on the power switch of main machine.
9. Open the computer operation procedure and start the instrument self-check.
10. After the self-inspection of the instrument is completed and the red indicator light of the feeding platform is extinguished, put the test tube rack with the test sample tube into the feeding platform on the right side of the feeding platform. When the test tube rack is added later, the red indicator light on the feeding platform should be put out.
11. Click the **[run]** menu at the top. Select the appropriate operation mode and the instrument will start testing.
12. After the instrument testing is completed, the test tube rack will be automatically pushed to the test tube rack pushing area. At this point, you can remove the tube rack, or you can remove it once the region is full.
13. After all samples are tested, if they are no longer tested, please close the main machine, exit the running program and close the computer.
14. For necessary maintenance of the instrument, refer to section 6 Maintenance Methods for Product.

Cautions

- The equipment must be used counting chamber series of products by COBIO Smart Healthcare Technology Co., Ltd. At the same time, it must be licensed by COBIO Smart Healthcare Technology Co., Ltd.
- The counting chamber is disposable, no reused.
- No touching the unused counter chamber, any stain may affect the imaging quality of the equipment.
- Don't tear the seal before loading the counting chamber bars into the rotating disc, to prevent counting chamber tank falling off, must be installed on the rotating disk to tore to the sealing.
- Handle carefully the used counting chamber tank, because urine from human body fluids, should be handled according to hospital uniform biological hazards.

- When adding test tube rack must be in the red light is put out to the feeding platform, or push test tube rack hook will overturn the test tube rack at the time of return.

5 Quality Control

5.1 Quality Control

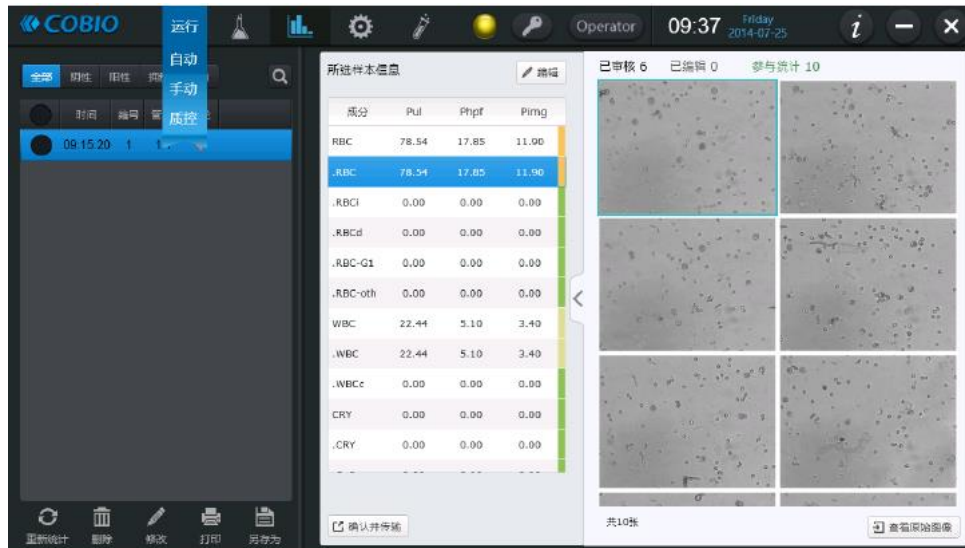


Figure 5-1

Select the [quality control] item in the [run] menu, that is, the following dialog box pops up:



Figure 5-2

Click [**Start**] to start quality operation.

5.2 Quality control Serum Management

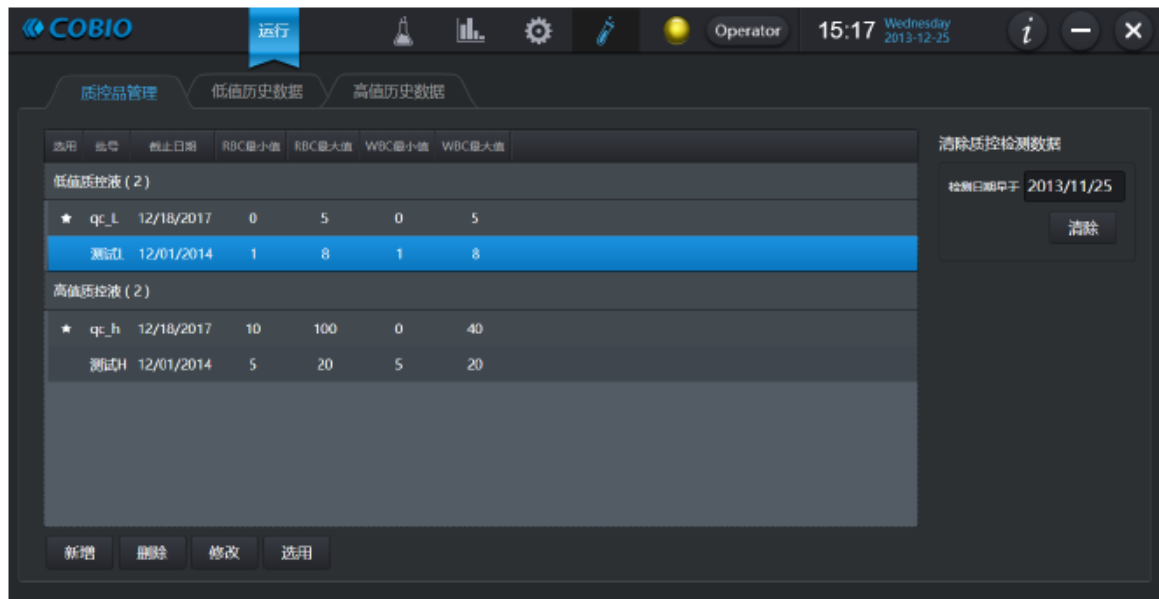



Figure 5-3

On the left is the quality control serum list, which lists all the quality control serums that can be used. The quality control serum can be added through the **[Add]** button at the bottom, be deleted through the **[Delete]** button and be modified a quality control parameter through the "modify" button. Use the **[Select]** button at the bottom to select the quality control serum for the instrument.

On the right is the cleared quality control history data.

5.3 View History Data

Select the low (or high) value history data label, enter date range, and click  button to view the low (or high) value history data information, as shown in the figure below. If there are multiple entries in the table, click on different entries to view the historical data of different quality control serums.

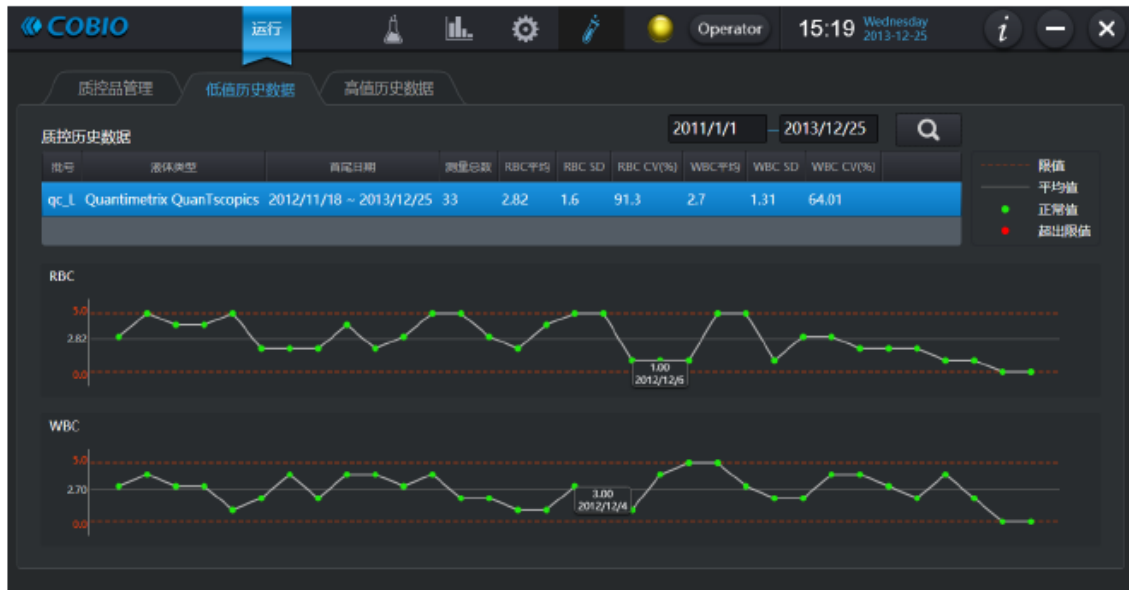


Figure 5-4

6 Maintenance Methods for Product

To avoid the spread of disease, pay attention to the full cleaning of S80. Use that such as a small amount of alcohol, a small amount of disinfectant (bacteria, fungi, viruses) as a cleaner.



Warning

- Because urine is a fluid from people, there may be contagious and the biological risk.
- Counting chamber tanks and urine containers used are careful handling.
- AS S80 being operated, pay attention to wear rubber gloves and other protective clothing.

In order to keep S80 in the best working condition, it is recommended to carry out the following maintenance work every day:

1. After turning off the instrument power switch, open the waste materials box from the left side of the equipment and empty and clean it.
2. Empty the liquid waste tank and wash with 2% sodium hypochlorite solution and then rinse with water.
3. The feeding module should be cleaned simply with a cloth soaked with a small amount of alcohol and non-aldehyde disinfectant. It should be careful not to let the liquid flow into the bottom of the test-tube rack platform, where there are wires and sensors.
4. Remove the following elements: rear rail of counting chamber, centrifugal cover and centrifugal arm. To open the enclosure, you must first remove the former rail of the counting chamber and then unscrew the butterfly screw on the centrifugal cover so that the centrifugal enclosure can be easily removed.
5. The centrifugal arm, centrifugal cover and diaphragm shall be cleaned by the operator. After the centrifugal arm and the centrifugal cover are removed, the operator wipes the centrifugal arm and the inner cavity of the centrifugal cover and diaphragm with medical

alcohol. After wiping clean, use clean medical cotton ball to absorb the residual alcohol, and then install clean centrifugal arm and centrifugal cover back to the equipment. It is required to clean after use every day. When cleaning, carefully check whether the centrifugal arm is intact. If the defects such as damage and crack are found, they need to be replaced immediately. It is forbidden to use them again.

6. Use a disinfectant to clean the disassembled parts, but the most effective method is to use a spray disinfectant. In the absence of spray disinfectant can also be used medical alcohol for disinfection cleaning, wipe dry with a dry medical cotton or cotton ball after cleaning. Pay special attention to cleaning hidden parts.
7. Carefully clean the tray part under the former and rear guide rail of the counting chamber, and fix the needle with a cloth soaked in disinfection solution.
8. Dry all the disassembled parts thoroughly before putting them back.
9. Wipe the surface of the instrument with a damp cloth if necessary.
10. For piping within the equipment, regular inspection and replacement is required.
11. When installing the centrifugal arm, it is necessary to align the locating pin hole with the semi-waist hole on the centrifugal arm and align the center at the same time. Under the action of magnetic force, it can be pushed to the bottom gently. Note: The centrifugal arm and the upper nut have been balanced and calibrated at the time of delivery and cannot be adjusted by themselves. If the nut has become loose, please send it back to us or our professional customer service engineers for re-balancing and adjustment.

Declaration:

Before using a cleaning and disinfection method not recommended by the manufacturer, the user should consult the manufacturer to ensure that the method does not damage the equipment.

Check the centrifugal module.

- a) After installation, the engineer must check the integrity and motion reliability of the centrifugal arm module.
 - b) Before delivery, it is necessary to check whether all the screws of the centrifugal parts are loose, whether there are cracks in the centrifugal arm and whether the dynamic balance of the centrifugal arm is appropriate.
 - c) Before operation, the operator shall confirm whether the protective cover has been installed and whether the screw fixing the protective cover is loose.
12. The scanning module is damaged, please contact the manufacturer or its after-sales service unit to replace the module of the same model.

Importance!

- To close software after work every day.
- Do not use spray cleaning inside the equipment. Remove the relevant removable parts before using a wet duster cloth to clean the internal parts.
- Do not move and loose the counting chamber shuttle arm retaining screw at the top of the microscope.
- Do not use hand to touch microscope lens, can only use cotton cloth to wipe clean.

- Do not use alcohol cleaning fluid other than liquid to wipe the lens.

7 Errors and Handling

Error Code	Trouble	Troubleshooting
001	Distilled water is insufficient	Add distilled water
003	Liquid waste is full	Empty the liquid waste in the liquid waste barrel
004	The work door is open	Close up the work door
005	Without counting chamber former rail	Install the counting chamber former rail
006	Without counting chamber rear rail	Install the counting chamber rear rail
007	Counting chamber is insufficient	Add the counting chamber
008	Counting chamber waste materials box is open	Install the counting chamber waste materials box and push it in
009	Centrifugal door is open	Install a centrifugal cover
010	Test tube racks are full in exit area	Remove the test tube racks from the exit area
011	The abandoned counting chamber waste materials boxes are full	Empty the counting chamber waste materials boxes

Table 7-1

Please contact professional maintenance personnel of COBIO Smart Healthcare Technology Co., Ltd., if the above error report or failure cannot be solved by the above methods.

8 Performance Analysis

Function Parameter

1. Parameter Setting
 - 1) The number of pictures for each sample can be filmed to be 5, 10, 15 and 20 pieces.
 - 2) The user can customize the start number.

2. Storage

Have storage functions for parameter setting and test result.

3. Data System

The data system should have the following functions:

- 1) Input patient information, hospital information and test results to form test reports and save them.
- 2) Search report records according to patient information and test date.
4. Have report printing function.

Performance Index

1. recognition accuracy

The analyzer automatically identify, and the negative and positive coincidence rate between the single result and microscopy were: red blood cells $\geq 70\%$, white blood cells $\geq 80\%$, and cylinder $\geq 50\%$.

The false negative rate of the analyzer is no more than 3%.

2. Repeatability

The coefficient of variable CV of counting result for the analyzer is when the cell concentration is 50 cells/ μ l, $CV \leq 25\%$; when the cell concentration is 200 cells/ μ l, $CV \leq 15\%$.

3. Stability

Within 8 hours of starting the analyzer, the coefficient of variation of cell count is $CV \leq 15\%$.

4. Contamination rate

The contamination rate of cells by the analyzer should be $\leq 0.05\%$.

5. Background Count

Analyzer blank counts for WBC and RBC should be 0.

6. Detection Limit

The analyzer can detect the sample of red blood cells and white blood cells with the concentration level of 5 / μ l.

9 Support

9.1 Maintenance Statement

Only trained professionals are qualified to maintain the instrument.

Only the original parts can be used for repair and replacement.

Before performing any instrument maintenance operation, including instrument transportation, the power should be turned off and the power cord of the main engine should be unplugged.

The manufacturer reserves the right to make final changes, so the description of this manual may be slightly different from the actual situation.

Updated documentation of specific versions of the instrument is available from the manufacturer.

9.2 Order Information

Consumables:

COBIO series counting chamber

Accessories of S80:

D1-3+D003-4

1394A 线 1.5 米

RS232(公母) 1.5 米

T6.3AL250V

T3.15AL250V

Power cord for main engine

Image acquisition firewire cable

Gigabit Ethernet cable 1.5m

Connecting cable

Fuse (power socket)

Fuse (control circuit board, power box)

Liquid level alarm switch assembly

	VGA cable male female 1.5m
	USB cable male female 1.5m
GB/T3098.20-2000	M5×35 Butterfly bolt
GB/T3098.20-2000	M5×10 Butterfly bolt
S80.Ab0000.00	Rear rail module
S80.A70000.00	Former rail module
S80.200000.00	Feeding module
S80.A80000.00	Waste materials affix
S80.800000.03	Cleaning fluid barrel
S80.800000.04	Liquid waste barrel
S80.421100.00	Injection needle welding parts
S80.520000.00	Centrifugal arm assembly (including nuts and turnheads)
S80.350000.00	Rotary components
S80.AC0000.02	Feeding disk
S80.A20000.01	Test tube rack
	Catheter ϕ 6
	Catheter ϕ 8
	Test tube designated by COBIO
	Test tube cap designated by COBIO

10 Product Performance, Specification and Storage

Condition

Memory capacity standard with 25,000 measurements (including all sample images)

Size of the Main Machine

Size: (Length x Width x Height) 616x534x670mm (except the flexible pipe)

Weight: 66kg

Power Supply:

230 VAC 50 Hz 220 VA

Fuse:

T6.3AL250V (power socket)

T3.15AL250V (control circuit board, power box)

Operation Condition:

Operating Temperature: 15-30°C

Operating Humidity: 30%-75%

Atmospheric Pressure: 760hPa~1060hPa

Storage Condition:

CB-MF-SOP-002

A/1

Storage Temperature: -20-40°C

Storage Humidity: <93%

Atmospheric Pressure: 760hPa~1060hPa

Bar-code Scanner:

Barcode identification type:

One-dimensional: code39\Codabar\code128\UPC\EAN, etc.

Two-dimensional: QR Code\Data Martix, etc.

Scanning peak wavelength of light: 451nm, 575nm

Maximum laser power: <0.39mW

Safety of laser products - part 1: equipment classification and requirements, this instrument belongs to Class I laser product.

Test Tube rack

Use the test tube rack of original factory only.

Test Tube

Minimum sample size of the test tube: 2ml

Urine homogenization treatment: Absorption and spitting mixed

Height(conical bottom tube): 100 - 110 mm

Height(Flat bottom tube): 100 - 105 mm

Tip diameter of test tube: 16 - 17.5 mm

Maximum diameter on top of test tube: 16.5 mm

Counting Chamber (consumables)

Package: 50pcs/container

Maximum counting chamber load: 600pcs (12 containers)

Sample size: 175 μ L

Centrifuge:

Centrifugal speed: 2000RPM, Centrifugal time: 10s

The centrifugal liquid can only be urine samples, water and related quality control products, etc. If the user lets the equipment absorb other unknown samples, the consequences will be their own.

The main material of the centrifugal arm module was POM, the density is about 1.41g /cm³, the embedded metal material is S136, the density is about 7.85g /cm³.

The overall mass of the centrifugal arm assembly is about 35g.

The overall volume of the centrifugal arm module is about 13 cm³.

Fixing method of centrifugal arm assembly: Locate by the locating pin and mounting seat of centrifugal arm, and fixing by magnetic force of 2 magnetic steel on mounting seat of centrifugal arm.

Light Source:

Green

S80 Pictures:

Number of images per sample: 5,10,15,20 (default 15)

Image location: The middle area of the counting chamber where does not overlap each other

Image size: 1280x960 pixel

Sample size of image visible area: 0.16 μ l initial urine
















Cleaning Fluid barrel

Cleaning fluid in the barrel

Capacity: 5L

Solution consumption: 5 liters of distilled water can wash at least 300 measured samples

11 Symbol Description

	CE mark of conformity		Warning
	Consult operating instructions		Warning! Danger high voltage
	IN VITRO DIAGNOSTIC MEDICAL DEVICE		BIOLOGICAL RISKS
	Manufacturer's serial number		Beware of electric shock
	The name and the address of the manufacturer		Risk of pinch hand
	Beware of belts		Electrostatic discharge
	Ground terminal		Don't throw it away
	Be careful with the laser	I/O	Power on/off

12 Replace Fuse of Power Socket

1. Disconnect the power from the device and remove the power cord. Locate the fuse position at the power outlet below the rear of the device. See the figure below.

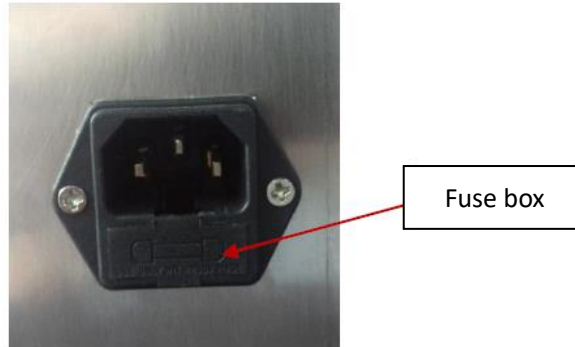


Figure 12-1

2. Use tweezers to gently pry open the fuse box and pull it out. See the figure below.



Figure 12-2

3. Remove the fuse with tweezers and other tools. See the figure below.



Figure 12-3

4. Change fuse of specified specification: T6.3AL250V.
5. Reclose the fuse box.

Attention:

CB-MF-SOP-002

A/1

- Fuses on the circuit board inside the equipment shall not be replaced unless by professional maintenance staff of COBIO Smart Healthcare Technology Co., Ltd.

13 Transport Condition and Method

1. Arrange the equipment according to clause 1 ~ 5 of 2.5 Dealing for Nonuse for S80 in this manual.
2. Disconnect the power supply and unplug all external connection wires and pipes behind the equipment, and pack the removed wires and pipes.
3. Separate the feeding platform from the host, pay attention to the data wire harness between the feeding platform and the host, and disconnect the data wire connection.
4. Prepare the original packaging boxes and foam boxes of the equipment.
5. Place the foam box on the bottom of the packing box first.
6. Put the feeding platform into the foam box. See the figure below.



Figure 13-1

7. Load the device host into the foam box. See the figure below.



Figure 13-2

8. Close the foam cover and cover the packing box. See the figure below.



Figure 13-3

9. Finally unscrew the self-tapping screws at the edge of the bottom of the packing box. Because of the heavy equipment, it is recommended to use special equipment such as forklift. Storage and transportation shall meet the requirements of EN ISO 780-2015 Packaging — Distribution packaging — Graphical symbols for handling and storage of packages, and shall also meet the requirements of storage and transportation environment in the technical parameters of this specification.

Attention:

- Again carrying and packing the process should pay attention to handle gently, because the host as the heavy equipment, at least two people carrying, to pay attention to the safety of personnel and equipment.

14 Product Feature

1. Product feature: It is continuous running bench laboratory equipment, connected with the power grid through the dismountable power cord.
2. Safety Class: Class II
3. Rated pollution grade: level 2
4. Operating environment: indoor use shall meet the operating environment requirements of item 10 in this manual.

15 Caution, Warning and Note

1. **Check whether the parts are intact or not according to the packing list before installation. If the package is incomplete or damaged, please contact your dealer immediately.**
2. **Do not put the instrument in direct sunlight, because strong sunlight will interfere with the instrument's optical sensor.**
3. **It is very important to remove the plastic tape and fixation screw of the sampling module before starting up. When the power is turned on, the instrument is initialized, including the motion check of each component. If the strap and fixing screw are not removed, the instrument may be damaged.**

4. Since pipes, wires, etc. need to be connected behind the equipment, cleaning fluid barrel and liquid waste barrel need to be installed, so the equipment should be placed to facilitate personnel's access.
5. The instrument will adjust the power supply voltage automatically within the working voltage range of ~100-240 volts. Do not exceed this power supply range.
6. Non-professional personnel shall not open the rear panel of the instrument.
7. The counting chamber is disposable and cannot be reused.
8. Do not touch the unused counter chamber, or any stain may affect the imaging quality of the equipment.
9. Please do not tear the sealing strip of counting chamber before loading the rotary disk to prevent the counting chamber plate from falling off.
10. When adding the test tube rack, it must be carried out after the red indicator light on the feeding platform is off, otherwise the hook pushing the test tube rack will be overturned when it is returned.
11. When the red indicator light on the feeding module of the test tube is on, it is forbidden to load the test tube rack on the feeding platform, otherwise, the instrument will fail or possibly damage it. It is not allowed to be put into the test tube rack until the red light is off.
12. The used counting chambers should be handled with care, as the urine is derived from human body fluids and should be treated in accordance with the uniform rules for hospital biological hazards.
13. Carefully dispose of used counting chambers and urine containers.
14. Wear rubber gloves or other protective clothing when operating S80.
15. Do not spray cleaning inside the equipment. Remove the relevant removable parts before using a wet cloth to clean the internal parts.
16. Do not move and loosen the counting chamber mounting screw above the microscope.
17. The fuses on the circuit board of the equipment shall not be replaced unless by professional maintenance personnel of COBIO Smart Healthcare Technology Co., Ltd.
18. Don't touch the microscope lens with your hands. Only use cotton cloth when cleaning.
19. Do not use any cleaning liquid other than alcohol to wipe the lens. Alcohol should be anhydrous alcohol and dip by medical cotton balls to be used. Professional maintenance personnel of non COBIO Smart Healthcare Technology Co., Ltd. are not allowed to carry out this operation.
20. The equipment must use the counter chamber series of COBIO Smart Healthcare Technology Co., Ltd., and must be licensed by COBIO.
21. Again carrying and packing the process should pay attention to handle gently, because the host as the heavy equipment, at least two people carrying, to pay attention to the safety of personnel and equipment.
22. Only trained personnel can use the equipment.

23. The protection of equipment may be compromised if the equipment is not used in accordance with the method prescribed by the manufacturer.
24. If the product needs to be repaired, treated, transported or stopped using, it shall be cleaned and disinfected before disposal. The disinfection method shall refer to the maintenance method of product 6 in this manual.
25. Use in a well-grounded environment.
26. The device is prohibited from being used next to a strong radiation source, such as a non-shielded radio frequency source, or it may be interfere with the normal operation of the device.
27. Please raise the occlusion plate when the equipment is working.
28. Be careful with the laser. Do not look directly at the scanning light.
Caution: failure to use control or adjustment devices, or to perform steps, may result in harmful radiation warnings.

16 Product Information

Date of production: See the nameplate of the product

Use life: 7 years

Issued Date: 2015.12.23



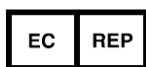
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