

A large, stylized blue wave graphic that curves across the middle of the page, starting from the left edge and extending towards the right, with a white diagonal line running through it.

Operating Instructions

MAGLUMI® Fully-auto chemiluminescence immunoassay analyzer

MAGLUMI X3

Dear users! Thank you for using our Fully-auto chemiluminescence immunoassay analyzer!

To make sure you using the analyzer safely and skillfully, and improve your working efficiency, please read the instructions carefully before operating the analyzer.

Please properly keep the instructions after reading, and placed it in a readily accessible place in order to obtain easily at any time.

If you have any questions regarding your Fully-auto chemiluminescence immunoassay analyzer, please contact your local representative.



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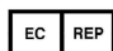
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Device	Catalogue Number
MAGLUMI X3	010101003301

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Product-related information

Product Name: Fully-auto chemiluminescence immunoassay analyzer

Model: MAGLUMI X3

Structure and components: The analyzer is composed of the main machine, accessories and software, wherein the main machine includes the material provision module, the liquid path module, the temperature control module, the mechanical drive module, the optical path detection module and the circuit control module; and the accessories include a desktop computer suite and cables.

Intended Use: Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

About Operating Instructions

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Cautions

This section contains all important safety-related and proper use information and regulations.


Please read the Operating Instructions before using the analyzer.

Instructions

The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer and reagents are strictly limited to professional in-vitro-diagnosis use. Please use reagents and consumables manufactured by Shenzhen New Industries Biomedical Engineering Co., Ltd. only, so as to prevent measurement errors or product failures.

This Operating Instructions provides a guide on the usage of the MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer, aiming to help users understand the structural principles, operation and usage, routine maintenance, troubleshooting and other aspects of the MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer. Please operate the analyzer in accordance with the instructions herein.

Alert description

Symbol	Text	Description
	Warning	Warning reminds the user that it could lead to personal injury, damage to the instrument, error in data or risk of biological infection under this condition.
	Note	Note reminds the user of an important message worth attention.

Safety precautions

Please read the Instructions carefully before operating the analyzer for safe use of the system. Any operation that violates the safety precautions could lead to personal injury or damage to the analyzer.

This system has been manufactured in compliance with the requirements for the safe production of electronic analyzers and medical analyzers. There are corresponding requirements of laws and regulations for the installation and operation of this system, therefore the installer and operator are obliged to comply with the related laws and regulations.



Warning:

1. The user should regularly check and maintain the analyzer by strictly following the instructions, so as to prevent analyzer faults and hazards to personal safety.
 2. To ensure the safety and reliability of the analyzer, its installation and maintenance can only be carried out by our authorized technical service engineers and personnel or with their approval. All analyzer parts must be checked and provided by our company or our authorized distributors.
-

1. Prevention of personal injury from moving parts

Please comply with the following precautions to prevent the moving parts from causing personal injury when the analyzer is working.



Warning:

1. Please do not touch moving parts on the analyzer, or their path of movement, when the analyzer is working. Please do not place any obstacle in the path of movement as this may cause personal injury or damage to the analyzer.
 2. Follow the specified procedures when loading liquid or solid consumables into the analyzer and properly remove the cover, sealing film or other packaging from the consumables, so as to prevent personal injury or damage to the analyzer.
-

2. Prevention of electrical hazards

Please comply with the following precautions to prevent electric shock.



Warning:

1. Confirm that the input voltage complies with the analyzer requirements.
 2. Unauthorized maintenance personnel should not open the front or rear cover of the analyzer while the analyzer is powered on.
 3. Reagents, samples or other fluids entering the analyzer may cause analyzer faults or electric shock. Please turn off the power immediately and contact SNIBE's service department.
 4. If you need to open the front or rear cover to replace parts, please cut off power to the analyzer before proceeding.
 5. Improper grounding may lead to electric shock and damage to the analyzer.
 6. Do not touch or discharge static electricity from parts with electrostatic protection warning labels.
-

3. Prevention of fire hazards

The use of organic solutions can lead to a risk of fires. Please comply with the following precautions.



Warning:

1. Do not use organic solutions in tests.
 2. The analyzer is not designed to be explosion-proof. Do not use organic solutions with ignition points below 65°C near the analyzer. Otherwise, this may cause a fire or explosion.
-

4. Prevention of biochemical danger

Please comply with the following precautions to effectively prevent biochemical danger.



Warning:

1. Please carefully read the reagent and consumable SDS before use to understand the safety instructions and preventive actions.
 2. Avoid direct hand or clothes contact with reagents and consumables. If your hands or clothes are accidentally exposed, wash them with soap and water immediately. If something gets into your eyes accidentally, wash them with a
-

- large amount of water immediately and consult an ophthalmologist.
3. Improper use of samples may cause infection. Do not touch the sample, mixture and waste liquid with your hand or other body parts. Do wear gloves, a gauze mask and work clothes during operation to prevent infection, and wear protective glasses when necessary.
 4. Some reagents and system liquid may damage the skin. Use reagents and system liquid carefully to prevent your hands and clothes from being directly exposed to the reagents and system liquid. If your hands or clothes are accidentally exposed, wash them with soap and water immediately. If something gets into your eyes accidentally, wash them with a large amount of water immediately and consult an ophthalmologist.
 5. If a small amount of reagent or sample spatters on the analyzer during use, use a clean cotton cloth with alcohol to wipe the analyzer clean before operating it. If there is a large amount of reagent or sample on the analyzer, stop the analyzer immediately and contact an engineer authorized by our company to deal with it promptly.
 6. When the analyzer needs to be moved over a long distance, it should be completely disinfected to prevent the spread of potential infection sources.
-

5. Protection against laser hazard

Please comply with the following precautions to prevent laser burns caused by the barcode reader.



Warning:

The laser produced by the barcode reader will directly irradiate the human retina, causing damage to eyes. Do not look directly into the laser beam of the barcode reader. Please wear goggles if you need to check the laser beam of a charged barcode reader.

6. Disposal of waste liquid

To prevent environmental contamination and personal injury, please comply with the following precautions in the disposal of waste liquid.



Warning:

1. Some substances in the QC solution, calibration solution and waste liquid are controlled by pollution regulations and discharge standards. Please comply with local discharge standards and consult with the relevant reagent manufacturer or distributor.
 2. Waste liquid from infectious disease patients' samples should be discharged to an infectious disease treatment facility of the hospital.
-

7. Disposal of waste analyzers

Please comply with the following requirements to dispose of the waste analyzers.



Warning:

Some substances from the waste analyzer are controlled by pollution regulations. Please comply with local related regulatory requirements during disposal.

Precautions for use

Please read the following precautions for use carefully, in order to use the analyzer correctly and effectively.

1. General precautions

The purpose of this analyzer and general precautions should be defined before you use the analyzer. If the analyzer is not used according to the methods stipulated in the instructions, the protection provided by it might be damaged.

Note:

1. When making clinical decisions based on analysis results, please also consider the clinical symptoms or other lab test results.
 2. The Operating Instructions may be revised without prior notice. The user should consult the customer representative based on the condition.
 3. This analyzer is limited to medical inspection professionals' use only and requires basic analyzer operation abilities, experimental skills and laboratory knowledge.
 4. Do not touch the display, mouse or keyboard of the computer when you have chemicals on your hands.
 5. Please do not fold or press on the drainage pipe. Otherwise, waste liquid may spill from other places due to obstructed drainage, leading to damage to the analyzer in some serious cases.
 6. The analyzer produces heat during operation, which is dissipated from the rear. The work environment should have good ventilation to ensure good heat dissipation and a ventilation device should be used when necessary. However, avoid having the airflow blow directly to the analyzer. Otherwise, the reliability of test results might be compromised.
 7. Each component of the analyzer should be adjusted before initial use to make sure the parameters of each component are accurate.
 8. There should be no bubbles in the starter or system liquid. Otherwise, the reliability of test results cannot be guaranteed.
 9. Make sure the starter bottle of the immunology module is correctly connected. Do not use mixed starter. Otherwise, the reliability of test results cannot be guaranteed.
 10. Please use the supporting cuvettes designated by our company in order to ensure safe operation of the analyzer and accuracy of test results.
 11. Please do not use expired system liquid in order to ensure safe operation of the analyzer and stability of test results.
-



12. Start up the analyzer at least 30 minutes before use to stabilize the measurement system.
 13. Check whether there are sufficient consumables for testing before starting any tests (system liquid, starter, and cuvettes among others).
 14. Before starting a test, perform at least one BGW test and confirm that the BGW test result is within the normal range. Otherwise, the reliability of test results cannot be guaranteed.
 15. There should be no foam on the surface of a liquid sample when it is injected. Otherwise, this could lead to an error when sample is injected. The reagents must not be changed or moved before the reagents are fully injected.
 16. QC testing must be conducted when the analyzer is used for sample analysis. Otherwise, the reliability of test results cannot be guaranteed.
 17. The analyzer is equipped with an alarm light and a loudspeaker. When the analyzer has a fault warning, the alarm light and loudspeaker will send out an alarm signal. At such times, please rectify the fault in time to ensure normal operation of the analyzer and the accuracy of test results. Refer to the troubleshooting methods in Section 7 of the instructions: Common faults and troubleshooting.
 18. Please use the system tubing cleaning solution designated by SNIBE in order to carry out cleaning and maintenance of pipes.
 19. The analyzer surfaces and interior should be appropriately disinfected if any hazardous substance leaks or spills onto or into the analyzer. Do not use cleaning agents or disinfectants that may chemically react with materials contained in the analyzer's parts or components. Consult the manufacturer or agent for any questions regarding the compatibility of a disinfectant or cleaning agent with the materials contained in the analyzer or parts thereof.
 20. It is recommended that the technical service engineers authorized by Shenzhen New Industries Biomedical Engineering Co., Ltd. perform a calibration on the analyzer on an annual basis to ensure the equipment safety and normal operation.
 21. If any serious incident has occurred in relation to the device, please report to Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe) or our authorized representative and the competent authority of the Member State in which you are established.
-

2. Operation environment



Note:

Correctly install the analyzer in accordance with the installation environment specified in the Operating Instructions. Installation and use beyond the specified conditions may produce unreliable results and cause damage to the analyzer.

3. System maintenance



Warning:

1. Carry out regular maintenance of the analyzer based on the relevant parts of these Operating Instructions. Improper maintenance may affect the accuracy and precision of test results, and may even lead to analyzer faults or personal injury.
 2. The surface of the analyzer may collect dust if the analyzer is not used for long periods. Use a clean cotton cloth which has been soaked in water and wrung out to gently wipe the surface. Take necessary precautions to prevent water from dropping inside the analyzer.
 3. Please turn off the power before maintenance (excluding hotline maintenance). Otherwise, this could lead to analyzer faults or personal injury.
 4. The analyzer may be stained with samples from potentially infected patients. Do wear gloves and work clothes to prevent infection during maintenance.
 5. The analyzer itself does not contain any parts that the user can service. Do not try to open the cover case and remove any part. Contact one of SNIBE's authorized technical service engineers if you need assistance.
 6. Please contact an authorized technical service engineer to check whether the overheat protection or liquid level protective device or system is fully operational.
-

4. Samples, reagents and QC solution



Warning:

1. Substances such as drugs, anticoagulants and preservatives that exist in the sample may interfere with test results.
 2. Samples affected by hemolysis, lipemia and jaundice will affect test results.
 3. Make sure there are no clots in the sample. Otherwise, the pipettor will be blocked, which will seriously affect the test results.
 4. Take correct sample storage measures. Improper sample storage measures may change the component structure of samples, leading to incorrect test results.
 5. Do not leave samples open for long periods, to prevent them from evaporating. The evaporation of samples may lead to incorrect test results.
 6. Improper storage of reagents or QC solution could lead to incorrect test results and sub-optimal system performance, even if they are within their validity period. Reagents and QC solution should be used and stored in accordance with the instructions for use of the relevant reagent manufacturer.
 7. The calibration analysis should be conducted after changing the reagent. Correctness of test results may be compromised if calibration analysis is not conducted.
-

5. Data backup



Note:

The system possesses the function of automatically storing data on the computer hard disk. However, the data on the computer hard disk cannot be recovered if the data is deleted or the hard disk is damaged due to other reasons. Please regularly back up the test results and analyzer parameters to another medium, such as a CD-ROM.

6. Electromagnetic compatibility



Note:

1. The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer complies with the emission and disturbance immunity requirements stipulated in IEC 61326-2-6:2012.
 2. The user has the responsibility to guarantee the electromagnetic compatibility environment for the analyzer to enable the analyzer's proper operation.
 3. It is recommended to evaluate the electromagnetic environment before using the analyzer.
-



Warning:

1. The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer has been designed and tested as a type A device in accordance with IEC/CISPR 11:2010. The analyzer may cause radio interference in a home environment. Therefore, please implement protective measures in such scenarios.
 2. It is forbidden to use the analyzer near strong radiation sources (such as unshielded RF sources). Otherwise, these may interfere in the normal operation of the analyzer.
-

Chapter 1 Measuring principle

The operation principles of the analyzer include the test principle, analysis method and calibration method. This section will introduce these in detail.

1.1 Lab test steps

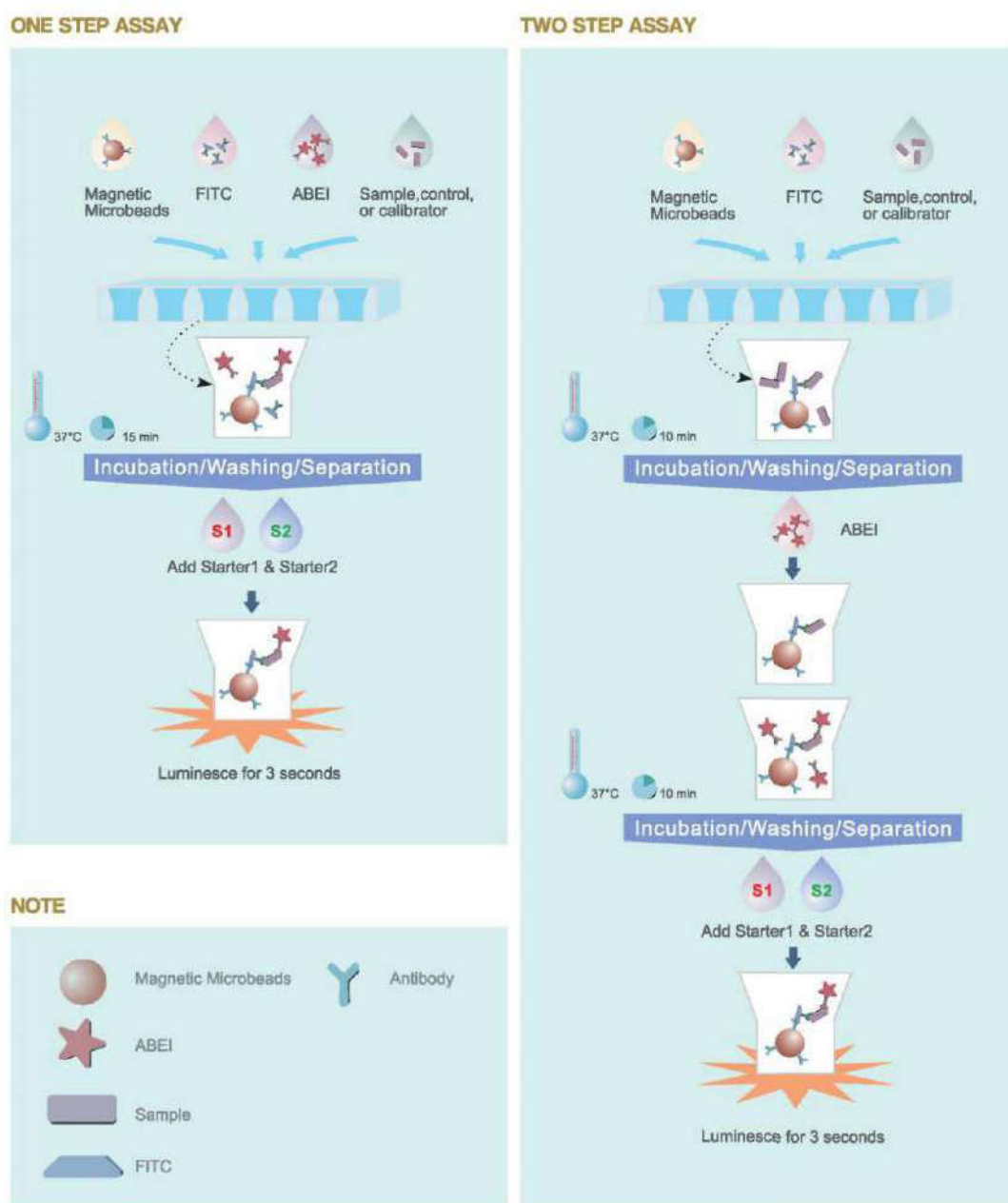


Fig. 1.1-1 Test steps

1.2 Measuring principle

The PMT in the analyzer is used to detect the light generated from the chemiluminescence reaction. The linear measuring range of light wavelengths detected by the PMT is 300–650 nm and the peak wavelength of light generated by chemiluminescence reactions is 420 nm. The light generated by the chemiluminescence reaction strikes the PMT where it is converted into an electrical signal. This signal is collected, processed and converted by the peripheral circuits into a digital value that reflects the magnitude of the light intensity.

We use relative light units (RLUs) as the quantitative unit of raw data in order to eliminate differences among individual PMTs and ensure the test result consistency among different analyzers.

After the sample and reagent are added to the cuvette, they undergo three steps of mixing, washing and separation, and then the cuvette enters the chamber. Starter S1 is injected into the cuvette, then after a 2.5 second delay, starter S2 is injected into the same cuvette to stimulate a chemiluminescence reaction. Detection of the optical signal starts 0.1 seconds after the chemiluminescence reaction occurs to obtain the optical signal within a period of 3.0 seconds.

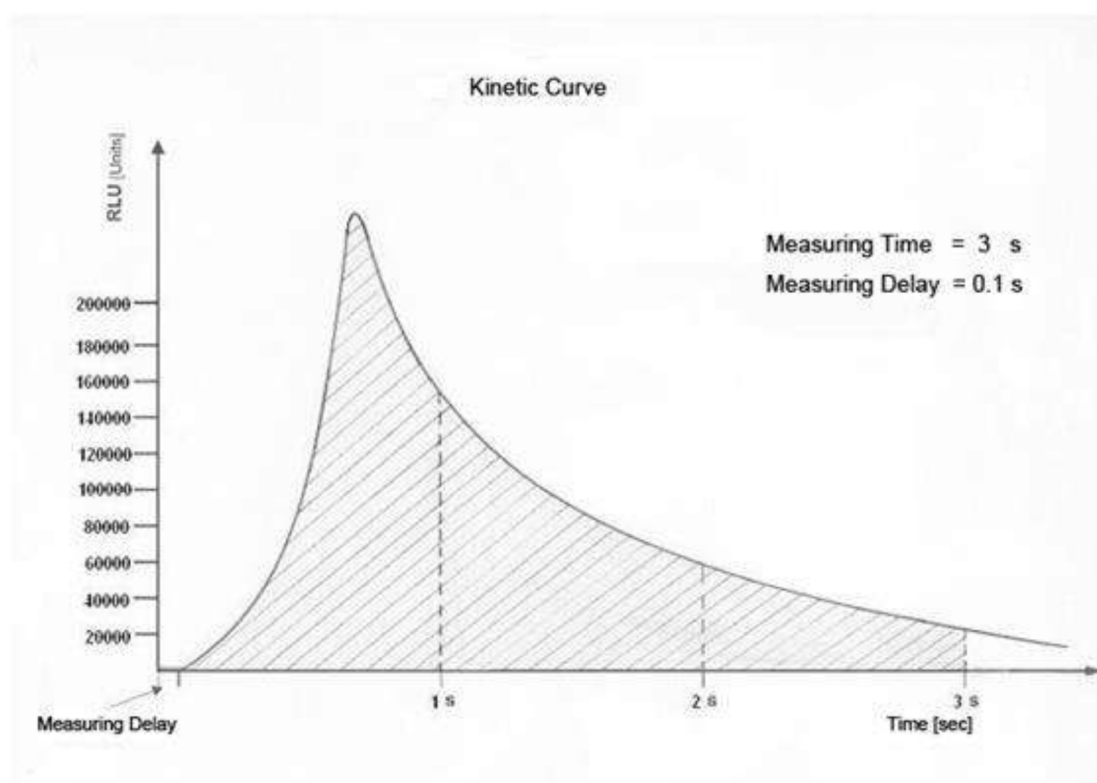


Fig. 1.2-1 Chemiluminescence kinetics curve

1.3 Calibration method

The master curve should be corrected due to the difference between the actual work environment of the analyzer and the lab environment, to generate a work curve that is consistent with the actual work

environment.

Brief description:

- The master curve is determined using ten standard points.
- Compare the relative light units of two calibration points obtained from the calibration with the relative light unit of the corresponding concentration in the master curve.
- The difference in relative light intensity between the two calibration points and the relative light intensity of the corresponding concentration in the master curve is calculated and a linear inference is made based on the recalculated relative light intensity (y-axis) and concentration (x-axis).
- For other points in the master curve, the difference of their relative light units is calculated with the assistance of the compensation curve, and the relative light intensity (y-axis) and concentration (x-axis) are recalculated.
- This recalculated curve is the valid work curve (see Fig. 1.3-1: Calibration principle).

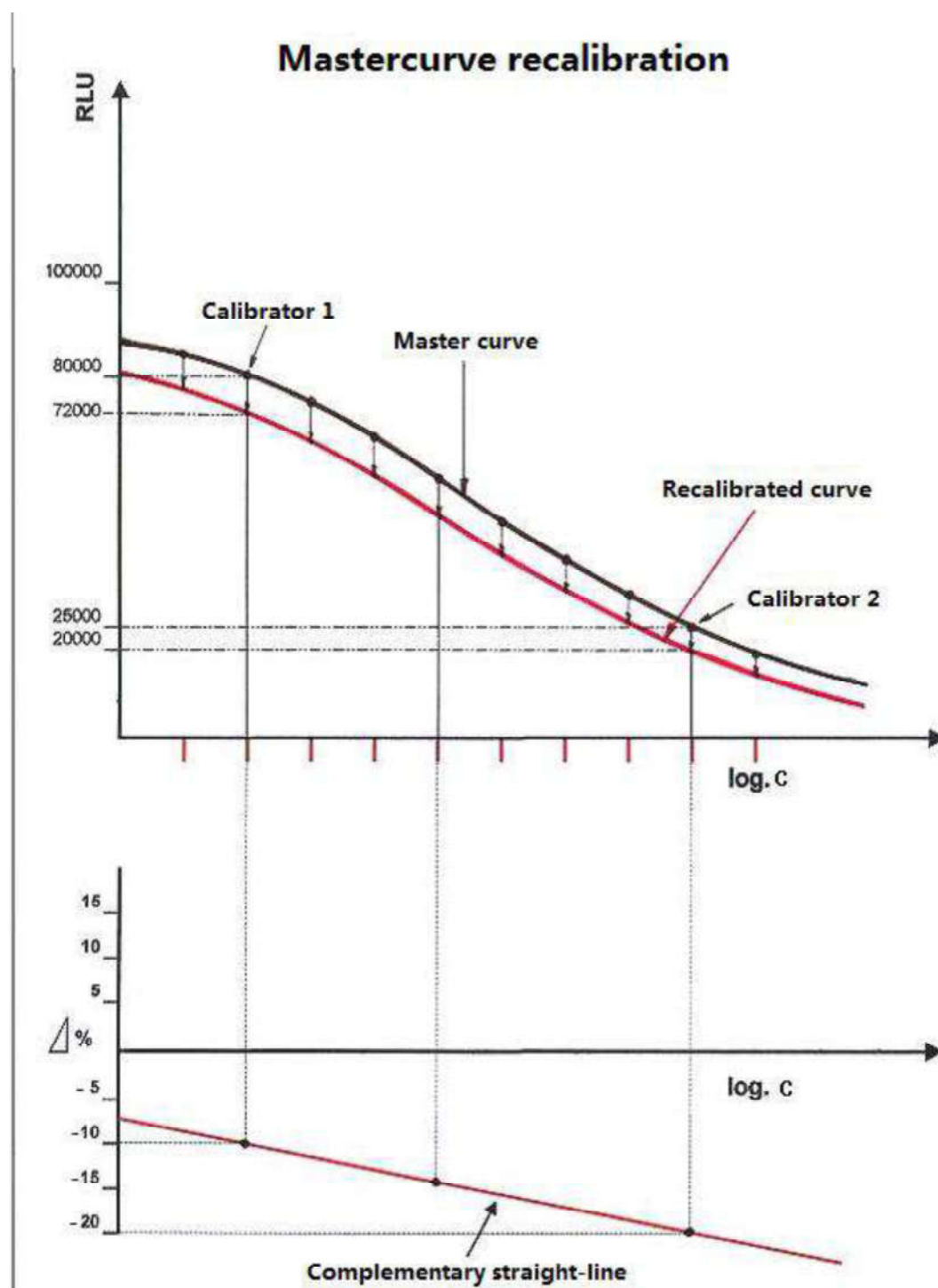


Fig. 1.3-1 Calibration principle

Chapter 2 Analyzer overview

2.1 Overview

The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer and the supporting diagnostic reagent series constitute a magnetic separation, ABEI-labeled, and accurate direct chemiluminescence micro immunoassay system. The system is used for qualitative or quantitative analysis of the analytes in human samples. The analyzer performs automatic sample pipetting, reagent loading, incubation, washing, measurements, and result calculations, which reduces test errors and improves the accuracy and precision of test results.

2.2 Specifications of analyzer

Table 2.2-1 Specifications of analyzer

Item		Specification
Basic characteristics	Test speed	200 tests/hour
	Sample type	Serum, plasma, urine
	Barcode type	Code128, Code39, Code93, Codabar, 2/5 Interleaved
	QC	Monthly QC analysis
Analyzer characteristics	Sample volume	10–200 μ L
	Sample reagent area	A total of 72 sample positions and 20 reagent positions on six sample racks
	SampleArm	Liquid level detection, measure-and-track, clot detection, anti-bubble interference, collision detection, automatic washing
	Reagent volume	10–450 μ L
	Temperature of sample reagent area	Reagent area temperature is $10^{\circ}\text{C} \pm 3^{\circ}\text{C}$
	Cuvette quantity	A total of 364 can be loaded
	Reaction temperature	$37.0^{\circ}\text{C} \pm 0.3^{\circ}\text{C}$, with the fluctuating no more than 0.2°C
	Mixing method	Mechanical oscillation
External interface	Interface	Ethernet
Work environment	Temperature	$10\text{--}30^{\circ}\text{C}$
	Relative humidity	$\leq 70\%$
	Atmospheric pressure	$85.0\text{--}106.0\text{ kPa}$
	Other	Keep away from electromagnetic field interference sources

Analyzer overview

Storage environment	Temperature	-20–55°C
	Relative humidity	≤93%
	Atmospheric pressure	50.0–106.0 kPa
	Other	Room free of strong sunlight and corrosive gas, with good ventilation
Safety classification	Anti-electric shock grade	Type I
	Overvoltage type	Type II
	Pollution grade	Grade 2
Total	REF ID	010101003301
	Weight	161 kg
	Outer dimensions Length * width * height	90 cm*75 cm*78 cm
	External packing size Length * width * height	104.8 cm*89.8 cm*97.7 cm
	Power supply	AC 100-240V,50/60Hz
	Power consumption (VA)	600VA

2.3 Overall composition of analyzer

The analyzer is composed of the main machine, accessories and software, wherein the main machine is composed of the material preparation module, the liquid module, the temperature control module, the mechanical drive module, the optical path detection module and the circuit control module; and the accessories include a desktop computer suite and cables.

- The material preparation module includes the cuvette storage module, the sample reagent area module, the starter module, and the cuvette dustbin module.
- The liquid module includes the pipetting liquid module, the washing liquid module, the optical path detection module, and the cooling liquid module.
- The temperature control module includes the incubator heating module (which can incubate 80 cuvettes at the same time), the sample reagent area cooling module, and the PMT temperature control module.
- The mechanical drive module includes the cuvette storage, the sample disk, the SampleArm, the washer, the chamber, the claw, and the sample reagent area shaker.
- The optical path detection module is composed of the chamber module, the PMT module, and the main control circuit module.

- The circuit control module is composed of the power source module, main control board, wiring harness, and different types of sensors, motors, etc.

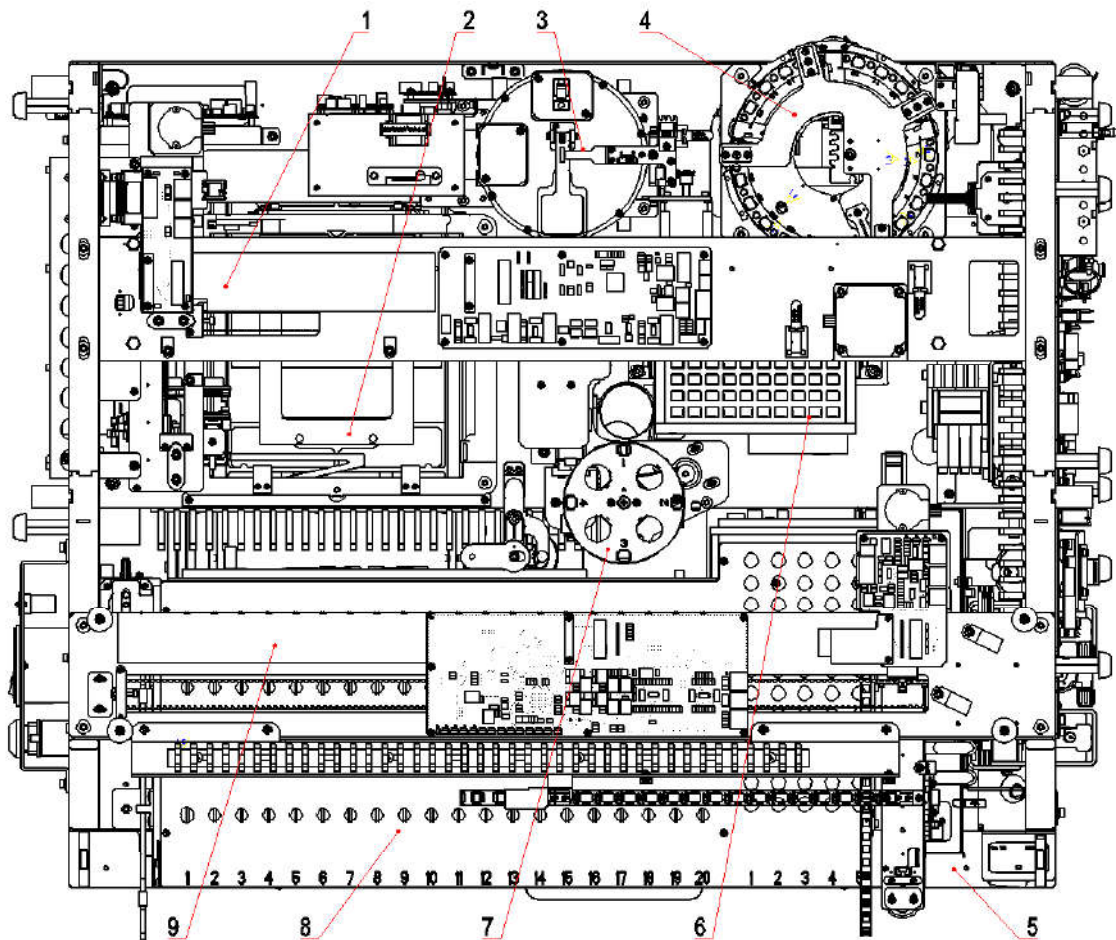


Fig. 2.3-1 Internal structure of analyzer

- | | | |
|-----------------|-------------------------|---------------|
| (1) Claw | (2) Cuvette storage | (3) Chamber |
| (4) Washer | (5) Rack component | (6) Incubator |
| (7) Sample disk | (8) Sample reagent area | (9) SampleArm |

2.4 Main components of analyzer

A rundown of the specific components of each module of the MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer is as follows.

2.4.1 Cuvette storage



Warning:

Do not touch the new cuvette box usage area of the cuvette storage while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

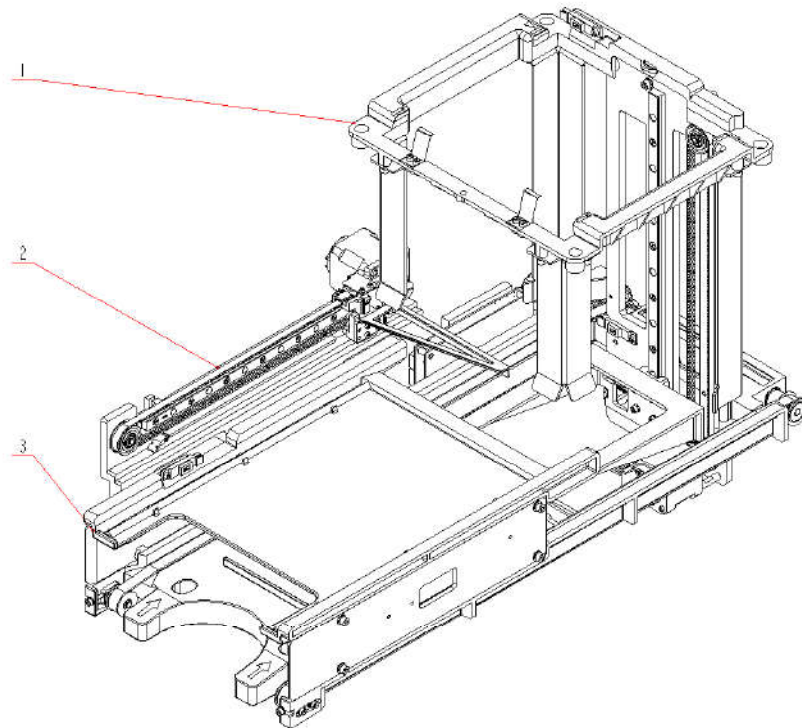


Fig. 2.4-1 Cuvette storage line drawing

1. Lifter

2. Waste box recoverer

3. New box transfer

(2) Function

The cuvette storage transfers new cuvette boxes containing cuvettes to the usage area and recovers waste cuvettes.

The cuvette storage can be divided into three layers. The bottom layer stores the new boxes transferred by the new box transfer. The middle layer stores the waste boxes transferred by the waste box recoverer. The top layer stores the boxes currently in use transferred by the lifter. It can store two boxes of cuvettes.

2.4.2 Sample reagent area

(1) Components

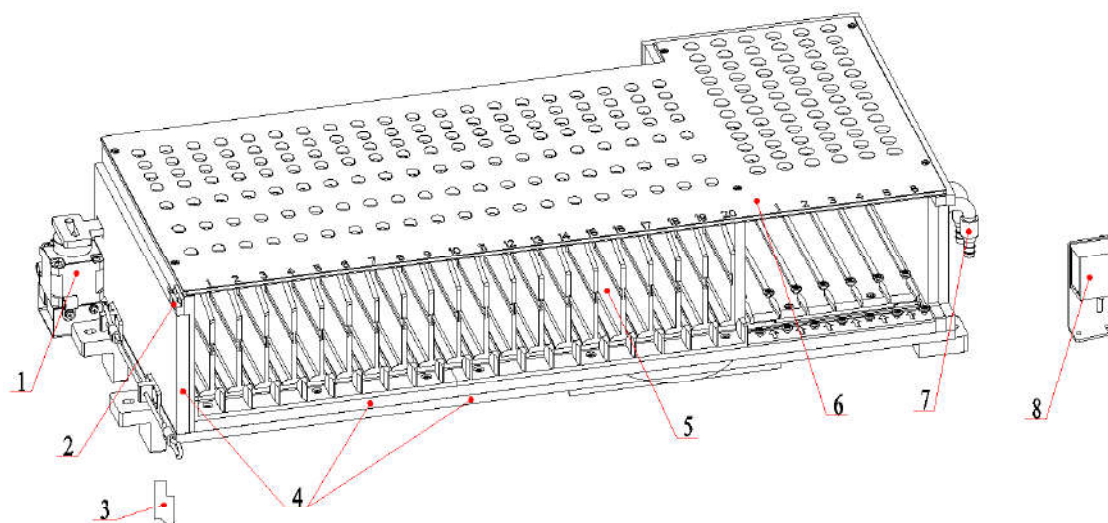


Fig. 2.4-2 Sample reagent area line drawing

- | | | | |
|---------------------|--------------------------|---------------------|----------------------|
| 1. Shaker component | 2. Door detection sensor | 3. RFID card reader | 4. Insulation cotton |
| 5. Area component | 6. Plate | 7. Radiator | 8. Barcode reader |

(2) Function

Places the reagent kit and the sample rack. The pipettor aspirates reagents and samples through the holes in the cover plate. The reagent area of the sample reagent area is cooled by water medium, and the temperature in the area is lowered down by heat conduction of the area metal to refrigerate the 20 boxes of reagents in it. If you need to turn off the refrigeration system, turn off the main power supply.

2.4.3 SampleArm



Warning:

Do not touch the SampleArm while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

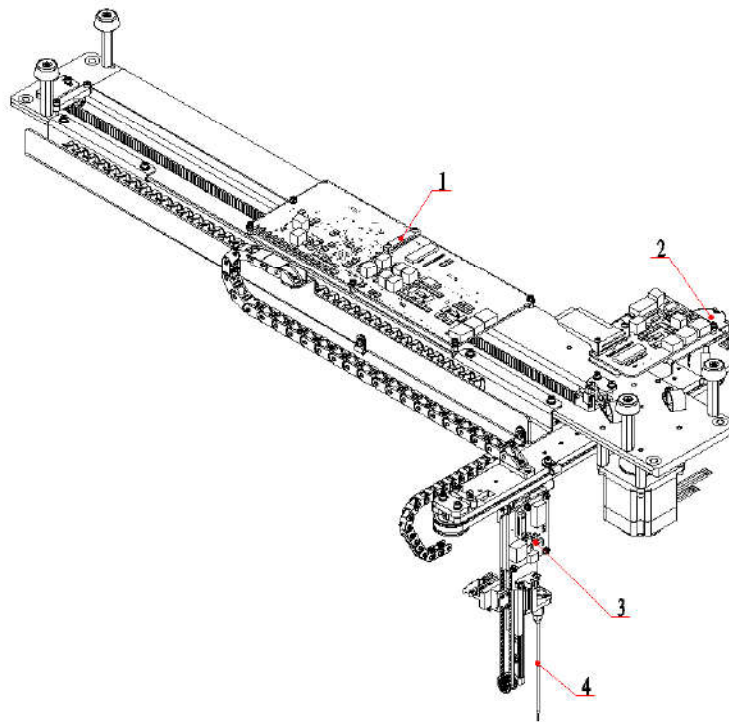


Fig. 2.4-3 SampleArm line drawing

1. X-axis

2. Y-axis

3. Z-axis

4. Pipettor

(2) Function

Transfers reagents from reagent kits in the sample reagent area and samples in sample tubes on the sample rack to cuvettes. It has liquid level detection, measure-and-track, clot detection, anti-bubble interference, collision detection, and automatic washing functions.

2.4.4 Sample disk

**Warning:**

Do not touch the sample disk while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

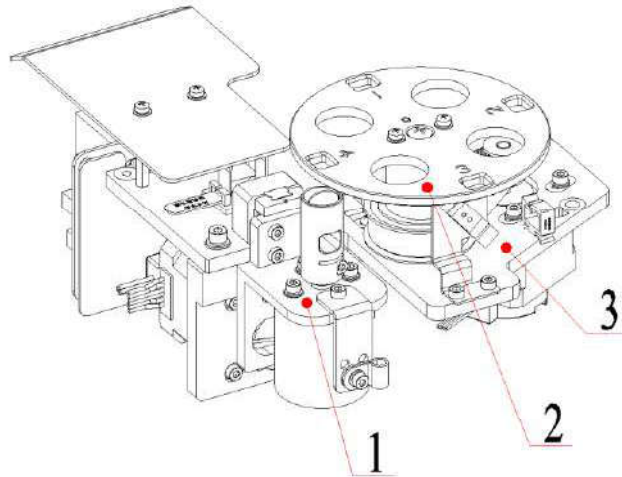


Figure 2.4-4 Sample disk line drawing

1. Lifter

2. Mixer disk

3. Turntable

(2) Function

Transports empty cuvettes to the corresponding work locations for sample and reagent loading, and mixes sample-loaded or reagent-loaded cuvettes.

2.4.5 Washer



Warning:

Do not touch the washer while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

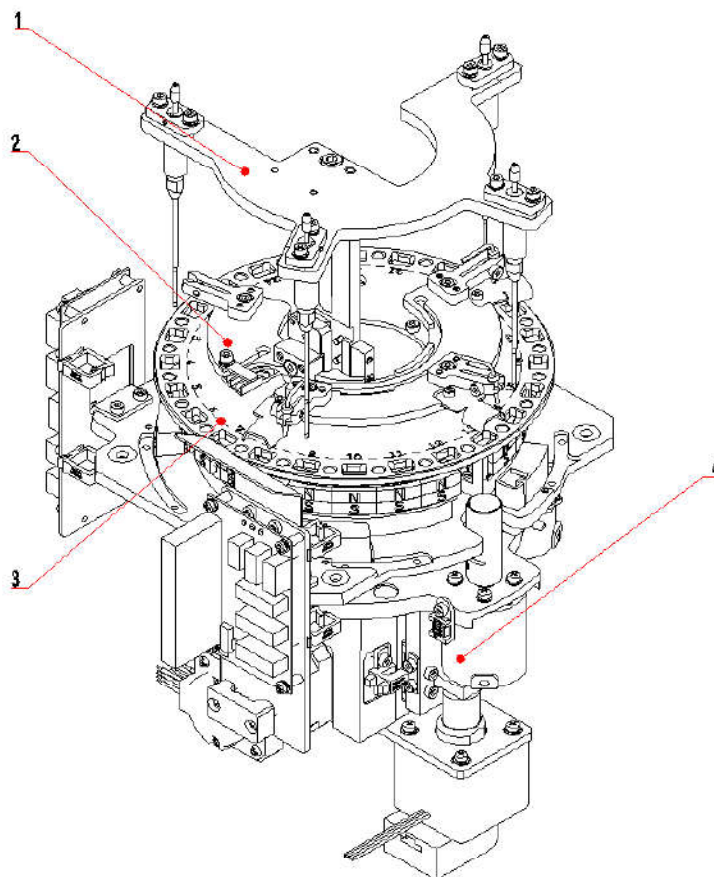


Figure 2.4-5 Washer line drawing

- | | | | |
|-----------------------|-------------------------|----------------|-----------------|
| 1. Waste liquid probe | 2. Washing liquid probe | 3. Washer disk | 4. Washer mixer |
|-----------------------|-------------------------|----------------|-----------------|

(2) Function

The main function of the washer is to remove impurities that are not bound to the solid-phase antigen of the magnetic spheres in the reaction liquid, by means of tertiary washing. The washer disk is responsible for transporting cuvettes to the magnetic field or various work locations. The four groups of waste liquid probes are responsible for aspirating waste liquid. The three groups of washing probes are responsible for injecting washing liquid. The washer mixer is responsible for mixing the mixture in the cuvettes.

2.4.6 Chamber

**Warning:**

Do not touch the chamber components while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

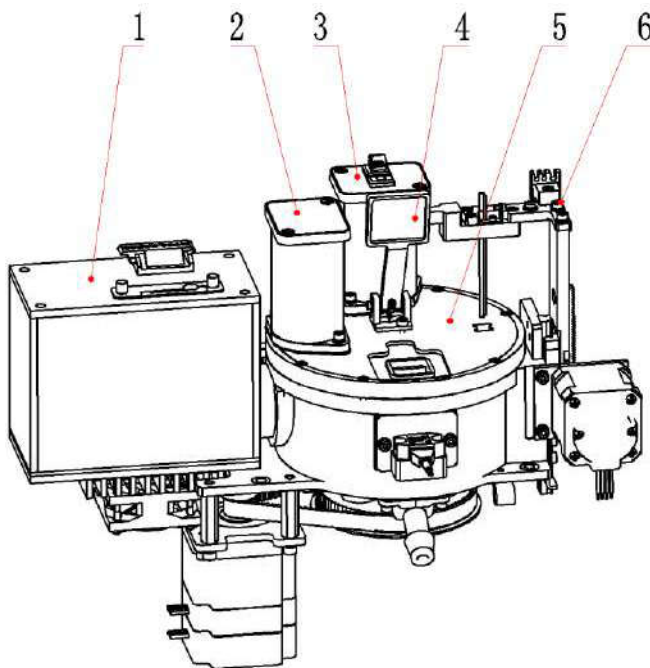


Fig. 2.4-6 Chamber line drawing

- | | | |
|-------------------|---------------------|---------------------------|
| 1. PMT module | 2. Starter 2 nozzle | 3. Starter 1 nozzle |
| 4. Shading module | 5. Chamber disk | 6. Waste liquid extractor |

(2) Function

In the chamber, starters 1 and 2 are injected into the cuvette that has been washed and shaded by the shading module. It then acts on the analyte to generate an optical signal. The optical signal is collected by the PMT and control circuit and processed, then converted into a light intensity value. The waste liquid extractor is responsible for extracting the waste liquid in cuvettes that have been tested.

2.4.7 Cuvette claw



Warning:

Do not touch the cuvette claws while the analyzer is operating. Otherwise, this could lead to personal injury or damage to the analyzer.

(1) Components

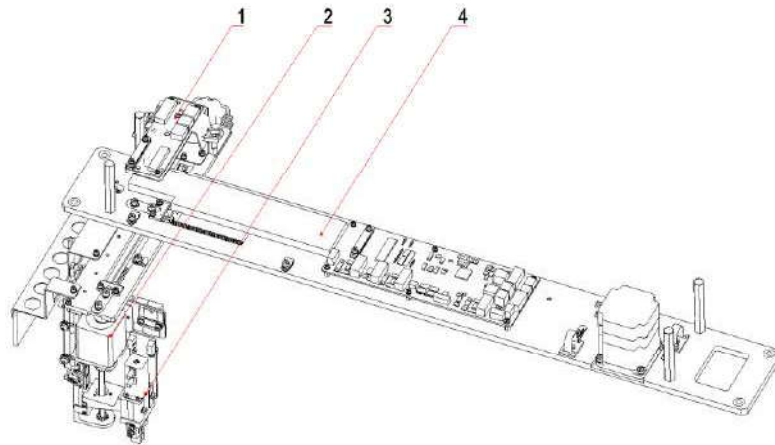


Fig. 2.4-7 Cuvette claw line drawing

- | | | | |
|-----------|-----------|------------|-----------|
| 1. Y-axis | 2. Z-axis | 3. Gripper | 4. X-axis |
|-----------|-----------|------------|-----------|

(2) Function

The claw transports cuvettes among various components of the analyzer.

2.5 Operation unit

The operation unit is a computer which has the analyzer operating software installed. It is composed of a display, computer, keyboard and mouse.

- Basic configuration of the computer: CPU frequency ≥ 3.0 GHz; hard disk ≥ 500 GB; RAM ≥ 4 GB; RS-232 interface; USB interface; RJ45 network interface; LCD; keyboard; and mouse.
- Supported OS: Windows 10.
- Security software: Common security software such as 360 Total Security, 360 Antivirus, Tencent PC Manager and Kingsoft Antivirus are supported.
- Data interface of software: wired network interface; data is stored in the XML format and in MySQL databases.
- User access: User management is available. Permission management based on two roles is supported: administrators and users.
- Network conditions: The software and the analyzer are connected via a wired network (TCP/IP), and the analyzer doesn't need to be connected to a local area network (LAN).

2.6 Analyzer labels

2.6.1 Module labels

"Protective grounding symbol" label

Protective grounding label

Located in the following positions:

- 1) One on the rack grounding block.
- 2) One on the left support of the reagent area.



"Cuvette bin" label

Cuvette bin for storing waste cuvettes.

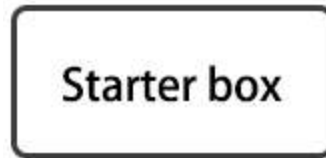
Located on the inside plate of the cuvette bin door.



"Starter box" label

Starter box for storing starter.

Located on the inside plate of the starter box door.



"S1" label

Store the starter 1.

Located on the inside plate of the starter box.



"S2" label

Store the starter 2.

Located on the inside plate of the starter box.



"Beware of laser" label

Remind users to be ware of the laser here and not to look straight at the beam.

Located in the laser beam area on the analyzer: the left door plate of the reagent area of the sample reagent area.



Laser window

Remind users of the laser window here.

Located in the laser beam window on the analyzer: the right door plate of the sample area of the sample reagent area.

**External liquid interface label**

Connect to the external system liquid, thick waste liquid and light waste liquid devices.
Located on the left side of the external liquid interface.

**Tip labels of new cuvette box**

Prompt users to note the correct positions of loading new cuvettes and recovering waste cuvette boxes.
Located on the left door plate of the cuvette storage.

**Tip label of power switch**

Tip label of the network interface, main switch, and submain switch.
Located above the power switch.

LAN

Main Switch

Submain Switch

"Cuvette storage" label

Cuvette storage that stores cuvettes and recovers waste cuvette boxes.

Located on the inside plate of the cuvette storage door.

Cuvette storage

"Main switch of cover" label

Remind users to lock the analyzer during the analyzer's normal operation.

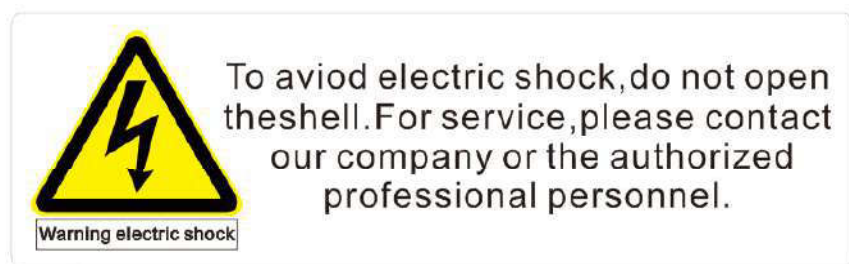
Located beneath the flip cover.



"Warning on opening casing" label

Remind users not to open the casing to prevent electric shock. If you need services, please contact our company or our company's authorized service technicians.

Located at the rear of the casing.



"Test counter" label

Record the number of tests.

Located inside the right part of the casing.

Test counter

"Beware of infection" label

This reminds the user to beware of potential biological infection in the particular area in question.

Located in the following positions:

- ① Located on the inside plate of the cuvette dustbin door.
- ② Located on the left side of the external liquid interface.
- ③ On the inner plate of the sample area door.

**"Thick Waste Liquid" label**

Remind users that thick waste liquid is stored in the tank.

Located on the thick waste liquid tank.

**"Thin Waste Liquid" label**

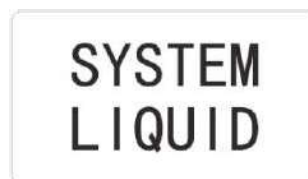
Remind users that Thin waste liquid is stored in the tank.

Located on the Thin waste liquid tank.

**"System liquid" label**

Remind users that system liquid is stored in the tank.

Located on the system liquid tank.




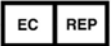





"No mixing" label

Remind users that starter 1 and starter 2 must not be mixed.

Located on the inside plate of the starter box door.



2.6.2 Symbols use in label

Symbol	Description
	Manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Catalogue number
	In vitro diagnostic medical device
	Serial number
	Note: Refer to attached documents

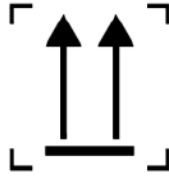
The definition for the following WEEE tag applies to EU member states only. WEEE tagged item indicates that this item should not be processed as domestic waste. By ensuring the proper disposal of this device, you help avoid the potential impacts of hazardous substances on the environment and human health. For more information, please contact the distributor from whom you purchased this product.



Up

This symbol means the transport package should be kept upright during transportation.

Located in the upper center of the packaging box sides.

**Keep dry**

This symbol means the transport package should be kept away from rain.

Located in the upper center of the packaging box sides.

**Fragile**

This symbol indicates that the content in the transport package is fragile and you should handle it with care when moving.

Located in the upper center of the packaging box sides.

**Do not roll**

This symbol indicates that the transport package should not be rolled when moving.

Located in the upper center of the packaging box sides.

**Stacking layer limit**

This symbol means this package can be stacked two layers high at the maximum.

Located in the upper center of the packaging box sides.

