



# INSTRUCTION FOR USE

## HyperLyse

## Automatic Nucleic Acid Extractor

Model: L0400

# Disclaimer

To ensure proper usage of the nucleic acid extractor, operators must strictly adhere to the instructions outlined in the "Instruction for Use". Failure to comply with these instructions may compromise the instrument's protective capabilities and result in damage.



## Manufacturer

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# Chapter 1 Safety Precautions

## 1.1 Definition of Symbols

Symbols are found in the "Instruction for Use":



**Warning:** Failure to follow the specified procedures or instructions may result in physical injury or damage to the instrument.



**High Temperature:** potential heat damage on the surface of the instrument.



**Biohazard:** Caution must be taken when coming into contact with substances that potentially pose an infectious risk.

Symbols found on the instrument:



**Read the Instruction for Use Carefully:** found on the nameplate.



**Biohazard:** found on the front panel of the instrument.



**High Temperature:** found next to the metal thermal wells.



**Serial Number:** found on the nameplate of the instrument.



**Refer to Instruction for Use:** found on the nameplate of the instrument.

## 1.2 Operation

HyperLyse automatic nucleic acid extractor should only be operated by personnel who have been trained and are proficient in its use.



- This instrument is an electromechanical device. If it is not used strictly in accordance with the operating instructions, it may pose potential hazards such as electric shock or physical injury to the user.
- Operate strictly in accordance with the safety prompts on the instrument.
- Replace fuses according to procedures in the " Instructions for Use ". Do not open the instrument or replace any other components. Damage from unauthorized disassemble or repair voids the warranty.
- Only manufacturer technicians are authorized to repair the instrument.

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Install the instrument indoors in:

- area with good ventilation
- away from corrosive gases and strong magnetic fields
- away from direct sunlight
- within specified temperature and humidity levels



- Operate the instrument indoors under the following conditions:
  - Temperature: 10°C to 30°C
  - Relative humidity:  $\leq 80\%$

This instrument processes biological samples with potential biohazard. Follow these safety precautions:

- Wear eye protection, clothing, and gloves when handling samples
- All biological substances and waste are potentially hazardous - follow local disposal regulations. In case of splashes or leaks, immediately disinfect to prevent contamination
- Never handle biohazard samples without proper precautions
- For repair, disinfect the instrument first, then send it to the manufacturer



- Do not touch the thermal modules of the instrument right after running to prevent burns.

## 1.3 Electrical Safety

- Connect to a grounded outlet that meets safety regulations and supplies 100-240V AC, 50/60Hz power.
- Ensure the power supply matches the instrument's voltage and frequency requirements.
- Turn off the power before connecting the power cord.
- Do not touch the power switch or cord with wet hands.
- Do not unplug the power cord while the instrument is on.
- Do not clean the instrument while it is on.
- Do not replace fuses while the instrument is on.
- Turn off the power when not in use.
- If power outage happens during operation, restart the operation after power is restored.

## 1.4 Electromagnetic Compatibility

- The manufacturer provides electromagnetic interference precautions to customers and users.
- The operator must ensure the installation environment of the instrument complies with the electromagnetic interference precautions.
- This instrument has been tested and complies with the standard EN 61236 (group 1, class B).
- It is recommended to evaluate the electromagnetic interference before installing the instrument.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation. Strong electromagnetic radiation may interfere with the proper operation of the instrument.

## Chapter 2 Overview

This product is a nucleic acid extraction device used for sample pre-processing in PCR tests.



# Chapter 3 Technical Specifications

## 3.1 Name and Model

HyperLyse automatic nucleic acid extractor (hereinafter referred to as the "instrument") is manufactured by Wuxi Opulen Technology Co., Ltd. (hereinafter referred to as the "company") has a model number of L0400.

## 3.2 Intended Use

For the extraction and purification of nucleic acids from samples in PCR tests.

## 3.3 Working Principle

This product extracts nucleic acids using the magnetic bead method. It is used with compatible extraction cartridges.

### **To use:**

- 1.Prepare the sample. Load sample and magnetic sleeve into the extraction cartridge.
- 2.Insert the cartridge into the tray then retract.
- 3.Start automatic extraction procedures.

### **The instrument will:**

- Heat the sample to lyse cells
- Use a magnetic rod and sleeve to capture magnetic beads and move them to the sample well
- The beads will bind with released nucleic acids
- Move the beads to the wash well for washing
- Transfer beads to the elution well and elute purified nucleic acids

The main steps are: lysis → bead binding → washing → elution. After elution, remove the beads to obtain the nucleic acid.

## 3.4 Basic Parameters

Item	Parameter
Sample throughput	1 ~ 4 samples
Processing volume	20 $\mu$ L ~ 1000 $\mu$ L
Heating temperature	Room temperature to 120°C
Applicable reagents	Magnetic bead extraction kits
Temperature accuracy	Within $\pm 1.5^{\circ}\text{C}$
Temperature uniformity	$\leq 2^{\circ}\text{C}$
Temperature stability	$\leq 1^{\circ}\text{C}$
Oscillation speed error	Not exceeding $\pm 10\%$
Magnetic flux	$\geq 5000\text{Gs}$
Magnetic bead recovery rate	$\geq 99\%$
Extraction efficiency	1.6 ~ 1.9
Extraction repeatability	CV $\leq 3\%$
Cross-well variation	CV $\leq 5\%$
Contamination control	Built-in ultraviolet disinfection module
Power supply	100-240VAC frequency: 50/60Hz
Dimensions	Width 254mm x Depth 317mm x Height 265mm
Weight	8.5kg

## 3.5 Product composition

### The mechanical systems include:

- exterior case
- chamber door
- cartridge tray
- control panel

### The electrical systems include:

- control module
- thermal control module
- UV disinfection module

### 3.6 Diagrams

L0400 is a 4-wells nucleic acid extractor, which requires the use of compatible consumables (cartridge, magnetic sleeves).

The diagram of the front structure of the instrument is shown in Figure 3.6.1:

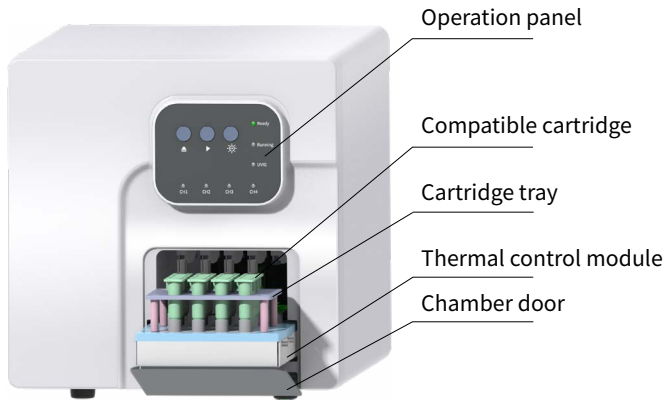


Figure 3.6.1

The diagram of the rear structure of the instrument is shown in Figure 3.6.2:

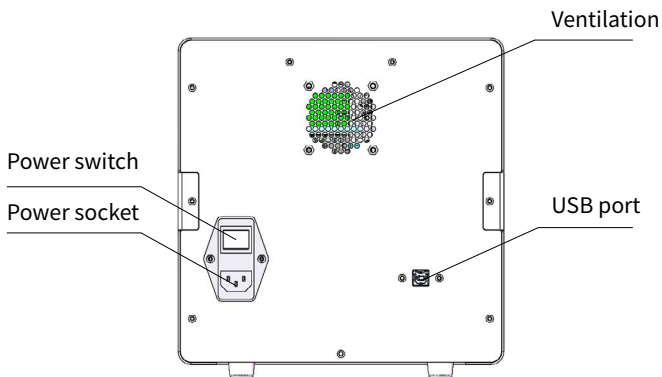


Figure 3.6.2

The diagram of the internal structure is shown in Figure 3.6.3:

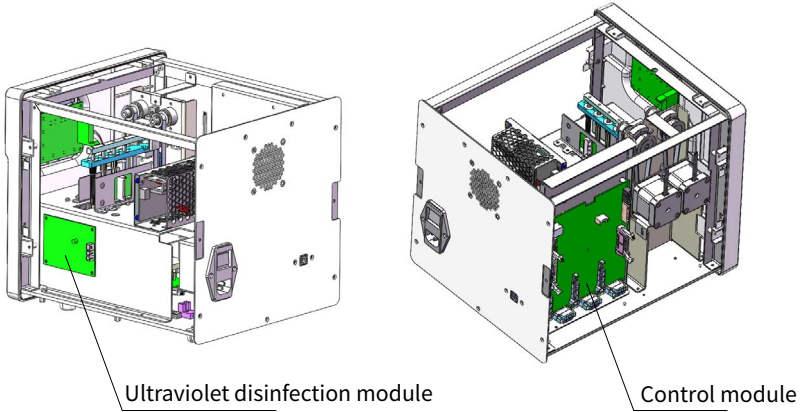


Figure 3.6.3

The diagram of the compatible cartridge is shown in Figure 3.6.4:

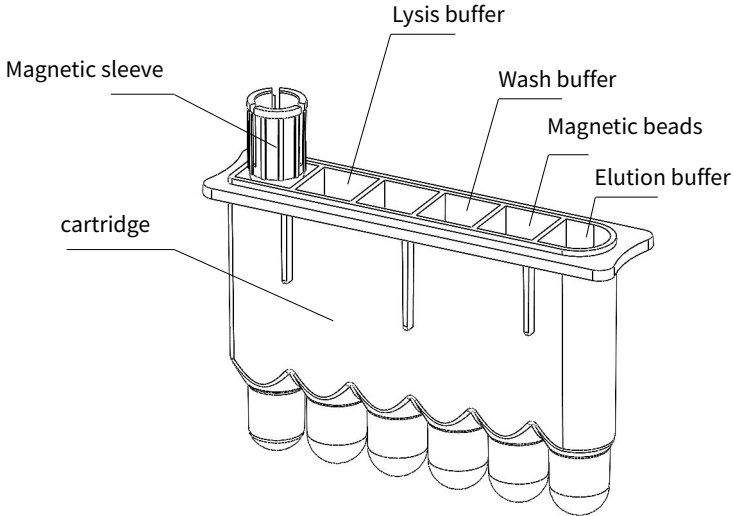


Figure 3.6.4

Insert the magnetic sleeve in the position shown on the cartridge. The instrument automatically picks up the sleeve before extraction and retracts it after extraction.

The instrument checks whether the cartridge and magnetic sleeve are in place.

Load sample to the indicated well before extraction.

### 3.7 Classification

Classification category	Level
Electric shock protection type classification	Overvoltage category: Class II
Contamination Classification	Class 2
Electromagnetic compatibility classification	Group 1, Type B

Following Regulation (EU) 2017/746, this instrument is classified as Class A diagnostic medical devices.

### 3.8 Contraindications

This instrument is for in vitro diagnostic use only and has no contraindications.

### 3.9 Lifespan

- Lifespan: 5 years (excluding human damage).
- Production date: see nameplate.
- Dispose of expired or obsolete instruments and accessories in accordance with relevant local laws and regulations.

The lifespan of this instrument is in accordance with GB/T 34986-2017 "Accelerated Product Testing Procedure". The instrument should be maintained and repaired in accordance with the product manual.

# Chapter 4 Storage, Transportation, and Installation Requirements

## 4.1 Storage

### 4.1.1 Instrument Storage Requirements

Store indoors under the following conditions:

- Temperature: -20°C to 55°C
- Relative humidity:  $\leq 90\%$
- Atmospheric pressure: 75 kPa to 106 kPa
- Good ventilation
- Avoid corrosive substances

### 4.1.2 Transportation

The instrument is fragile and should be handled with care. Move the instrument short distances indoors without packaging. For transportation in vehicles, use the original packaging. Users should retain all packaging materials. During transportation and handling, protect the instrument from moisture, shocks, and inversions. Handle it with care, place it horizontally, and avoid strong impacts, rain, and sunlight. Transport under the following conditions :

- Temperature: -20°C to 55°C
- Relative humidity: below 90%
- Atmospheric pressure: 75 kPa to 106 kPa

## 4.2 Use Location and Environment

### 4.2.1 Use Location

Install the instrument indoors on a level, stable workbench. Choose a location with:

- Low humidity and low dust
- No water sources like pools or pipes nearby
- Good ventilation and no corrosive gases
- Leave at least 10 cm of space on both sides and 20 cm behind the instrument for heat dissipation, ventilation and easy access to controls. The space behind should allow the power supply to be opened fully. Do not install it in an enclosed space with limited access



Avoid high temperatures to ensure proper performance. Keep the instrument away from heat sources like heaters, stoves, and other appliances.

During operation, nothing should be placed over the filter fan of the instrument.

### 4.2.2 Operating Environment

- Power supply: 100-240VAC, 50/60Hz.
- Ambient temperature: 10°C to 30°C.
- Relative humidity: not greater than 80%.
- Atmospheric pressure: 86 kPa to 106 kPa.
- Indoor use, altitude below 2000m.
- Away from mechanical vibration and shock
- Free from strong electromagnetic field interference
- Proper grounding

## 4.3 Unpacking

After unpacking:

1. Inspect packaging for damage. Report issues.
  2. Check all items against the packing list.
  3. Note damage/missing items for after-sales support.
- This ensures safe transport and facilitates after-sales service.

packing list

No.	Name	Specifications	Quantity
1	HyperLyse Automatic Nucleic Acid Extractor	L0400	1
2	Power cord	EU standard, 250V, 10A	1
3	Fuse	Φ5×20mm-F10AL250V	2
4	Cartridge rack	-	1
5	Instruction for Use	-	1
6	Quick start guide	-	1
7	Certificate of conformity	-	1
8	Warranty card	-	1
9	Packing list		



If the product is seriously damaged during shipment, do not use it. Contact customer service immediately for assistance.

## 4.4 Instrument Installation

1. Place the instrument according to the requirements in section 4.2.1.
2. Connect the provided power cord to an outlet.
3. Turn the back power switch to "I" to power the instrument on.
4. To power off, turn the back switch to "O" and unplug the power cord.



# Chapter 5 Operation Instructions

## 5.1 Operating Panel

The functions of the operating panel buttons and status lights are shown in Figure 5.1.1:

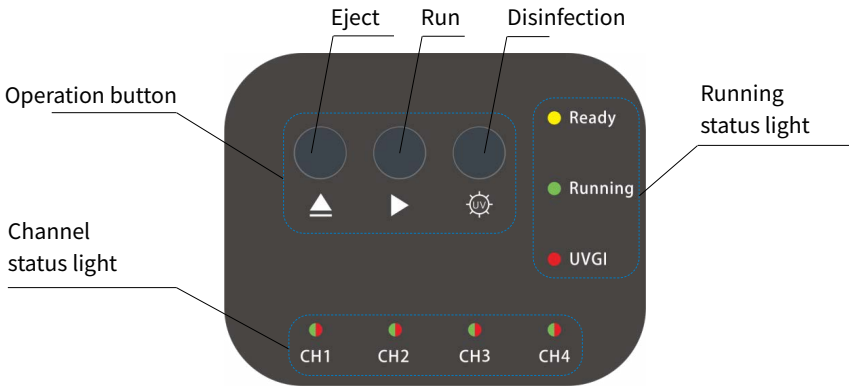


Figure 5.1.1

### 5.1.1 Channel Status light

The channel status lights have three states: off, red light, and green light.

**Off:** The channel is empty.

**Red light:** The channel is loaded.

**Green light:** The magnetic sleeve is picked up as expected in this channel, or the magnetic sleeve is detected (it is only detected after operation starts, or self-check when power-on the instrument).

The red and green lights can be on at the same time or separately. During extraction operation, the red and green lights are on at the same time.

During the extraction workflow, the status of a channel should be:

Red: channel loaded

Start the operation

Green: magnetic sleeve has been picked up correctly

## 5.1.2 Operation Status light

The operation status indicator has three lights: yellow (Ready), green (Running), and red (UVGI).

**Ready:** yellow light flashes; eject, retract, and disinfection operations are available.

**Fault:** yellow light (Ready) stays on; eject operation is available.

**Running:** green light stays on; nucleic acid extraction in progress, and any other operations are unavailable.

**UVGI:** red light stays on; only end disinfection operation is available. All other operations are unavailable.

## 5.1.3 Buttons

**Eject:** eject/extract the cartridge tray. Button has no effect in the middle of running or disinfection state.

**Run:** Press to start the extraction program. Button has no effect in the middle of running or disinfection state.

**Disinfection:** Starts or stops UV disinfection. Button has no effect in the middle of running state. Press again to manually turn off the UV disinfection, otherwise the UV lamp automatically turns off after 30 minutes.

## 5.2 Buzzer Prompts

**Power-on and self-test complete:** 2 beeps

**Operation complete:** 3 beeps

**Malfunction:** The buzzer keeps beeping. Press the Eject button to turn off alert.

## 5.3 Using the Instrument

When using the instrument, please follow the steps below:

Connect the instrument to power and turn on the switch. It will self-check during the start.

After self-check completes, the buzzer sounds twice and the instrument enters standby mode. If the status light remains yellow, the self-check fails. Contact service personnel for assistance.

### ① Load Extraction Cartridge

After shaking the new extraction cartridge. Place it on the rack, and then tear off the top seal. As shown in Figure 5.3.1, load the test sample to the sample well and place the magnetic sleeve in the sleeve well.

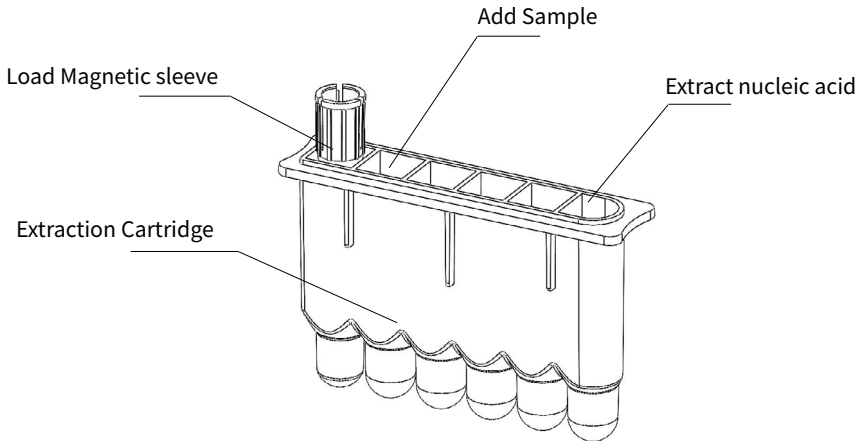


Figure 5.3.1

### ② Insert Extraction Cartridge

Press the Eject button to eject the cartridge tray.

Insert extraction cartridges into the tray and ensure it is properly positioned. Confirm the magnetic sleeve is in the correct position.

The status light will turn red once the cartridges are inserted.

### ③ Start Extraction

Press the Eject button. After the tray is extracted, press Run.

As extraction starts, the status light changes from yellow to green. Within 5 seconds, the consumable light changes from red to red/green, indicating the magnetic sleeve was picked up. Extraction takes around 10 minutes.

The buzzer sounds 3 times indicates extraction is complete. The status light changes from green to yellow.

**If the buzzer sounds continuously and extraction stops within 5 seconds, the magnetic sleeve was placed incorrectly. Press Eject button, adjust the sleeve, and restart extraction.**

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## ④ Extraction Complete

After extraction, the cartridge tray ejects automatically. Remove the cartridges and place it on the holder. Press the eject button again to retract the tray. Use the extracted nucleic acid for PCR test.

The extraction cartridge and magnetic sleeve are single-use. After extraction, properly dispose of waste consumables according to laboratory procedures.

## ⑤ Disinfection

In standby mode, press the disinfection button. UV lamp will be on for 30 minutes and turns off automatically as disinfection is complete.

## ⑥ Shutdown

After disinfection is complete, turn off the power switch at the back of the instrument.

# Chapter 6: Instrument Maintenance and Repair

## 6.1 Cleaning

The instrument has a closed system. Unless otherwise specified, clean only with alcohol.

For external surfaces:

- Use a lint-free cloth dampened with 75% alcohol to clean the surfaces.

Internal disinfection:

- Run the UV lamp for at least 30 minutes for disinfection. Or:
- When the cartridge tray is ejected, wipe with 75% alcohol.



**Before cleaning the instrument, turn off the power and unplug the power cord.**



**Avoid using strongly corrosive reagents or organic solvents to clean the instrument. Before using disinfectants or cleaning agents not recommended by the manufacturer, consult with them first.**

## 6.2 Replacing the Fuse

Two 10A fuses protect the instrument. To replace a blown fuse:

1. Turn off the power and unplug the power cord.
2. Use a screwdriver to open the fuse box drawer.
3. Replace the fuse ( $\Phi 5 \times 20\text{mm}$  - F10AL 250V).
4. Close and tighten the fuse box drawer.
5. Plug in the power cord.



**Before replacing the fuse, make sure to turn off the power and unplug the power cord.**

# Chapter 7

## Common Problems and Solutions

During the use of instruments, some faults may inevitably occur and affect use. This sections is to suggest common problems, potential causes, and solutions.

No.	Scenario	Cause analysis	Solution
1	the buzzer sounds continuously after startup and the instrument stops running	(1) extraction cartridge was never inserted (2) the magnetic sleeve is loaded in the cartridge as required; (3) The magnetic sleeve dropped during operation; (4) The magnetic sleeve failed to be discarded.	Press the "eject" button and wait for the cartridge tray to eject. Inspect the cause, and then take appropriate action.
2	The kit shakes vigorously while the instrument is running	Deformation or bending of magnetic sleeves or improper placement of cartridge.	Stop operation and check the consumables
3	No response after pressing the 'eject' or 'start' button	The instrument may be in the middle of disinfection	Check and manually turn off disinfection

For unknown issues:

- Make a detailed record of the scenario, behavior, and troubleshooting steps.
- Provide this information to technical support



**If the instrument malfunctions and the fault is not listed above, stop using immediately and contact after-sales support for assistance.**

# Chapter 8: After-sales Service

## 8.1 Warrant period

The instrument is warranted for 12 months from the installation date recorded on the warranty card. This assumes:

- The instrument was packaged, transported, stored and used according to guidelines.
- The warranty card was filled out during installation

## 8.2 Warranty Scope

The company will repair, replace parts, or replace the product free of charge if the instrument fails to function properly due to defects in materials or workmanship within the warranty period. The company is responsible for ensuring normal operation as long as the product is used as intended during the warranty period.

## 8.3 Non-warranty Items

Paid repair services are required for:

1. Damage due to non-compliance with operating instructions
2. Unauthorized modifications
3. Damage due to fire, flood or other events beyond our control
4. Use of incorrect power supply
5. Repairs by non-authorized technicians



**Repairs after the warranty expires will not be covered and paid services are applicable.**

# Chapter 9: Labels and Identification

## 9.1 Instrument Nameplate

The content, layout, and positions of the instrument nameplate label are shown in Figure 9.1.1:

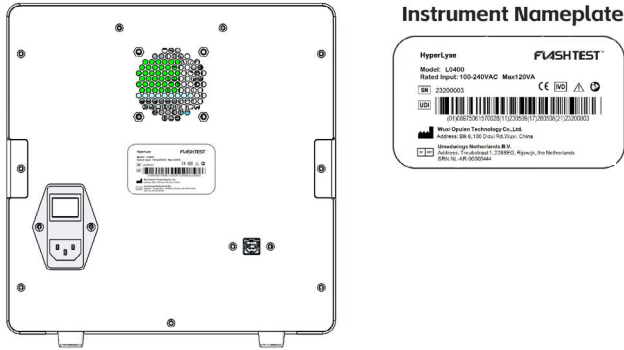


Figure 9.1.1



## 9.2 Packaging Label

The content, layout, and positions of the product packaging label are shown in Figure 9.2.1:

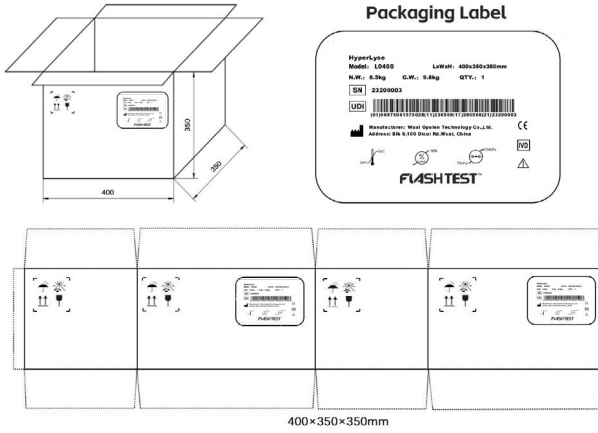













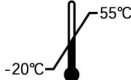

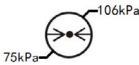


Figure 9.2.1

## 9.3 Other Labels

	serial number		warning
	Please read the Instruction for Use		Manufacturer
	Keep dry		Avoid direct sunlight
	Upward		Fragile
	In Vitro diagnostic Medical device		Authorized representative in the European Community
	CE mark		Unique Device Identifier
	Maximum stacking limit		Maximum temperature limit
	Maximum humidity limit		Maximum pressure limit

————— END —————



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