

User Manual

LS-1000 Immunofluorescence Analyzer

Preface

Respected customers:

This Manual is suitable for the LS-1000 Dry Fluorescence Immunoassay Analyzer produced by Nanjing Lansion Biotechnology Co., Ltd. (hereinafter referred to as LansionBio).

This product adopts the modern photoelectric technology, for the in-vitro quantitative detection of HbA1c, TSH, T3, T4, D-Dimer, CRP, PSA, cTnI, NT, CTNI/CKMB/MYO, PCT and LP-PL A2 in serum, plasma and whole blood or urine, detection results applied to clinical diagnosis. It is convenient, accurate and fast to detect the relevant parameters of human body with various fluorescent reagents when applied to clinical use.

This product has been widely used in medical and health care departments at all levels. It is an indispensable detection instrument for clinical examination.

The basic principle of this product is to transform the fluorescent signal into a digital signal and calculate the concentration by the data processing system.

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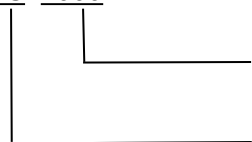
1.Product Name and Model

1.1 Product: Dry Fluorescence Immunoassay Analyzer

1.2 Model: LS-1000

1.3 Model Division Explanation

LS- 1000



Indicates the type: single channel;

Indicates company name: Nanjing Lansion Biotechnology Co., Ltd.

1.4 Software

Software Name: Dry Fluorescence Immunoassay Analyzer

Model: LS-1000

Release Version: V 1.3

Full Software Version: V 1.3.2.11

2.Registrants and After-sales Service Units

Company Name: Nanjing Lansion Biotechnology Co., Ltd.

Manufacturing Address: Science Park, No.2 Qiande Road, Jiangning District, Nanjing

Tel: 025-58775705

E-mail: biz@lansionbio.com

Website: en.lansionbio.com

Medical Apparatus and Instruments REG No.:

Product Technical Requirements No.:

Manuel Revision Date: Oct 6, 2017

Performance Characteristics

3.1 product classification

Classification by shock protection:Transient overpressure class II,Rated pollution level 2

By work:Continuous running equipment

Sheet 1-Main Parameters

Item	Parameters
Individual Test Speed	15s
Test Scope	-
Wavelength Range	365nm±5nm
Average Trouble-free Working Time	≥1000 h
Data Interface	RS232 and Bluetooth
Storage	≥ 5000 test results

Sampling Method	Manual Sampling
Display	7" LCD Screen
Device Size (L×W×H)	225mm×152mm×105mm
Weight	N.W.: 1.3kg
Power Supply	AC 100~240V、50~60Hz、60VA
Detection range (mV)	0-600
Resolution (mV)	0.0003

4.Main Structure Composition

This product is composed of reaction module, optical detection module, data processing module and power line.

5.Application Scope

This product with the special kit by fluorescent immunoassay can in-vitro quantitatively detect HbA1c, TSH, T3, T4, D-D, V-D3, CRP, PSA, CTnI, NT, CTNI/CKMB/Myo, PCT and LP-PLA2 in serum, plasma and whole blood or urine, which is applied to clinical assistant diagnosis.

6.Contraindication

There isn't known contraindication yet.

7.Attention Matters, Warnings and Precautions

7.1 Tips and Warnings

This instruction contains four categories of hazards, which are represented by hazard, warning, attention, and danger of electric shock.

 Biohazard	The reagents and specimens used in the instrument may be corrosive or contagious. Please pay attention to the self-protection when operating the instrument and waste centralized processing.
 Warning	Before operating the instrument, please check the instructions first and strictly operate it by its steps.
 Attention	The instrument has many dynamic parts in the working process, and the dynamic parts shouldn't be touched by hand to avoid the injury.
 Danger of Electric Shock	When the instrument works in high temperature and high voltage, please pay attention to the sign on the instrument when used, so as not to do the harm.

7.2 Attention Matters of Starting and Working

Connect the installed instrument to the power line and turn on the power switch. Such instruments are completed self-checking. If normal, it sounds short and displays like the

picture pasted as below. If abnormal, the error code will be said in the upright tip box of the instrument. Please refer to the fault list.

7.3 Operation Precautions

- a) Ensure the table clean and tidy. The samples to be measured and containers are properly put aside and the samples are numbered.
- b) Ensure the instrument connected to the correct power supply.
- c) Ensure the used test kits not placed in the sampling parts.
- d) Confirm the good quality of the test kits and samples, no deterioration and the enough quantity.
- e) Confirm the ID card matched with the test kits.
- f) Safety and safety protection, safety signs and instructions in pre-operation and use
- g) Please confirm the stability of the instrument installation to prevent the instrument slipping to hurt people.
- h) The operator needs to wear gloves in the operation.
- i) This instrument is only matched with the fluorescence immunoassay kit produced by Nanjing Lansion Biotechnology Co., Ltd.
- j) The anti-dust of installation and use environment, indoor temperature 15~35 °C , supposed to be equipped with air conditioning.
- k) All spare parts except printing paper and consumables must be provided by our company. Otherwise, our company won't be responsible for any problem.
- l) Power Supply: AC 100~240V $\pm$ 10%、50~60Hz $\pm$ 3 、60VA。
- m) If the instrument is shut down for reasons such as blackout, please turn on the machine after 30 seconds.
- n) If there is something wrong with the instrument, please contact with us in time. Without permission, anyone not authorized as professional maintenance staff by our company can't check and disassemble any parts of the instrument. Otherwise, our company won't be responsible for any problem.
- o) In the case of standardized operation and reasonable maintenance, the service life of the instrument is 5 years (no more than 8 hours per day).

7.4 Warning and Prompting

- a) The portable fluorescence immunoassay analyzer is only suitable for the in-vitro analysis of human blood or urine samples, no other specific use.
- b) Only the test kits mentioned in this instruction can be adopted, otherwise the obtained results might be unreliable.
- c) Read this instruction carefully before operating and keep it properly for future use.
- d) If the instrument gives off an unusual smell or smoke, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.

e) e.If any liquid enters in the interior of the instrument, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.

f) f.Take proper safeguard measures according to health and safety standards in local country, including wearing protective goggles, surgery gloves and laboratory coat (even more).

g) The operator or charge person of the instrument shall be trained upon attention matters and operation guidance of the instrument by the after-sale engineer, and the instrument only can be operated after the training.

7.5 Waste disposal

The processing of instrument packs, used test kits and waste scrap apparatus refer to local laws and regulations; to stop the use of instrument due to maintenance or handling, and the user should do a good job of disinfection and other preventive measures to minimize biological hazards in transportation, disposal or destruction of the analyzer. It is suggested that users process or destroy it according to the Type B electronic instrument regulations. The used test kits should be destroyed according to the local biological hazardous material handling regulations.

8. Installation and Operation

8.1 Installation

Carefully unpack the analyzer and check the appearance. If there is any transport damage, please make a statement immediately. Check the analyzer and confirm the packing list to ensure the complete configuration. If you find that the configuration is not complete, please contact our After-sales Department or the agent in your area.

Place the mainframe of the dry fluorescence immunoassay analyzer on the platform. Connect the power adapter and normally open the machine.

After the installation is completed, test the quality control product and compare the result with the target value. If the result is correct, it turns out the successful installation of the analyzer.

 Attention	a) Avoid direct sunlight or near heat source and wind regime. The loading capacity of the installed table must be over 20Kg. b) Not used in a strong magnetic and wet field. c) The instrument is installed in the laboratory accord with technical requirements of the temperature and humidity. d) The instrument should avoid excessive dust erosion. e) The staff for installation and operation of the instrument must be trained professionally. f) Do not place the instrument in a position where it is difficult to
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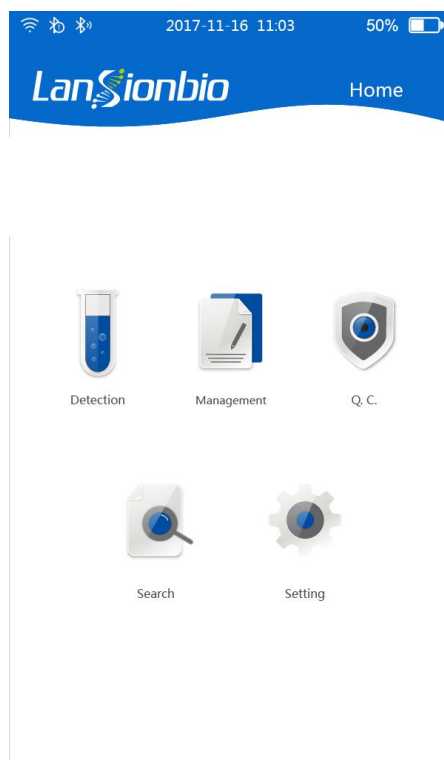
	disconnect. g) Correctly use the power adapter configured in this instrument, connect the power line and attach the power plug. h) When the instrument installed, please do not connect the power line first, and prevent the wrong starting. i) If encountering the resistance as installing the components, please find out the cause, and avoid violence to prevent damage to the instrument. j) Ensure the instrument installation space large enough, and ensure the back and the two sides of the instrument from the wall at least 20cm, convenient for future operation and maintenance. k) Please do not use other power adapters instead of the originally equipped power adapter, so as to ensure the suitable power supply socket.
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8.2 Operation

8.2.1 Software Module and Function

This product can be divided into 6 modules according to its functions and applications (see P1):

Measure	This function can be used for sample test (one-step test), patient information input and so on.
Search	This function can search historical data and print selected records. Users can search through time, item, sample No. And date.
Management	This function is used to import the project data in the ID card. The data can be used as an important reference data for this batch of reagents, and the project data can not be detected without the introduction of the project data.
Q.C.	This function can control the quality of the instruments and reagents, and ensure the stability of the instruments and reagents.
Setting	This function is used for the basic maintenance and setting of the instrument.
On/Off	This function can realize the one-switch turning on or off the instrument.



P1- Homepage

8.2.2 On/Off

This function is realized by the 'Start' on the interface. When the screen back-light is off, the button can awaken the screen by this key. Long pressing for 2 seconds to turn on and long pressing for 2 seconds to turn off. When the instrument is turned on, it will automatically initialize and self-check, and the screen shows the system is self-checking (see P2).



System Self-checking...

P2- Starting

8.2.3 Measure

a) When the initialization is completed, click the 'Measure' on homepage to enter the measure page (see P3).

b) After entering the test interface, you first need to add samples to detect. At this time, please click 'Add', then it will pop up the sample addition page (see P4). At this time, the bar code of test kit can be scanned by the external scavenger. After the scanning completed, the instrument will have a sound of "Beep", indicating the scanning is completed. At the same time, the test items will be refreshed automatically. After scanning code completed, users click on the edit box to input necessary sample and other information. After inputting, click 'Confirm' to complete the sample addition, and return to the measure page. If this batch of test items is not leading in, it will pop up the warning, "the current item is not leading in, please lead it in again!"

c) After the sample added, the sample information column just added will appear in the list of samples to be checked. When the sample information column clicked on the measure page, you can enter the check page of this sample (see P5). In the sample check page, we can modify other sample information except test items and sample types. If you totally confirm, you can click 'Confirm' to save the information and return to the measure page.

d) After the sample added, insert the kit added with sample into the instrument detection channel. Click 'Start', the test starts. (if the kit in the wrong position, it will pop up "Wrong position, please insert the kit first". Wait for the test completing and it automatically

pop up test results check page (see P6). Click "Print" and it can print the current test results and return measure page. Pull out the test kit and click 'Return' on measure page to return to homepage. By far, the instrument goes through a complete testing process.

No.	Sample#	Item	Name	Age	Gender
000	000	TSH		00	Male

Add Return

P3- Measure

Sample# Name

Test item PCT Age

Sample type Whole blood Gender Male

Inspector ☐ Emergency ☐

Yes Continue Item Addition Return

P4- Project

2017-11-16 11:03 50%

Lansionbio Sample Check

Sample# 000 Name

Test item TSH Age 00

Sample type Whole blood Gender Male

Inspector Emergency

Start Deselect Return

P5- Search

2017-11-16 11:03 50%

Lansionbio Detection

No.	Sample#	Item	Name	Age	Gender
000	000	TSH		00	Male

Result

Sample# 000 Name

Test item TSH Age 00

Sample type Whole blood Gender Male

Reference 0.40-4.00 Result 2.43

Emergency Unit uIU/ml

Inspector

Test time 2017-06-14 12:24:27

Print Upload Return

Add Start Return

P6-Measurements results interface

8.2.4 Record queries

a) In the main interface, click the "Record queries" button and enter into the queries interface (see Fig.7)

b) In the interface, Users can be manually enter the test starting date, test items, sample number, patient name, age, sex in one or more of the conditions to search for the

corresponding detection record. Test time Input Format: 4-bit year, 2-digit month, 2-digit date, such as 20170101, if the input is incorrect, it will pop "time input wrong, please re-enter!" Hint box;

c) In the interface, click on the corresponding column in the list to eject the record-viewing interface for the sample detection of the column. (see Fig7-1);

d) Click on the "Print" button in the record viewing interface to print out the current record and return to the record query interface.

e) Click on【upload LIS】in record-viewing interface to upload the current record to the LIS system and return to the record query interface.

2017-11-16 11:03 50%

Lansionbio Record Search

Item Sample#

Test item Inquiry

Name Age Gender

Test item	Sample#	Name	Item	Result
2017-06-14 12:24	000		TSH	2.43
2017-06-14 12:31	000		TSH	40.00 ↑
2017-06-14 12:30	000		TSH	<0.10 ↓
2017-06-14 12:27	000		TSH	<0.10 ↓
2017-06-14 12:26	000		TSH	0.47
2017-06-14 12:24	000		TSH	<0.10 ↓
2017-06-14 12:20	000		TSH	7.50 ↑

Select All Print Return

P7-Record queries" interface

The screenshot shows the 'Record Search' interface of the LanSionbio LS-1000. A 'Result' dialog box is displayed over a table of search results. The dialog contains the following information:

Sample#	000	Name	
Test item	TSH	Age	00
Sample type	Whole blood	Gender	Male
Reference	0.40-4.00	Result	0.35 ↓
Emergency	☐	Unit	uIU/ml
Inspector			
Test time	2017-06-14 12:14:23		

Buttons at the bottom of the dialog: Print, Upload, Return.

Buttons at the bottom of the main interface: Select All, Print, Return.

P7-1- record-viewing interface

8.2.5 Items Management

a) In the main interface, click the **【Items Management】** button and enter into the Items Management (see Fig.8)

b) Please check whether ID card is inserted properly

Firstly make sure to insert ID card matching with chip into the instrument ID card slot. Then click on the "Read Card" button, dialog box will pop up again to confirm that the ID card has been inserted, click OK to lead-in the item data from the ID card into the item information list of the interface, indicating that the item in the ID card has been successfully lead-in.

c) In the interface, click on the **【Query】** button to search for the appropriate item data basing on the item name and batch number.

2017-11-16 11:03 50%

Lansionbio Management

Batch Item Inquiry

Item	Batch#	MFD.	Exp.
PCT	1701	20170620	20170620
CRP	1701	20170620	20170620

Read Return

P8-Items Management

8.2.6 QC

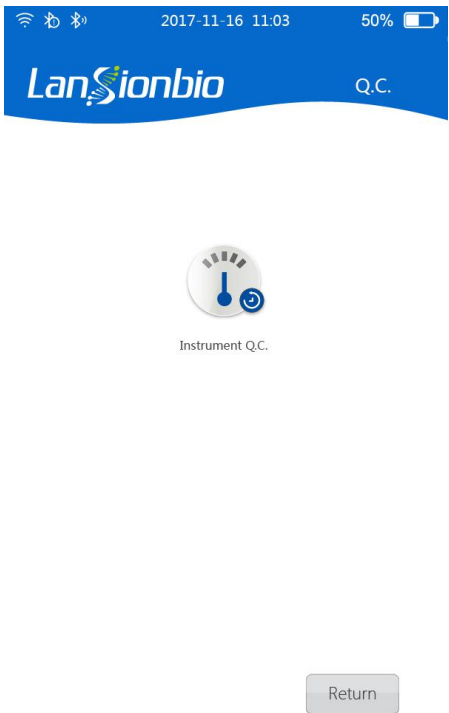
a) In the main interface, click on the **【QC Management】** button and enter into the QC interface (see Fig.9);

b) In QC Management interface, click on the **【Device QC】** button and enter into the instrument QC interface (see Fig.10);

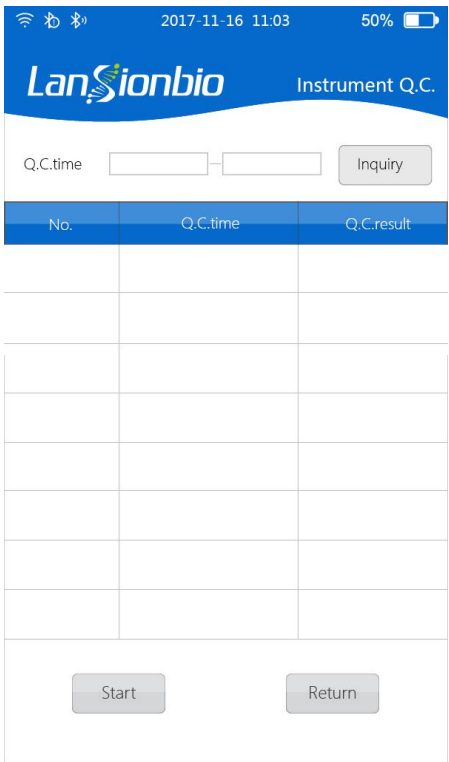
c) Users can manually enter the query condition after clicking the query button to search the corresponding quality control records, the user can select a quality control record to delete or empty all the quality control records;

d) Click on the **【Start test】** button to carry on the quality control after confirmation of inserting QC card, waits for the QC end will pop up the quality control result interface (see Fig.11), indicating the detail work of QC process is normal or not, if abnormal, please contact with the supplier. In the QC results interface, Click on the **【Ok】**、**【back】** button can be directly returned to the instrument QC interface. Meantime, the QC record list in the instrument QC interface will be added a just test record.

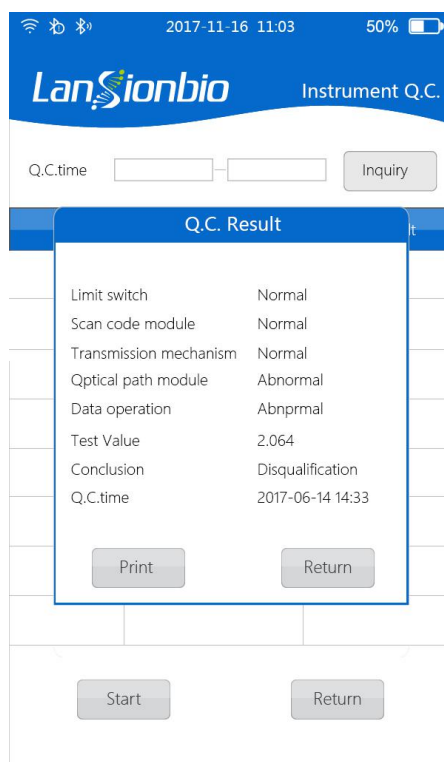
e) In the instrument QC interface, users can manually enter the QC start date (standard format: 4-bit year, 2-digit month, 2-digit date, such as, 20170101) Click on the **【Query】** button to perform the corresponding QC records retrieval.



P9-QC Management interface



P10-Device QC Management interface



P10-QC results interface

8.2.7 System settings

a) After the completion of power-on initialization, click on the system settings button and enter into the system settings interface(see Fig.11);

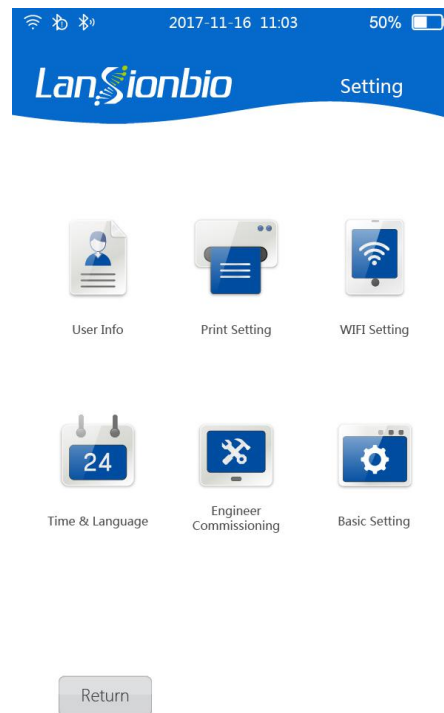
b) Click on the “ User Information Settings” button to enter the user information settings interface, users can be manually enter user information, click on the confirmation button to save;

c) Click on the “ print settings ” button to enter the print settings interface, users can choose print content and whether to print the test results automatically, click ok to save settings results;

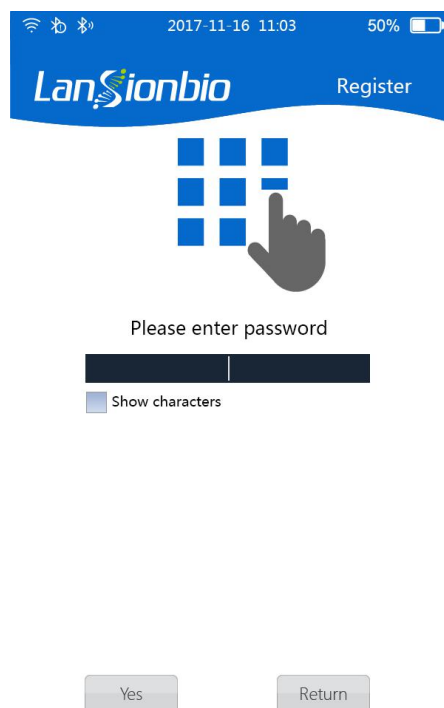
d) Click on the "WIFI ” Settings" button to enter the WIFI setting interface, which allows internal users to access the current attachment available WIFI and to connect to the user's designated WIFI by entering password;

e) Click on the "Time Language Settings" button to enter the time language settings interface, the interface users can manually enter the time and select the language, click OK to save settings;

f) Click on the "Engineer debugging" button to enter the password into the engineer debugging interface (see Fig.12), the interface using is only for supplier internal engineers to maintain device, not open to users.



P11-System settings interface



P12-password interface

9. Repairing, Inspection and Maintenance

9.1 Daily Cleaning

Use medical alcohol sponge (75%) to clean and wipe Detection Port around the device. The surface should be cleaned after each using in the way referred to above.

 Attention	The device must be stopped before Maintenance, please refer to the operation procedures, methods and precautions section of the downtime.
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9.2 Calibration

The device shall be calibrated on a regular basis of using a QC card (recommended for one month) to ensure the device's measurement results accurate.

9.3 Maintenance procedure

9.3.1 Monitor Maintenance

Due to temperature, power supply voltage changes or other factors, the monitor may not display, or the handwriting shown is too light or too dark. The person concerned should be requested to maintain the service.

9.3.2 Lubrication Maintenance

After each use of the analyzer for 6 months, please contact with the professional engineer to add lubricant on the metal shaft and metal guide of the device (Vaseline can be used).

9.4 Maintenance and repair for longtime shutdown

Firstly remove the reagent card and clean the device refer to the daily cleaning procedures, and then lubricated maintenance, with a dust cover for the device, stored in a dry and shady place.

9.5 Alarm analysis and processing methods

Error code	Troubles	analysis of the cause	troubleshooting methods
/	No display on boot, no action on the device	the power adaptor is not connected or burned	connect the power adaptor/contact with the supplier
non-stop clicking sound hoot	non-stop clicking sound hoot	the user took out the sample that was reading	insert the removed sample

If the above phenomenons, the customer can not deal with the trouble, pls contact with the manufacturer timely. The above issues related to the instrument parts, the company service engineer should be requested to determine and provide replacement parts.

10. Storage and Transport

10.1 Working environment:

- Temperature: 15℃～35℃;
- Relative humidity: 20%～70%, No condensate;

c) Air pressure: 86.0kPa~106.0kPa.

d) Other instructions: The workplace should try to avoid dust.

Please stay away from the strong electromagnetic field interference source.

Keep away from sunlight, good grounding environment, and maintain good ventilation.

Should be placed in the flat work area in order to cause vibration, do not put the instrument in the location which is difficult to operate and disconnect the device, should be facilitate the operation of personnel and daily maintenance.

10.2 Storage and transportation conditions

a) Temperature: -40℃~55℃;

b) Relative humidity: <93%, No condensate;

c) Air pressure: 50.0kPa~106.0kPa;

d) Other instructions: Non-corrosive gas and well-ventilated place.

The packaged analyzer shall be transported according to the conditions stipulated in the contract.

Hoisting and transporting should be handled with care.

To ensure the master carton, pay attention to waterproof and moisture.

 Attention	This instrument is a precision laboratory equipment, please use both hands to hold the bottom of the instrument when moving. The instrument must be placed in the carton to be transported by crash roll package.
 Biological risks	The instrument should be prepared for the special waste containers, the waste is only to be thrown into the container, the waste in the container discharged shall be treated according to the laboratory which has biological risks provisions. For the risk of potential biological infectivity, such as samples, reagents etc. users should wear standard laboratory protective clothing and gloves, and comply with the laboratory safety operation regulations.

11. Production Date and Expiry Date

Date of production:

service period: 5 years

12. Label

Symbols	Description
---------	-------------

	Caution
	Biological risks
	Beware of electric shock
	Earthling Protection
	Symbol for “Environment protection – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice”
	B type equipment
	This way up
	Fragile
	Keep away from rain
	Consult instructions for use
	Manufacturer
	Serial number

13. Packing list

No.	Description of goods	Qty'	Remarks
1	Mainframe	1 unit	LS-1000
2	Power adapter	1 pc	AC 100~240V $\pm$ 10% to DC 15V 4.0A
3	QC card	1 set	
4	Certification	1 pc	
5	Power cord	1 pc	
6	Packing list	1 pc	
7	product manual	1 pc	
8	External heat sensitive printer	1 pc	match
9	printing paper	1 roll	Match,Thermal printer paper,specification:57mm

14. Electromagnetic compatibility

Electromagnetic compatibility (EMC) is defined as a product, device, or system in normal work in its electromagnetic environment and not to constitute an unsustainable electromagnetic disturbance to anything in the environment.

Anti-EMI is the ability of a product, device or system in normal work in the presence of electromagnetic interference (EMI).

Dry Immunity fluorescence analyzer is designed and manufactured according to the existing standards of electromagnetic compatibility and related requirements.Using an analyzer in the presence of an electromagnetic field may result in reduced performance such as repeatability or accuracy. If this phenomenon occurs frequently, it is recommended to check the analyzer's use environment to identify possible sources of harassment.These harassments may come from other electrical devices used in the same room or neighboring rooms, or from mobile phones, walkie-talkie, portable and mobile RF communication equipment, or from nearby radio equipment, television or microwave transmission equipment. If EMI interferes with the analyzer, it may be necessary to move the analyzer to another location or take the appropriate EMI suppression measures.

Analyzer in line with national standards GB/T 18268.1-2010 and GB/t 18268.26-2010 requirements.

15. Copyright Notice

Copyright

Nanjing Lansion Biotechnology Co.,Ltd. 2017

Version No.: 1.0

Release Date: 2017/12/14

Item No.: LS-1000

Production License No.:

Registration No.:

Technical Requirement No.:

Notice

Disclaimer: in the following cases, our company will collect cost according to the actual fe

es even if the instrument in the warranty period.

- (1) Infringe the instruction of this manual or damage the relevant parts on user' s own.
- (2) Instrument can not normally work for not using our spare parts.
- (3)

The labels of the reader or reagents are damaged, and such as contracts and invoices etc as warranty proof for instrument can not be provided.

- (4) Equipment that is damaged by a natural calamity beyond human control.

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