URIT-600/610 Coagulation Analyzer

Operation Manual

URIT Medical Electronic Co., Ltd

NOTE

1) Carefully read this manual before first operating the analyzer.
2) Inspect the electrical requirements of the analyzer before power on, and properly connect the grounding wire.
3) Turn off the power to the analyzer and disconnect the power cord if the analyzer is idle for a long time.
4) Do not run the analyzer if it's in an abnormal or damaged condition.
5) There is potential biohazard of the reagents and samples; operator should follow proper biosafety practices. Dispose of waste reagent and sample in accordance with local, national regulations.

Contents

Copyright and Declaration

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Declaration:

All contents in this manual were strictly compiled according to related laws and regulations in China, as well as the specific condition of URIT-600/610 coagulation Analyzer, covering all the updated information before printing. URIT Medical Electronic CO., LTD is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference and subject to real object if any differences.

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Limitation of Liability:

URIT warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year from the later of the date of original purchase or installation.

URIT assumes no liability in the following situations even during the period of warranty.

1. Failure due to abuse the analyzer or neglect the maintenance.

2. Use reagents and accessories other than manufactured or recommended by URIT.

3. Failure due to operate not under the instructions described in the manual.

4. Replace accessories not specified by URIT, or after maintenance or repair by a service agent not approved or authorized by URIT.

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Chapter 1 System Description

1.1 Overview

URIT Coagulation Analyzer is one kind of semi-auto analyzer with two or four test channels (URIT-600 has two test channels and URIT-610 has four test channels); it adopts the principle of magnetic ball solidification method to measure the coagulating time of blood components. With the use of URIT reagent, the analyzer can test PT, APTT, FIB, TT, and blood coagulation factors. The analyzer guarantees that test results would not be interfered by hemolysis, chyle, icterus, tubidity, plasma viscosity and other factors.

This analyzer is mainly used in hospital, research and teaching institutes to analyze blood coagulation, anticoagulation, fibrinolysis and antifibrinolysis.

The analyzer is for in vitro diagnostic use.

NOTE: the URIT reagent is a must to guarantee the test precision.

1.2 Technical Specification

a) Test principle: magnetic ball solidification method.

b) Test item: PT, APTT, FIB, TT, Blood Coagulation factor Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ, Pro C, Pro S, HEP, LMWH.

c) Test channel: URIT-600 has two test channels and URIT-610 has four test channels. The channel deviation is less than 10%.

d) Incubation time and temperature control: incubation time is less than 30 minutes after power on the analyzer when the environmental temperature is 25℃. After incubation, the temperature of constant temperature device and incubation cell will keep 37.0℃±1.0℃.

e) Repeatability:

The repeatability of analyzer should be complied with table 1.

Table 1 Repeatability

Item	CV	
	Normal sample	Abnormal sample
PT(s)	≤5.0%	≤10.0%
APTT(s)	≤5.0%	≤10.0%
FIB(g/L)	≤10.0%	≤20.0%
TT(s)	≤15.0%	≤20.0%

The abnormal sample means its value is not less than the twice median value of normal sample.

f) Accuracy: The relative deviation of FIB is less than 10%.

g) Linearity and related coefficient:

- FIB linearity: 6.5g/L～1.0g/L (650mg/dL～100mg/dL), measurement range: 13g/L～0.5g/L（1:20,1:5 dilution）
- Related coefficient: γ ≥0.990

h) Display: LCD, English menu, operation information and test result.

i) Printer: the internal thermal printer would print the test result automatically if it's set to be ON; external stylus printer is available.

j) Environment specification:

Operation: 15℃～35℃, RH≤85%, 75kPa～106kPa

Storage: -20℃～55℃, RH≤85%, 75kPa～106kPa

k) Control function: functions like self-checking, testing and error judgment

are controlled by microprocessor.

l) COM port: the analyzer can be connected with computer through COM port.

m) Data capacity: the analyzer can memorize 500 samples data.

n) Power specification: AC100V~240V, 50Hz /60Hz, 45W

o) Net Weight: 5.6Kg

p) Dimension: 380mm×340mm×130mm

q) Life span: 10 years

1.3 Principle

URIT-600/610 tests the blood coagulation time process with the principle of magnetic ball solidification method. By simulating blood coagulation condition, with the chemical reaction of reagent, the analyzer starts the coagulation waterfall effect to transform fibrinogen into cross linked fibrinogen, and make the sample solidified. The analyzer measures the solidification time or sample concentration by testing the movement of magnetic ball. The solidification time could be exact to 0.005 second. The test results would not be interfered by hemolysis, chyle, icterus, tubidity, plasma viscosity and other factors.

1.4 Structure

The analyzer appearance is depicted in the following figure.

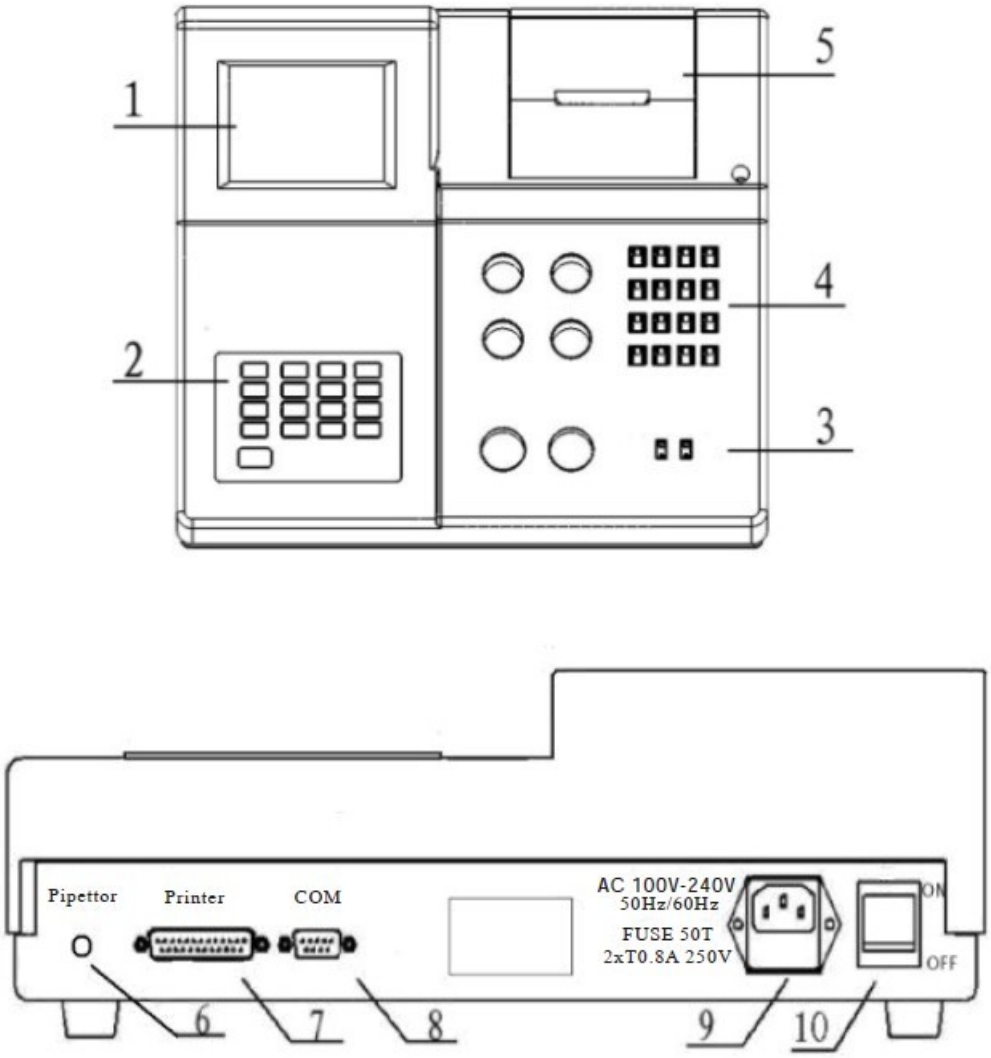


Figure 1

1) Display: displays test result and information.

2) Keyboard: 0~9 keys, decimal point key and function key.

3) Test channel: channel 1 to channel 4 is located on the panel from left to right. Place the incubated sample on the test channel and user can start the sample testing.

4) Incubation cell: it is used to incubate the reagent and sample.

5) Internal thermal printer.

6) Pipettor port.

7) Printer port: it is used to connect the external printer.

8) COM: it is used to connect the computer.

9) Analyzer power plug connector.

10) Power switch.

Chapter 2 Installation

2.1 Package Inspection

Unpack and check the shipping container as follows:

a) Carefully unpack the shipping container and take out the analyzer and accessories.

b) Check the contents according to the packing list for the correct quantity.

c) Please notify the authorized distributor immediately in case of any damage.

2.2 Installation Requirements

a) Install the analyzer in the room which complies with the operating environment. It's recommended to use an air-conditioner to reach the requirements of temperature and humidity.

b) Install the analyzer on a clean, level and firm surface, which is away from direct sunlight, intensive magnetic field and moisture environment.

c) Ensure the power outlet is well grounded.

2.3 Printer Installation

a) Press the printer cover to open it (see figure 2).

b) Pull the paper rod and remove the remaining paper if there is any. Mount the printer paper in it and reset the rod (see figure 3 and figure 4).

c) Make the paper go through the slot of cover, and then close it.

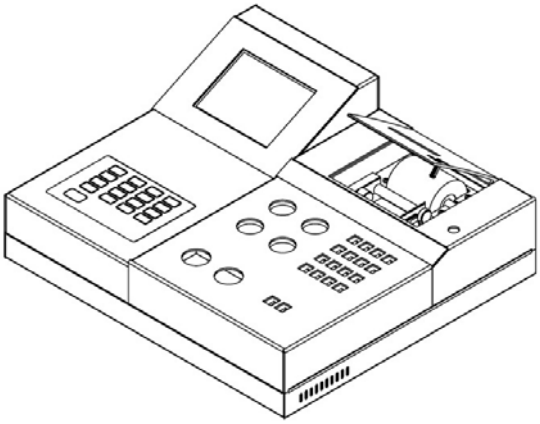


Figure 2

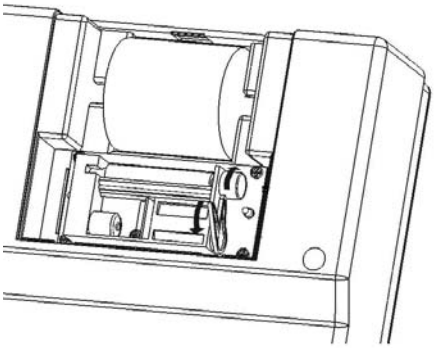


Figure 3

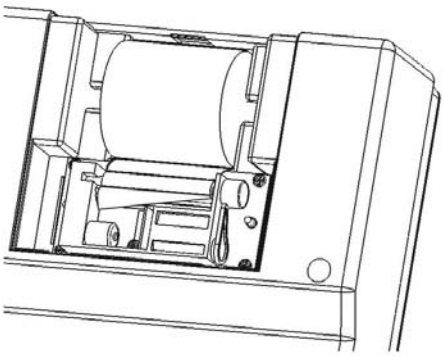


Figure 4

2.4 Accessories Connection

Connect the other accessories to the analyzer including power cord, pipettor, external printer and computer through the corresponding ports. Ensure the power is off when connect these accessories.

Chapter 3 Operation

3.1 Power On

Power on the analyzer and the initialization may take approximate 30 minutes. The analyzer will be ready to start testing when it accords with the constant temperature.

NOTE: To ensure the accuracy of test results, please test sample under the constant temperature.

WARNING: When using reagents, avoid contact with skin and clothing. In case of that, clean with water and soap immediately. If contact with eyes, flush with water immediately and seek medical advice.

WARNING: Potential biohazard. Consider all specimens, surfaces, or components that contain or have contacted blood, serum as potentially infectious. Wear gloves, a lab coat, and protective eyewear, and follow other biosafety practices.

3.2 Test Screen Description

Test screen will display after analyzer self-checking, which could be divided into four areas like figure 5.

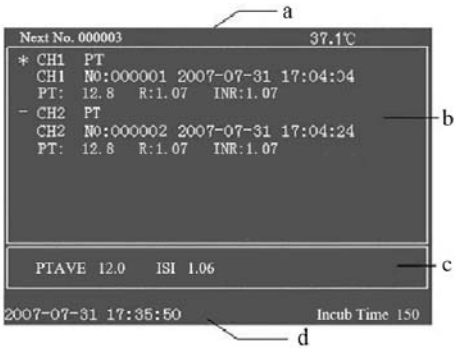


Figure 5

a) In this area, it shows the number of next sample and incubation cell temperature. The temperature may be different from the temperature of incubated reagent or sample. It will display “T: H” on the screen if the temperature is higher than 39℃.

b) Result area: this figure showing URIT-600 test screen, there are 2 channels: CH1 and CH2. Following the channel number, test item, sample No., time and result will be displayed.

“*” means the selected test channel.

“!” means the testing channel.

Press CH key to change test channel and the selected channel will be displayed with “*”.

Press 2 or 8 on the keyboard to change test item.

Press Start key or press pipettor switch, the analyzer begins to test.

c) PTAVE indicates the PT mean value of normal sample. Each lab should set its own PTEVE and mean time.

ISI coefficient should be corresponding with ISI value given by reagent.

d) In this area, current time and incubation time will be displayed.

3.3 Keyboard

The following figure depicts the keyboard.

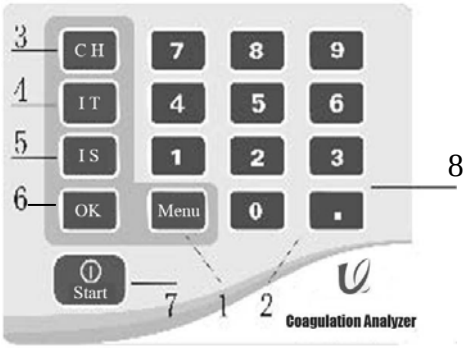


Figure 6

1) Menu key: press this key to enter the main menu, or give up the current operation and exit.

2) 0~9 numeric keys: press these keys to input figures, such as: incubation time, concentration, date, etc. Press 2 or 8 to change the test item. Refer to chapter 3.4.4 for more query functions.

3) CH (channel) key: press CH key to select the test channel.

4) IT (incubation time) key: press this key to set the incubation time.

5) IS (incubation start) key: press this key to start the incubation, and the analyzer begins to count down the incubation time. Audible beeps indicates that the incubation processing is completed, press this key again to stop the beeps.

6) OK key: press this key to confirm the operation.

7) Start key: press this key to start test.

8) Decimal point key: press this key to input decimal point when input figures; from test screen and query screen, press this key to paper throw one row.

3.4 Main Menu

Press Menu key, the main menu screen like following figure will be displayed.

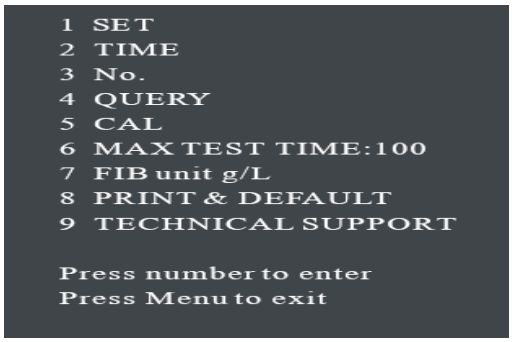


Figure 7

3.4.1 Set

From main menu screen, press 1 to enter the SET screen, on which the low limit and high limit values of test items could be set. Press numeric keys to input desired figures; Press OK to confirm the input. Press Menu key to give up the input and back to the previous menu.

 NOTE: The date must be input completely, including decimal point and after figures.

3.4.2 Time

From main menu screen, press 2 to enter the DATE screen, on which the current date and time could be set. Press numeric keys to input desired figures; Press OK to confirm the input. Press Menu key to give up the input and back to the previous menu.

3.4.3 No.

From main menu screen, press 3 to enter the NO. screen, on which the sample number could be set. Press numeric keys to input desired figures; Press OK to confirm the input. Press Menu key to give up the input and back to the previous menu.

3.4.4 Query

From main menu screen, press 4 to enter the QUERY screen, on which the sample data would be reviewed. From this screen, press 2 to review data downwardly; press 8 to review data upwardly; press 3 to review page down; press 9 to review page up; press 1 to print current screen data; press 0 to print continuous 10 data forwardly. Press Menu key to give up the input and back to the previous menu.

3.4.5 Calibration

a) FIB concentration calibration

Before FIB test, the concentration calibration must be performed using the valuing plasm or calibrated normal plasm. Firstly, dilute the plasm to four different concentrations; secondly, test each concentration at least 10 times, and then calculate the mean values of these four concentrations. Thirdly, input the test values as the following steps.

- From main menu screen, press 5 to enter the CALIBRATION screen with the password of 000000.
- Press numeric key to select FIB calibration, the last lot number will be displayed and input the new calibration lot number at the cursor position, press OK to save it.
- The last calibration data will be displayed on the screen, and input the new calibration data at the cursor position. Press OK to confirm the input. Press Menu key to give up the input and back to the previous menu.

b) Blood coagulation factor calibration

- From main menu screen, press 5 to enter the CALIBRATION screen with the password of 000000.
- Press numeric key to select factor calibration, ten factors of Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ Ⅹ, Ⅺ, Ⅻ, HEP, LMWH will be displayed. Select one factor, THE last lot number will be displayed and input the new calibration lot number at the cursor position, press OK to save it.
- The last calibration data will be displayed on the screen, and input the new calibration data at the cursor position. Press OK to confirm the input. Press Menu key to give up the input and back to the previous menu.

From the calibration screen, press 1 to set the APTT-R and TT-R to be ON or OFF. If it's set to be ON, APTT and TT should be set from SET screen, and their test results will be displayed and print when output.

3.4.6 Max Test Time

Press 6 to set the max test time. Max test time indicates that when the testing time reaches the max value, the analyzer will stop timing no matter whether the sample coagulated or not. Max test time could be set by user between 60 to 999 seconds.

3.4.7 FIB Unit

Press 7 to alternate the FIB unit between "g/L" and "mg/dL".

3.4.8 Print and Default

Press 8 to enter Print and Default screen, from which set the internal printer to be ON or OFF, and reset the analyzer to be factory default.

3.4.9 Technical Support

Press 9 to enter the technical support screen, and user can view the serial port setup and manufacturer information.

3.5 Test Item

Please carefully read this chapter before testing, and ensure all parts needed are available.

a) URIT-600/610 Coagulation Analyzer

b) Reagent

c) Pipettor

d) Ball adding device

e) Test cup (disposable cup)

f) Sample

g) Magnetic ball

Set the test items accordingly before test, and refer to the reagent instruction for more information about sample handling and reagents making and incubating.

3.5.1 Quality Control

Necessary quality control to the measurement system is required to insure the accuracy for counting and analyzing, as well as duly eliminating the system error. So it's recommended to perform quality control with normal and abnormal control everyday. Each lab should establish its own reference values.

User can set the reference value based on various normal human blood.

3.5.2 PT Test

Perform PT test according to the following procedures:

a) Put a magnetic ball in the test cup and inject 50μL sample by pipettor.

b) Incubate the sample.

c) After incubation, add 100μL incubated PT reagent, and press Start key or pipettor switch to start the test.

d) The counter and magnetic mix device will stop when fibrin polymerization and coagulum present. The test is finished and the results will be displayed

on the screen.

3.5.3 APTT Test

Perform APTT test according to the following procedures:

a) Put a magnetic ball in the test cup and inject 50μL sample by pipettor.

b) Inject 50μL APPT reagent into test cup.

c) Incubate the sample.

d) After incubation, inject 50μL incubated $CaCl_2$ reagent and press Start key or pipettor switch to start the test.

e) The counter and magnetic mix device will stop when fibrin polymerization and coagulum present. The test is finished and the results will be displayed on the screen.

3.5.4 TT Test

Perform TT test according to the following procedures:

a) Put a magnetic ball in the test cup and inject 100μL sample.

b) Incubate the sample.

c) After incubation, inject 100μL PT reagent and press Start key or pipettor switch to start the test.

d) The counter and magnetic mix device will stop when fibrin polymerization and coagulum present. The test is finished and the results will be displayed on the screen.

3.5.5 FIB Test

Perform FIB test according to the following procedures:

a) Put a magnetic ball in the test cup and inject 100μL diluted sample.

b) Incubate the sample.

c) Put the cup on the test channel after incubation. Set the test channel correctly, then inject 50μL FIB reagent into cup. Press Start key or pipettor switch to start the test.

d) The counter and magnetic mix device will stop when fibrin polymerization and coagulum present. The test is finished and the results will be displayed on the screen.

⚠ NOTE: “Clauss” method is taken to test FIB value. FIB calibration must be done in the initial use. When changed the reagent lot, the normal and abnormal quality control must be done. If the QC results are unconformity, please make the FIB calibration.

3.5.6 Blood Coagulation Factor Test

For testing blood coagulation factors such as Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ, ProC, ProS, HEP and LMWH, the concentration curve calibration of these test items must be done firstly. Press 2 or 8 to select the desired test item, then select the corresponding reagent and refer to its instruction to calibrate the concentration curve. Chapter 3.4.5 offers more information concerning calibration. After calibration, perform blood coagulation factor test using proper reagent in accordance with its instruction.

3.5.7 Result Report

The test result will be displayed after finishing a sample test, and print the result automatically if the printer is ON. If the test results are abnormal, test the sample again to ensure the results are correct. If there is no magnetic ball in the test cup or the ball is not driven, message of “No ball” will be displayed on the screen.

3.5.8 Concentration Curve Calibration

Refer to chapter 3.4.5 for details.

3.5.9 Sample Collection and Storage

a) Sample collection: collect venous blood into laboratory test tube or vial which contains 1/10 volume of 0.109mol/l natrium citricum anticoagulant (i.e. one volume of venous blood and nine volumes of anticoagulant are mixed). After the sample mixed completely, centrifuge the sample for 15 minutes at 3000rpm. Collect the plasma locating on the upper layer after centrifugation.

b) Sample storage: the sample shelf life is various depending on the storage temperature.

- The sample will be stable for 30 days when stored at－80℃.
- The sample will be stable for 14 days when stored at－20℃.
- The sample will be stable for 6 hours when stored at 2℃~ 8℃.
- The sample will be stable for 2 hours when stored at 22℃~ 24℃.

 NOTE:

a) Please refer to the reagent instruction for details concerning reagent dosage, defreeze, re-dissolve, making and incubation.

b) Take the factors influencing blood coagulation into consideration, please perform testing as soon as possible after sample collection.

Chapter 4 Maintenance

This analyzer is one kind of precise instrument which requires proper maintenance to keep optimum performance. Any accessories damaged or improper operation will affect the analyzer function. If any malfunction occurs, it should be maintained by authorized engineer or contact URIT Service Center.

4.1 Attentions for Maintenance

a) Please carefully read this manual before operating the analyzer.

b) Install the analyzer on a clean, level and firm surface, which is away from direct sunlight, intensive magnetic field and moisture environment. The preceding conditions may cause analyzer malfunction.

c) Please use the proper reagents offered by URIT to ensure the test accuracy.

d) Power supply should meet specific requirements.

e) The analyzer must be well grounded.

f) If the analyzer is not used for a long term, place a plastic or cloth cover on it for protection. Before re-using the analyzer, perform normal and abnormal reference blood simultaneously, and perform quality control with control material to monitor the reference value. These operations could eliminate the interference caused by analyzer components, reagents and abnormal operation.

g) DO NOT disassemble the analyzer by yourself.

h) Keep the analyzer clean and dust-free. Clean the analyzer appearance with toweling or other absorbent material moistened by mild detergent. Wipe the display only with ethyl alcohol, it’s forbidden to use water, ketone and aromatic detergent. Any components of the analyzer cannot be

contaminated by grease, silica gel or lubricant.

i) Keep the magnetic balls away from electromagnet to avoid magnetization. In case of that, DO NOT use the balls.

j) If any malfunction occurs, troubleshoot according to the chapter 5 for details. If the problems are not solved, please contact URIT Service Center.

4.2 Waste Disposal

Please handle and dispose of the waste in accordance with local, state and federal regulation.

4.3 Storage and Transportation

4.3.1 Storage

Store the analyzer in the environmental condition of ventilation, corrosive gas-free, harmful gas-free, and in accordance with following specifications:

a) Environmental temperature: -20℃～55℃

b) Relative Humidity: ≤85%RH

c) Barometric pressure: 75kPa～106kPa

4.3.2 Transportation

Transport the analyzer protecting from impact, keep dry and away from direct sunlight.

Chapter 5 Troubleshooting

This chapter gives instructions for troubleshooting. If a problem is detected, the display will indicate the message. The following table guides users to judge fault condition and take corresponding corrective action. If the malfunction still occurs, please contact URIT Service Center. If the malfunction caused by reagents, please read reagent instruction carefully for problem solution. The troubleshooting personnel should be trained or authorized by URIT.

 WARNING: Electrical Hazard.

Malfunction	Probable Cause	Corrective Action
Nothing displayed on the screen.	a) Power off. b) Circuit malfunction.	a) Check the fuse in analyzer. Ensure the analyzer has connected to the power supply. b) If the malfunction caused by circuit problem, please contact URIT Service Center.
Self-checking error	Analyzer internal memory or IC error.	a) Shutdown the analyzer and check the voltage of power supply. Re-start the analyzer after 30 seconds. b) Analyzer inside RAM/ROM is broken, please contact URIT Service Center.
No ball	a) The ball is not placed in test cup. b) Reagent is insufficient.	a) Ensure the ball placed normally. b) Ensure there is sufficient

Malfunction	Probable Cause	Corrective Action
	c) Other problems.	reagent. c) Check the voltage of power supply, if the problem still occurs, please contact URIT Service Center.
Test results cannot be printed by internal printer.	a) The printer is set to be OFF. b) There is no print paper. c) Printer cable is loose. d) Printer problem.	a) Set the printer to be ON. b) Install new print paper. c) Check the printer cable. d) Please contact URIT Service Center.
Key-press problem	a) Key-press is broken. b) Circuit problem.	a) Shutdown the analyzer and re-start the analyzer after 30 seconds. b) Please contact URIT Service Center.
T:H (the temperature is high)	a) Incubation cell temperature is high. b) Sensor is disabling. c) Circuit problem.	a) Ensure the environment temperature is in the acceptable range. b) Please contact URIT Service Center.

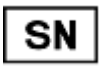
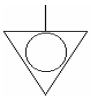
If the following situations present, please contact URIT Service Center for problem solution:

a) The malfunction cannot be solved according to the preceding table.

b) Accessories or components are damaged in operation.

c) Main part of the analyzer is damaged.

Appendix A： Instrument Symbols

	Caution		Biohazard
	Off (Supply)		On (Supply)
	Protect from heat and radioactive sources		In vitro diagnostic medical device
	Manufacturer		Serial number
	Authorized representative in the European Community		Separate collection for electrical and electronic equipment
	European Community		Equipotentiality