OPERATING MANUAL

URIT-800 Chemistry Analyzer



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Copyright and Declaration

Copyright: URIT MEDICAL ELECTRONIC CO., LTD (URIT)

Thank you very much for your purchase of the model URIT-800 chemistry analyzer.

All contents in this manual were strictly compiled according to the related laws and regulations in china, as well as the specific condition of URIT-800 chemistry analyzer, covering all the updated information before printing. The URIT is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notice. Some of the demonstration pictures in this manual are for reference and subject to real object if any differences.

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All instructions must be followed strictly in operation. In no event should URIT be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions outlined herein.

Limitation of Liability

URIT warrants to the original purchaser that this instrument 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 instrument 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.

Caution:

URIT makes no warranties, either express or implied, as to product quality, performance, and value as a commodity or applicability for any particular purpose.

Technical service and troubleshooting are provided by URIT.

If the instrument has malfunction, please contact the agency authorized by URIT.

If the problem cannot be solved through telephone directions, professional technician and sale representative will be sent to offer you timely service.

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Preface

This operating manual is applied to URIT-800 chemistry analyzer. The purpose is to help user know the instrument's principle, structure, operation, maintenance and troubleshooting etc. Please strictly operate the instrument under the instructions described in this manual.

Meanings of Symbols

Caution: Potential human injury or instrument damage.



Warning: Dangerous electric shock



Note: Beware scald



Biologically dangerous



Grounded



Power on



Power off

Precautions:

For safety and efficiency, please read the following safety tips carefully. Any operation against the following precautions may incur system damage or human injury.



Caution:

If user dose not follow the instructions presented in this manual when operating the instrument, the protective measures provided by the system may be failed.

Electric shock due to high voltage



Warning:

When the power supply is on, do not open the cover other than the authorized maintenance man.

If liquid leaks into the instrument, cut off power supply immediately. Improper operation may cause electric shock and system damage.

Eye damage due to light beam



Caution:

When the instrument is active, do not directly look at the light beam emitting from the lamp source, which may cause injury to your eyes.

Skin damage due to chemicals



Biologically dangerous

If chemical adheres to the human body, infection may occur. Do not directly touch the sample, mixed solution and waste solution. Be sure to put on protective gloves, clothes, or even goggles when necessary.

If chemical sticks to the human body, handle it according to the working standard procedure and consult a physician.

Some reagents are strong acid or basic. Please use them carefully and avoid direct contact. If the reagent sticks to hands or clothes, immediately wash it off with water and soap. If the reagent goes into the eyes, wash it off with a lot of water and consult an oculist.

Disposal of waster solution



Biologically dangerous

The discharge and disposal of reagent, control solution, calibration

solution, detergent, and waste solution are regulated by certain standard provisions. Please observe the local discharge standards and consult the reagent supplier or distributor.

Intended use



Caution:

The instrument is mainly employed to quantificationally analyze the serum, plasma, urine and cerebrospinal fluid etc. If the instrument is to be used beyond the intended use, consult URIT first.

When doing clinical diagnosis based on the test result, clinical symptom and other test results should also be considered.

Ambient



Caution:

The instrument should be installed in the ambient specified in the manual; otherwise, inaccurate results or even system damage may occur.

If relocation is necessary, please contact URIT or local representatives.

Usage



Caution:

- (1) Operate the instrument as the operating manual. Improper operation may incur error results or even system damage and human injury.
- (2) For the first use of the instrument, please perform calibration and quality control to confirm the instrument's working order.
- (3) Perform quality control before using the instrument. Otherwise, the results may be inaccurate.
- (4) The instrument's RS-232 port is required to be connected with the computer's RS-232 port, rather than any other cables. Please use the special cable provided by URIT or representatives.
- (5) As a special monitor for the software, the computer installed with any software and hardware other than specified by URIT may cause bad influence on the instrument. Do not run any other software

- when the instrument is active, otherwise, computer virus infection may incur.
- (6) Do no touch the display, mouse and keyboard when your hands are wet or stuck with chemicals.

1 General Description

The URIT-800 chemistry analyzer ("instrument" for short) is a computer-controlled instrument based on the principle of photoelectric colorimetry, integrated with electronics, optics and mechanics. The instrument is intended for use in conjunction with certain reagents to measure a variety of samples, such as serum, urine, cerebrospinal fluid and plasma. Its features are speediness, convenience, high sensitivity, accuracy, standardization and micro-volume, etc.

This software with friendly interface is convenient for operation. User can operate the instrument through clicking the mouse, and export the test results, statistical results and working curves through the external printer.

1.1 Specifications

1.1.1 Technical Specifications

- 1. Light Source: Long-life halogen lamp 6V/10W
- 2. Wavelength Range: 300~800nm
- 3. Assay Method: Endpoint, rate, two-point, dual-wavelength, multi- standard, absorbance, turbidimetry, reagent blank, coefficient, single-point calibration and multi- point calibration, etc.
- 4. Photometric Range: 0~3.0 Abs
- 5. Linearity Error: $\leq 0.5\%$ (within $0.5 \sim 1.8$ Abs)
- 6. Resolution: 0.001Abs; (0.0001Abs for Internal calculation)
- 7. Drift Rate: ≤0.002Abs/20min
- 8. Sample Volume: $200 \,\mu$ L $\sim 3000 \,\mu$ L (variable), $500 \,\mu$ L is recommended
- 9. Cell Temperature: NO(instrument inside temperature), 25° C, 30° C, 37° C. $\pm 0.1^{\circ}$ C
- 10. Carry-over: ≤1%
- 11. Reproducibility: CV≤1.0%
- 12. Item: Up to 200 items
- 13. Memory: Up to 100,000 test results
- 14. Output: Standard data port
- 15. Quality Control: with quality control and statistic procedure, showing QC curves

1.1.2 Power and Ambient

1. Ambient:

Temperature: 10 °C~30 °C

Relative Humidity: ≤80%

Extremity: 5° C \sim 40°C RH \leq 85%; Storage: \sim 20°C \sim 55°C RH \leq 95%

2. Power Supply: (110~240) V, (50~60) Hz

3. Power: ≤100W

4. Atmospheric Pressure: 75kPa~106kPa

5. Dimension: 330 mm by 310mm by 175mm (length by width by height)

6. Weight: About 5.5 Kg

1.2 Principle and Components

1.2.1 Principle

Beer's law:

When a parallel monochrome light beam goes through an absorbent object (gas, liquid or solid), some photons are absorbed and the light intensity decreases from I to Io. The formula is:

$$\lg \frac{I}{I_0} = KLC$$

K: Absorbance coefficient

L: Thickness of object

C: Concentration of object

I: Intensity of shoot-in light

lo: Intensity of shoot-out light

Measure I, lo and L, and then calculate C according to the formula above. The result will be obtained through data conversion. (Figure 1)

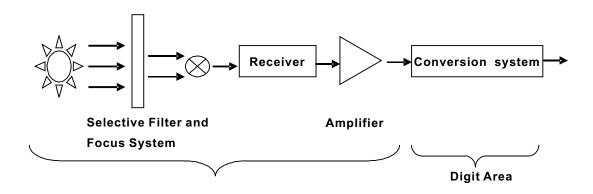


Figure 1

1.2.2 Components

The instrument consists of analyzer, computer and printer (figure 2). The URTI-800 system software monitors and controls the analyzer through the RS-232 port on the computer. Computer and printer are optional accessories.

Computer requirement: CPU over PentiumIII, stable running mainboard with RS-232 port, memory over 256M, and windows XP operation system. All the parts should consist with the relevant safety standards.



Figure 2

The analyzer is composed of sampling system, light path system, liquid circuit system and hardware circuitry. Figure 3 shows the appearance of the analyzer.

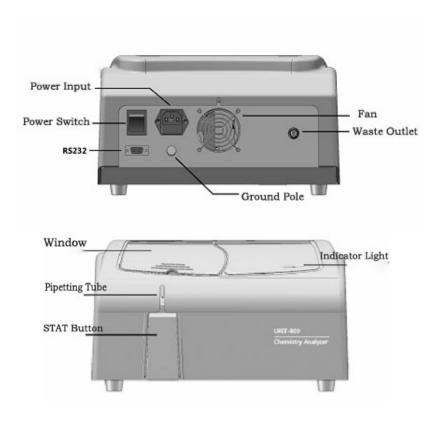


Figure 3

1.3 Functions

- (1) Integrated assay methods: Endpoint, rate, two-point, dual-wavelength, absorbance, etc.
- (2) Proper parameter setup: Reagent blank and distilled water blank are applied to test to ensure the accuracy of test results.
- (3) Credible calculating method: Coefficient, single-point calibration and multi-point calibration, etc.
- (4) Large capacity storage: Up to 200 items and 100,000 test results. Test results, QC data, item standard and item setup are saved in the system database for analysis and statistic.
- (5) Quality control: Perfect QC function for QC data statistic, storage and QC chart drawing.
- (6) Various print formats: Three print formats are selectable: traditional, economical and common.
- (7) Strong search function: Search indexes include: test date, patient's name, doctor, number of outpatient, operator, display all, etc.
- (8) Open reagent: Reagent is optional; user can set up items to be tested as required.
- (9) Data share: External date can be transmitted into the system.
- (10) Modifying results: Patients' information and test results can be modified in flexibility and convenience.
- (11) User-friendly interface: Allows multi-user management. The test results can be summed up and analyzed according to different users' requirement.
- (12) Visually dynamic display: Displays the whole test process and detects the abnormality, such as air bubble disturbance.

2 Installation



Caution:

User shall not attempt installation of this instrument after its delivery. URIT's service representative will install the instrument for its safe and exact operation.

Before installation, User shall make preparations for satisfying the installation requirements in accordance with this manual.

2.1 Unpacking

Please check the carton according to following procedures:

- 1) Carefully unpack the package and take out the URIT-800 chemistry analyzer and accessories.
- 2) Inspect the instrument and accessories for quantity and visible signs of damage according to the standard list.
- 3) If any loss or damage exists, contact the distributor or manufacturer immediately.

2.2 Instrument Installation

2.2.1 Requirement of Installation

Just for room installation and use.

Table-board(or ground) must be level (Gradient \leq 1/200).

Good ventilation.

Free from direct sunshine.

Free from hot source and wind source.

Free from corrosive and flammable gas.

No shake with the table-board (or ground).

Free from noise source and electricity source interference.

Do not be close to the brush-motor and the electric equipment which are often turned on or off.

Height above seal level of the working place should below 3500 meters.

Power supply: 110~240V, (50~60) Hz, three cores cable, well grounded.

A well-grounded power jack is required. The maximum power consumption is 1KVA. The instrument should be connected with exclusive cable, if possible.

The distance between jack and instrument should be less 5 meters.

Temperature range is $10^{\circ}\text{C} \sim 30^{\circ}\text{C}$ with the variation $<\pm 2^{\circ}\text{C}/\text{H}$.

Relevant humility range is $35\%RH\sim80\%RH$, no coagulation .

2.2.2 Procedure of Installation

- (1) Take out the instrument and place it on a level stable worktable. For heat dispersion, the rear of the instrument should keep away from wall or obstacles at least 20 cm. The bottom of the instrument should keep good air circulation.
- (2) Take out the onboard online control cable; connect one of the end to the RS-232 port on the computer, and the other one to the RS-232 port on the instrument. Fix them with screws to avoid looseness and online failure.
- (3) Connect the power cord to the power export port on the rear of the instrument.
- (4) Connect the joint end of the waste tube to the waste outlet, and the other end to the waste flask.
- (5) Before initial running, check the liquid tubes to make sure that they are not bent and the waste solution can be discharged to the proper flask.
- (6) Install the printer as the instructions provided by the printer supplier.
- (7) Before operation, warm up the instrument for 20~30 minutes until the heat and light source are stable.

2.3 Software Installation and Registration

2.3.1 Software Installation

Run the SETUP.EXE on the onboard CD, and execute the operation step by step according to the prompts provided by the system. When the installation has been completed, the shortcut icon of URIT-800 is set up automatically on the desktop by the installer program. then, you can run the URIT-800 through double click.

2.3.2 Software Registration

Run the URIT-800 software and select "Registration" in "Help" menu. The logon screen is displayed. Make your entry for "User Name", which will be showed on the test report as the title. Click the "Device ID" to get the device ID and feed it back to URIT to get the registration ID in return, and then input it in the "Registration ID". That done, click the "Registration" button. Alternatively, our engineer can finish the registration for you.

Note:

The methods of the software installation and registration are subject to

change without prior notice. Please refer to the installation instructions accompanied with the onboard CD.

2.4 Software Online

Turn on the power switch on the instrument. Click twice the URIT-800 icon on the desktop to run the registered software. The initial logon account is: **Operator: user**, **Password: user**. Input the password and click "**OK**". If the input password is correct, the "**OK**" button disappears; otherwise, the "**OK**" button does not disappear and checkup of operator and password is necessary.

Selecting "COM Setup" in "Maintenance", all the COM ports on the computer will be checked by the system automatically. After checkup, a dialog is displayed. Select proper COM and click the "TEST" button. If the buzzer rings, communication is successful. If the buzzer has no response, please select other COM until the communication is successful. After confirmation, click the "SAVE" button.

2.5 Software Initialization

After installation and registration, the software should perform initializing and read the internal instrument data before its normal running.

Selecting "System Initialization" in "Maintenance", the initialization screen is displayed. Select "Temperature parameter initialization" and "Pump parameter initialization" (by placing " \checkmark " mark), and click the "INIT" button. (For initial installation, both should be selected). Then, Reenter the software to achieve initialization for the software.

3 Operation



Caution:

For convenient operation, please refer to the online help when operating the instrument.



Biologically dangerous:

To avoid infection, please put on protective gloves, clothes, and even goggles when necessary.

To avoid unnecessary damage to the instrument resulting from improper operation, please read the operating manual with care prior to operation.

The system offers the convenient shortcuts toolbar that are indicated with icons under the menu bar. The routine work can be performed by clicking the icons in turn from left to right.

3.1 Start-up

- (1) Open the display and host computer.
- (2) Open the analyzer.
- (3) Run URIT-800 chemisty analyzer software and log in the main screen.

3.2 Preparations

- (1) Inspect the waste flask to see whether it is full. If so, dispose the waste solution according to relevant regulations.
- (2) Click the icon of "Rinse Tube" in the shortcut toolbar. The instrument is rinsed one time with distilled water then goes to standby status.
- (3) Click "Instrument Checkup" in "Maintenance" and set proper temperature for the cell (NO [instrument inside temperature], 25 °C、30 °C、37 °C). Default temperature for the cell is 37°C.
- (4) Half an hour later for standby, the light source lamp is expected to be stable and the temperature reaches the expected level.
- (5) Rinse the instrument five times with distilled water.
- (6) Click the icon of "Adjust A/D" in the shortcut toolbar to adjust the instrument automatically. If problem appears, refer to the seventh item in "Troubleshooting".
- (7) Confirm whether the instrument needs to be calibrated. Refer to chapter 5 "QC Analysis and Calibration" for details.

3.3 Setup of Item Parameters

For setup of item parameters, click the icon of "Item Parameters" in the shortcut toolbar. Refer to 4.1.1 for details.

3.4 Setup of Item test

Click the icon of "Item Test" in the shortcut toolbar to enter the item test screen.

3.4.1 Input of Patient Information

3.4.1.1 Edit of Single Item

- (1) Input the sample ID for "Sample ID" (Date, Name, Sex and Age can be input when registering results).
- (2) Select the items to be tested in "Item List". The selected items turn red. (The blue ones indicate individual items, the green ones indicate profiles).
- (3) Click "ADD" to complete the edit.

Return (1) to edit the next patient.

3.4.1.2 Edit of Multiple Items

- (1) Input the starting sample ID for "Sample ID". (Date, Name, Sex and Age can be input when registering results).
- (2) Select the items to be tested in "Item List". The selected items turn red. (The blue ones indicate individual items, the green ones indicate profiles).
- (3) Input the number of multiple items and click "COPY" to complete the edit. Each sample ID will add 1 in turn.

Return (1) to edit the next group of patients.

3.4.2 Test Start

When the patient information has been input, click the "CHECK" button and the test screen is displayed, then click the "TEST" button. When the progress bar of "stable temperature turns into "read time", locate the sample cuvette under the probe and press the START button on the instrument. The instrument will pipette the sample and perform test according to the item parameters that have been set up previously.

If abnormality is detected in the test process and you need to cancel the current test, click the "RETURN" button. A dialog is displayed for confirmation. Click "OK" to cancel the test.

3.5 Registration of Result

After a test has been completed, click the "RETURN" button. Then, click the icon of "Register Results" in the shortcut toolbar. Input the sample ID according to the test report, of which all the test results are displayed. Clicking "Calculated Item", all the items to be calculated are displayed. When a piece of sample information has been registered, click the "SAVE" button then register the next one until all the sample information is input.

3.6 Modification of Result

If the test results show abnormality, click the icon of "Modify Results" in the shortcut toolbar to enter the modification screen. Select the item to be modified and enter the "Modified Factor" calculated by the formula: "Factor=QC target value×QC measured value". Click MODIFY followed by clicking SAVE to complete the modification. To avoid blind modification, some objective factors, e.g., the condition of patient's sample, as well as the QC values tested several days ago should be taken into consideration.

3.7 Recall of Sample

Click the icon of "Recall Samples" in the shortcut toolbar to review desired results. Refer to 4.4.3 for details.

3.8 Help

For any problems and questions in operation, click "Help" to get convenient and detailed help.

3.9 Logout

When you have completed your test, click the icon of "**Logout**" in the shortcut menu. The login screen is displayed again for other users to enter system to manage their own test information conveniently.

3.10 Ending

Please carry out following operation when your work ends.

- (1) Put reagents into icebox.
- (2) Dispose the useless serum cuvette according to relevant regulations.
- (3) Rinse the instrument at least 10 times.
- (4) Click **Exit** in shortcut menu and turn off the instrument.
- (5) Turn off the host computer, display and power supply.
- (6) Wipe the worktable with clean soft cloth.

4 Settings

The software of URIT-800 chemistry analyzer mainly includes five menus: Test Setup, Maintenance, System Setup, Results Processing, and Help. Next are the detailed instructions.

4.1 Setup of Test

4.1.1 Setup of Item Parameters

The first step of item test is to set up item parameters. Proper item parameters can effectively ensure the accuracy of test results. Whatever assay method you take, the essentials include: item name, assay method, wavelength, unit and decimal, blank low, blank high, temperature, sample volume, reagent volume, stable time, measure time, standard low, standard high. When inputting the item name, please replace the "-" with the "_", if any.

Selecting the "Item Parameters", a screen is displayed for setting. The left field indicates the existing items, which are displayed as the order set in "Display and Print Order". When adding a new item, the parameters relating to Endpoint method are indicated as default values.

Setup of parameters

In the screen of item parameters setup, you can set up or modify parameters as required.

(1) Name and Byname

Input the English item name and its byname in "name" and "byname respectively.

(2) Assay Method

The assay methods include: endpoint, rate, two-point, dual-wavelength, etc. clicking the "Method" icon, an optional menu is displayed for selecting assay method.

(3) Wavelength

The main wavelength range is 340nm~800nm. For dual-wavelength method, you can select sub wavelength that also has the range of 340nm ~800nm. Clicking the "Wavelength" icon, an optional menu is displayed for selecting wavelength.

(4) Time

Stable time: the stable time of endpoint and dual-wavelength method is from the sample being pipetted into cell to the test beginning. The stable time of rate and two-point is from the sample being pipetted into cell to the fist point being tested.

Read time: used for rate and two-point method. The time is from the fist point being tested to the last point being tested.

(5) Blank

Reagent and distilled water are selectable as blank mediums.

(6) Volume

Set up volume of reaction solution to be pipetted.

(7) Unit

Set up unit for test result.

(8) Temperature

Selectable temperature: NO(instrument inside temperature), 25°C, 30°C, 37°C.

(9) Others

Set up parameters for reagent as requirement.

Blank L: Blank Low; Blank H: Blank High;

Normal L: Normal Low; Normal H: Normal High

(10) Standard

Standard number (stand. No.): The number of calibration. The Maximum is 6.

Standard factor: The factor is input manually or calculated by system after calibration.

Standard 1~6: Input concentration of calibration item as required.

Clicking the specified key causes the following actions:

ADD: Adds new items to be tested

DELETE: Deletes existing items

SAVE: Saves new added or modified items

PRINT: Prints selected items

RETURN: Returns to welcome screen

4.1.2 Setup of Other Parameters

"Other Parameters" is an extended function through which the items and test results from other instrument can be transmitted into the internal system and printed out with the same format.

Make your entries in the input fields.

Char: If the normal low value is equal to the high value, it means the results will be shown in char type, for example: "+", "-", "positive", "negative", etc.

Float: If the normal low value is lower than the high value, it means the content will be input in float type.

Clicking the specified key causes the following actions:

SAVE: Saves the input information into database

DELETE: Deletes selected information

RETURN: Exits current setup

4.1.3 Setup of Profile

Profile means an independent test name which is shared by some collected items. All the items for option in database are showed in the middle filed; the input profile names are showed in the left field, and the items that belong to a certain profile are showed in the right field.

Input the profile name and click "Add Profile". Then, add desired items to the profile through the function of "ADD" and "DELETE".

Clicking the specified key causes the following actions:

ADD: Adds items to profile

DELETE: Deletes items from profile

Add Profile: Adds profiles

Delete Profile: Deletes profiles RETURN: Exits current setup

4.1.4 Setup of Display and Print Order

For the order of display and print, sequence the targets to be tested, including biochemical items, external items and calculated items.

Clicking the specified key causes the following actions:

ADD: Adds selected items in the left item list to the right order list

INSERT: Inserts selected items in the left item list at the desired position in the right order list

SAVE: Saves sequenced items into system

RETURN: Exits current setup

4.1.5 Setup of Calculated Items

Some items are calculated and the corresponding results are named calculated results, which are of great help for doctors' diagnosis. The calculating aggregation composed of arithmetic function is called calculated item. For example: the formula of calculated item "SIDF" is: TG+UA+EXP(GLU).

For standardization of formula, some arithmetic function are offered by system.

For error avoidance in calculation, please replace the "-" with the "_" when inputting the item name, if any.

Clicking the specified key causes the following actions:

ADD: Adds new calculated items

DELETE: Deletes existing calculated items

SAVE: Saves input data

RETURN: Exits current setup

4.1.6 Setup of QC Target Value

Refer to chapter 5 "QC Analysis and Calibration" for details.

4.1.7 Input of QC Value

When selecting the desired item, the corresponding QC code is shown automatically. Then, you can input the QC code according to date and save the input content into system.

4.1.8 Analysis of QC Chart

Please refer to chapter 5 "QC Analysis and Calibration" for details.

4.1.9 Item Test

The first step of item test is to set up a job list. Clicking "Item Test", the setup screen for item test is displayed. First number the sample ID with the range of "1 \sim 999" (The ID 999 means QC). In the item list, the profiles are indicated with "P:" at the head and shown in white characters on the green background, while the individual items are shown in white character on the blue background.

For editing items, input sample ID, for example: "1", then select the desired items from "Item List", which will turn red. Click "ADD" or "OPY" to add the selected items to the "Pending Item" list.

For modifying the item of a certain sample, select the sample ID and the item to be modified, then click "Evaluate".

For testing the same item for multiple samples, select the item and input the sample number, then click " ${\bf COPY}$ ".

For deleting a sample, select the sample ID, then click "Delete Sample".

For deleting a pending item, select the item, then click "Delete Item".

Upon completion of setup, click "TEST" to enter the test screen. Click "RINSE" to rinse the cell one time. Then, click "START". When the progress bar of "stable temperature" turns into "stable time", place the sample cuvette at the proper position. Press the START button on the instrument, the instrument beginning to pipette sample and perform test automatically.

4.2 Maintenance

The maintenance menu includes following options: COM Setup, Instrument Checkup, Adjust A/D, Rinse Tube, ABS Checkup, Adjust Temperature, Adjust Pump and System Initialization.

4.2.1 COM Setup

Selecting "COM Setup" in "Maintenance", all the COM ports on the computer will be checked by system. After checkup, a dialog is displayed for user to select a COM. Select one and click "TEST", if the buzzer rings, communication is successful. If the buzzer has no response, select another COM until communication is successful. After confirmation, click the SAVE button.

4.2.2 Checkup of Instrument

This function aims at the instrument maintenance and debugging. Input the parameters according to prompts in the operation process, and select "TEST" to validate.

The current temperature of the cell is displayed by system, with the selectable temperature: NO(instrument inside temperature), 25° , 30° , 37° .

The A/D value of current filter can be obtained by setting up the gain.

The peristaltic pump's move step and rate is settable to adjust the pipetted volume each time. The factory parameter is $500\,\mu$ L at a time. If volume adjustment is necessary, make sure the liquid fills the cell fully and overflows the cell exit about 10cm without air bubble between.

The number of filter and the diameter of cell are settable.

The status of START button can be checked.

When done, click the "SAVE" button.

4.2.3 Adjustment of Initial A/D

The A/D value of each instrument has been adjusted in factory testing. The gain, A/D and offset value vary with different filters. Generally, when the gain is 3 or 4, the initial A/D value is about 34000, the offset value is within 70~130 (never 0), which are the optimum initial values for checking system.

Click "Adjust A/D" to enter the screen of initial A/D value. Click "SAMPLE" to fill the cell with distilled water prior to adjustment.

Clicking "ADJUST", the gain and offset of different wavelengths are adjusted by system. After adjustment, the buzzer rings and the adjusted results are saved automatically as reference values for the sequent tests.

It is recommended to adjust the initial A/D value under following conditions:

When installing instrument or replacing computer.

When operating the instrument after a long-distance shipping.

When replacing a halogen lamp.

When replacing a cell.

When filter has deteriorated.

Whenever test results show abnormal fluctuation.

4.2.4 Rinse Tube

Carrying out tube rinse can clean the tubes and cell, and keep the cell humid. Click "tube rinse" to enter the screen of tube rinse.

Input the rinse times and click the "RINSE" button to start rinsing automatically.

It is recommended to rinse tubes under following conditions:

At the start of the day's run.

At the end of the day's run.

After testing high concentration solution.

A long time for disuse.

The initial A/D value is abnormal.



Caution:

For the air bubble or foreign body that is difficult to wash off in the cell, try to rinse it with absolute alcohol or detergent recommended by URIT.

4.2.5 Checkup of ABS

In the Abs checkup dialog, you can check any filters in the left wavelength list, and quickly analyze the liquid of different absorbance.

Clicking the specified key causes following actions:

SAMPLE: Pipettes solution to be tested in the cell

ZERO: Zeros the ABS of current solution

RETURN: Exits current screen

4.2.6 Temperature Adjustment

This function is just for factory testing, only open to URIT technicians or technicians authorized by URIT.

4.2.7 Pump Adjustment

This function is just for factory testing, only open to URIT technicians or technicians authorized by URIT.

4.2.8 System Initialization

After installation and registration, the software must perform initializing and read internal data prior to normal running.

For initialization, select "Temperature parameter initialization" and "Pump parameter initialization" to initialize. That done, that is, the software has read out the default parameters, reenter the software as requirement to complete the initialization.

Note:

For initial installation, both two items should be selected for initialization.

4.3 Setup of System

The menu of system setup includes following items: Operator Password, Doctor, Department, Operator and Chart Color.

4.3.1 Setup of Operator Password

Click "Operator Password" in "System Setup" to set up or modify the password.

When initially inputting the user name, you can set up the corresponding password through this function. If the password has existed, it will be shown in the "old password". After modification, the new password will be saved as the operator password for the sequent login.

4.3.2 Setup of Doctor

The doctors can be denoted with codes or names, depending on the requirement of lab.

4.3.3 Setup of Department

The departments can be denoted with codes or names, depending on the requirement of lab.

4.3.4 Setup of Operator

The operators can be denoted with codes or names, depending on the requirement of lab.

4.3.5 Setup of Chart Color

You can set up your favorite colors for charts.

Default chart colors provided by system can also be customized as required. The changed colors are valid only after saved.

4.4 Processing of Results

The menu of result processing includes following items: Modify Results, Register Results and Recall Results.

4.4.1 Modify Results

Refer to 3.6 for details.

4.4.2 Register Results

Refer to 3.5 for details.

4.4.3 Recall Results

Click "Recall Results" to review the tested sample information. Select one search method: "date", "item", "doctor", "outpatient no", "operator" or "all", and click "SEARCH". The desired records will be shown in the patient information list.

Print: Prints the records selected from the "Patient Information List".

4.5 Help

The help menu includes three submenus: "Help", "Registration" and "About Software".

4.5.1 Help

If you have any problems in operation, click "help" to obtain details.

4.5.2 Registration

Input user's name and registration ID to complete registration for the software.

4.5.3 About Software

You can find the copyright number and registration information about this software here.

5 QC Analysis and Calibration

5.1 General

The meanings of reliability about test results have two aspects: one is high precision, i.e. the good repeatability of test results, which mainly aims at eliminating or minimizing the influence caused by random error and depends on the perfect room QC system to guarantee. The other one is accuracy, i.e. the test results are correct and close to the true values, which mainly aims at eliminating or minimizing the influence caused by system error and depends on the proper assay method and correct calibration to guarantee. Therefore, it is necessary to strictly select certified control sample and calibration solution, and use them according to their instructions.

5.2 QC and QC Procedure

The control sample is just used together with the sample to be tested. To minimize the test error, it is required to keep the control sample stable in storage.

5.2.1 Class of Control Sample

Mixed serum, freeze-dried and liquid control sample, classified by the different physical properties of control samples.

Fixed value and non-fixed value control sample, classified by the presence / absence of measurement value.

You can select one kind of control sample above as the room control sample as required.

5.2.2 Usage and Storage

Strictly use control sample according to the instructions provided by the supplier.

Make sure the high quality of the solution redissolved from freeze-dried control sample.

Make sure the added volume is accurate and consistent each time redissolving the freeze-dried control sample.

Fierce shake is avoided by all means when redissolving the freeze-dried control sample.

Store the control sample according to requirement; do not use the expired products.

Test the control sample at the same condition as that of the patient sample.

5.2.3 Setup of QC Target and Control Limit

The QC target and control limit value can be obtained from the control sample manufacturer or from following methods:

Setup of temporary target value: Test a new set of control sample. Obtain the results of at lest 20 control tests, and calculate their mean value and standard deviation (SD) as the temporary target value and temporary SD respectively.

Setup of regular target value: Obtain the accumulative mean values of the original 20 data and all the tested data collected for 3~5 months as the regular value and SD respectively.

Setup of control limit: The new set of control sample is required to fix the control limit that is usually denoted with some SD, i.e. denoted with the multiple of SD. The control limit of different items (quantitative test) depends on their QC regulations.

5.2.4 QC Procedure

In "Item Test", if you input "999" for "Sample ID", the code of the current control sample is required and the relevant QC results will be saved to database for control analysis.

5.3 Analysis of QC Results

5.3.1 Input of QC Target and Standard Deviation

Select "QC Target Setup" in "Test Setup", and input the QC code as well as the target and SD that obtained before.

5.3.2 Analysis of QC Chart

Select "QC Chart Analysis".

In the QC chart dialog, the red line marks the target value, while the blue lines mark ± 1 SD $_{\sim} \pm 2$ SD $_{\sim} \pm 4$ SD. Select the items from "item List", and make your entries in "QC Code" and "Test Date" respectively. The system will draw the QC curves in this period automatically. If you select the "Standard Qc" (by placing $\sqrt{\ }$ mark), the target value and SD are just those set in "5.3.1"; Otherwise, the system will recalculate the target value and SD of this period and draw the QC curves.

5.3.3 Normal Distribution

About 95% data are within $X \pm 2s$.

5 continuous data in the same side are not allowed.

5 continuous data step-up or step-down are not allowed.

2 continuous points outside $X\pm2S$ are not allowed.

Points outside X±2S are not allowed.

5.3.4 Abnormality

Drift: System error is prompted.

Tendency change: The capability of reagent or instrument has been changed.

Precision change: Accidental error is large, e.g. the instrument or reagent shows

instability.

5.4 Treatments for Abnormality

For abnormality, carry out following procedures to deal with.

Fill in abnormality report and report it to your lab manager.

Simply and quickly review the operation process to find out the possible cause.

If no evident error is found, follow the steps below to find out the cause.

- (1) Retest the same control sample. This step is mainly for checking whether operator caused the error. Additionally, this step can also check out whether the random error existed. If so, the retested results should be within the allowable rang (control limit). If not, proceed to the next step.
- (2) Obtain a new bottle of control sample to retest the abnormal items. If the retested results are within the allowable range, it means the previous bottle of control sample has expired or deteriorated as being laid aside for a long time. If not, proceed to the next step.
- (3) Obtain a new set of control sample to retest the abnormal items. If the retested results are within the allowable range, it means the previous set of control sample has problem. Then, Inspect the expiration date and storage ambient to find out the cause. If not, proceed to the next step.
- (4) Maintain the instrument and retest the abnormal items. Inspect the instrument for replacement of filter and cleanness of cell. If the retested results are not within the allowable range, proceed to the next step.
- (5) Recalibrate the instrument and retest the abnormal items. Perform calibration with the new calibration solution. If the retested results are not within the allowable range yet, proceed to the next step.
- (6) Obtain help from technician. If the test results are not within the allowable range yet after completing the five steps above, the instrument or reagent may be to blame. Contact URIT or reagent supplier to get more technical help.

5.5 Calibration and Procedure

Calibration sample is used to calibrate the numerical value of the assay method. The function is to eliminate or minimize the system error caused by instrument or reagent. It is recommended that human serum matrix be employed to minimize the error caused from matrix effect.

5.5.1 When to Calibrate

It is suggested to perform calibration every six months or under the below situations:

When installing and running the instrument initially.

When changing the reagent class or the batch number, unless otherwise specified.

When carrying out a protective maintenance or replace a essential component, which may influence the capability of the instrument.

When the QC results reflect abnormality, which cannot be rectified through general corrective measures.

5.5.2 Procedure of Calibration

Select the items to be calibrated in "Item Parameter", and input the numerical value offered by the supplier, then click the SAVE button. The system will perform calibration for this item prior to test, process the calibration result and save it as standard reference for the item to be tested next time.

All the calibration and validation work are required to be recorded and compiled into document. It is must be emphasized that the fixed-value serum should not be used as calibration sample because of the huge difference between.

6 Reagent, Sample and Waste

6.1 Reagent

The reagent parameters are settable for the URIT-800 chemistry analyzer.

Only the certified reagents can be used to test.

Carefully read the instructions provided by reagent supplier before using it.

6.2 Detergent

The detergent that the instrument employs is open for choosing.

6.3 Precautions

When carrying out test and daily maintenance, be sure to obey the operation regulations, put on protective gloves, clothes and goggles, and avoid contacting the sample.

All the clinic samples should be handled according to the operation regulations, as they may carry potential infectious disease. Put on protective clothes, gloves and eyeglasses. No smoking and eating in working area. Do not blow or suck the tubes.

Carefully dispose the wastes as they may carry potential contaminations and cause biologic and chemical hazard. Obey the relevant regulations constituted by local Medical and Health Administration to dispose and drain the waste solution.

Store reagents according to the instructions offered by reagent supplier. User has the obligation to establish measures for reagent keeping and use, thus avoiding using expired reagents. Storage should keep away from excessive hot or cold environment.

7 Maintenance

To ensure reliable capability and prolong the instrument's life, perform periodical maintenance for the instrument according to the operating manual.

For the problems cannot be solved or not be involved in this chapter, please contact URIT or the local representatives.



Caution:

Do not perform any maintenance other than specified in this chapter; otherwise, human injury and instrument damage may occur.

The unauthorized maintenance for instrument may cause system damage and human injury, and invalidate the terms of maintenance service stated in contract.

After maintenance, make sure the system is working in order.

Most maintenance is carried out with the instrument power off. For your safety, the main power supply sometimes is required to be cut off prior to maintenance.

Free of spills of water, reagent, etc. on the instrument and electric units.



Biological dangerous:

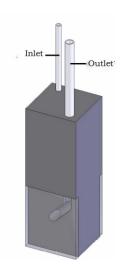
Be sure to put on protective clothes, gloves, and even goggles when necessary before maintenance.

7.1 Cell

The precisely designed flow cell with a stainless steel quartz window, can keep an accurate heat balance inside. The temperature in the cell is controlled by Peltier element. The inlet is narrow and close to light source while the outlet is a little wider (figure 4).

For replacement of the cell, first drain off the liquid in the cell and flow path. Then, press the cell with one hand, and take out the tubes of inlet and outlet with the other hand. Finally loosen the fixed clip on the cell and take out the cell from the cell hole.

For installation of the cell, properly embed the cell in the hole, and fix it with the fixed clip. Then, connect the tubes back to the corresponding inlet and outlet respectively.



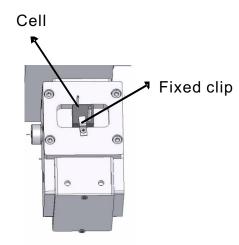


Figure 4



Caution:

For cleanliness of the cell, do not touch the quartz window on the cell. After each testing, rinse the flow cell and fill it with water before turning off the instrument.

Rinse the cell with detergent once a week. Aspirate detergent 2 milliliters, and keep it in the cell for 5 minutes, then aspirate distilled water 20 milliliters to wash off.



Biological Dangerous

To avoid infections, be sure to put on protective clothes, gloves and even goggles when necessary.

7.2 Peristaltic Pump

The peristaltic pump is an essential part for liquid entering and draining. The pump pipe is made of special silica gel. When the error of pipetted volume is large or the pipetting fails, replace the silica gel pipe with a new one in the same model (figure 5). The steps for replacement are as follows:

- (1) Drain off the liquid in the flow path, open the maintenance window on the left side of the instrument, and take out the tubes connected with the pump.
- (2) Forcibly nip the two clamps on the pump base with your thumb and index finger, and then take out the pump from the base.
- (3) Forcibly nip the two clamps on the upper cover of the pump with your thumb and index finger, and then take out the lower cover.
- (4) Take down the wore pump pipe from the upper cover, then take down the two closing rings from the wore pipe and clip them in the new pipe.

- (5) Push the new pipe into the interspace between the rotating wheel and the inner wall of the upper cover. Hold down the two closing rings to clip the outlet of the upper cover, with the opening upward.
- (6) Join the upper cover with the lower cover. Forcibly press until the covers join with each other totally.
- (7) Aim the center of the pump at the motor shaft, and press the pump until it is set on the base.
- (8) Connect the tubes back to the pump.

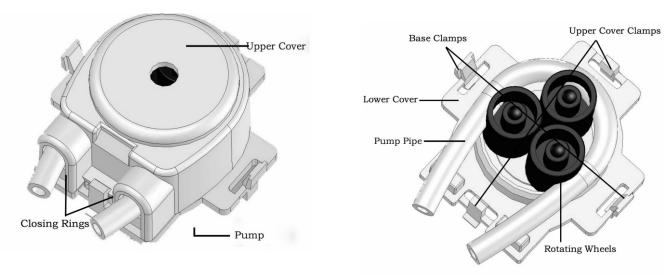


Figure 5

7.3 Cleanliness

7.3.1 Daily Maintenance

Perform rinse 10~15 times after turning on the instrument and 10~20 times before turning off the instrument.

Wash the waste flask.



Biological dangerous

To avoid infection, be sure to put on protective clothes, gloves and even goggles when necessary.

7.3.2 Weekly Maintenance

Using detergent contains active enzyme, soak the cell for certain time. (Note: do not soak a long time if the detergent is strong caustic.) Then, rinse the cell with

distilled water several times. The detergent that soaks the cell can be pipetted through the setting of "pipette" in "Abs checkup".

Perform rinse 10~15 times with absolute alcohol.

Shut off the power supply, and then wipe the appearance of the instrument with clean gauze, or gauze moistened with water or disinfector when necessary.



Caution:

Be sure to operate the instrument with care, avoiding being lacerated by the instrument shell.



Biological dangerous

To avoid infection, be sure to put on protective clothes, gloves and even goggles when necessary.

Do not discard the used gauze at will after wiping the instrument. Dispose it as per the relevant regulations.

7.3.3 Monthly Maintenance

The operation is as weekly maintenance.

Inspect the cell for air bubble and foreign bodies.

7.4 Precautions for Usage

- (1) Free from dust and moist. Air conditioner is recommended. The optimum ambient temperature is 15~25℃.
- (2) Free from electric leakage and static electricity. Make sure the instrument is well grounded. For the absence of earth wire on the power socket, the ground pole outside the instrument should be grounded to ensure safety and stability.
- (3) It is suggested that the power socket be for instrument exclusive use.
- (4) Be sure to use certified reagents.
- (5) Reagents taken out from icebox should not be used immediately until they reach the room temperature.
- (6) To avoid confusion, different samples should be registered with different codes,
- (7) After turning on the instrument and computer, execute "Tube Rinse" and wait for half an hour prior to routine test.
- (8) After work, execute "Rinse Tube" several times.
- (9) Do not perform any other irrelevant operation with the computer lest virus intrude and cause damage to the system.

8 Troubleshooting



Caution:

Be careful to handle with malfunctions, be sure to shut off the power supply before operation.



Biological dangerous

Be sure to put on protective clothes, gloves, and even goggles when necessary before operation.

Troubleshooting is presented in this chapter. If the malfunctions cannot be eliminated as per the instructions specified in this chapter, or if you need more and detailed materials, please contact URIT.

8.1 Troubleshooting Directions

Troubleshooting directions are designed to help user search and eliminate the malfunctions in the operation, and also offer the ways to obtain timely and convenient technical help from URIT.

For correct and quick troubleshooting, read through the operating manual carefully and be familiar with the operation and maintenance measures.

In general, troubleshooting can be followed as three steps below:

Confirming malfunction

Classing malfunction

Eliminating malfunction

The first step: confirming malfunction

You should find out what cause the malfunction, and know what the instrument should be when in order. This step is essential to eliminate malfunction.

The second step: classing malfunction

The instrument malfunction can be classed into three categories:

Malfunction relating to hardware

Malfunction relating to software

Malfunction relating to sample analysis

The malfunction relating to hardware and software only can be solved by URIT or the qualified engineer authorized by URIT. The malfunction relating to sample analysis can be eliminated by operator himself under the instructions from URIT.

The third step: eliminating malfunction

The maintenance engineer takes proper methods and procedures to get rid of malfunction. If the operator can eliminate it with the help of engineer, the delay is shortened much more.

8.2 Obtaining Technical Help

The common malfunction and troubleshooting are listed below. If the problem cannot be solved with the methods described in the list, or if you need more technical help, contact URIT.

NO	Symptom	Symptom Possible Cause	
1	Failed online.	A.The COM cable is loose. B.Improper COM.	A.Fasten the cable. B.Select a proper COM. C.If the problem recurs, please contact URIT.
2	Turning on the power supply, the fan and lamp don't work.	Defective fuse.	A.Replace the fuse (T 0.8Adelay fuse). B.If the problem recurs, please contact URIT.
3	Turning on the power supply, the fan works while the lamp doesn't.	Broken lamp.	Please contact URIT.
4	Pressing the START button, no liquid is aspirated.	A.The pump is not installed well. B.The pump has deteriorated or cracked. C.Improper parameter set for the pump. D.Failed online.	A.Reinstall the pump. B.Replace the pump. C.Reset up parameter for the pump. D.Press 1 to check up. E.If the problem recurs, please contact URIT.

5	No water runs out when performing rinse.	A.Leakage with tubes. B.The pump has. deteriorated or cracked.	A.Check up the leakage and reconnect the tubes. B.Replace the pump. C.If the problem recurs, please contact URIT.
6	The analyzer has no response to the directive from computer. The working indicator lamp is unlighted.	A.The COM cable is too long. B.The COM cable is not connected well. C.Strong electromagnetic interference nearby.	A.Use the onboard cable. B.Fasten the cable. C.Remove the high- power equipment. D.If the problem recurs, please contact URIT.
7	Failed A/Dadjustment.	A.The lamp is broken. B.Air bubble or insufficient water in the cell. C.Dirty cell.	A.Please contact URIT. B.Drain off the liquid in the cell and repipette liquid to adjust. If unfruitful, reset up parameter for the pump C.Rinse the cell with detergent or absolute alcohol several times. D.If the problem recurs, contact URIT.
8	Inaccurate test results or poor repeatability.	A.Air bubble is the cell. B.The silica get pipe has deteriorated or cracked resulting in inaccurate pipetteed volume. C. Ageing with the light source lamp. D.Improper parameter set for item test. E.Absence of earth wire with the power supply.	A.reset the parameter for the pump. B.Replace silica get pipe for the pump. C.Readjust the initial A/D. D.Reset item parameter according to the reagent instructions. E.Ground the instrument with the onboard ground pole. F. If the problem recurs, contact URIT.

9 Transportation and Storage

9.1 Transportation

The transportation must strictly follow the terms specified in order contact. Mixed transportation with poison, injurant and corrosive is forbidden.

9.2 Storage

Appendix A Replaceable Parts List

No	Item	Remark
1	Fuse	T800MA/250V (Power input is 220V)
1	1 430	T1A/125V (Power input is 110V)
2	Switching power supply	
3	Powerswitch	
4	Power supply filter	
5	Step motor	With plug
6	DC motor	With plug
7	Power cord Power cord	
8	Online control cable	
9	Mainboard	
10	Amplifier board	
11	Pump pipe	
12	Pump	
13	Cell	
14	Key-press	With plug
15	Fan	
16	Filter	300~800nm
17	Halogen lamp	6V 10W
18	Temperature sensor	With plug
19	Peltier	With plug

Appendix B Print Styles

Traditional

URIT MEDICAL

Name: M Sex:Male Age: 30	ike		Outpatient Inpatient N Departme		cine	7	Sample	ample ID:001 Type: serum ate:2007-08-11
No.	Item	Byname	Result	Prompt	Unit	Refere	nce(L	-H)
1	ALP		0.48	L	mg/l	1.00-3.0	00	
2	AST		0.70	L	mg/dl	1.00-3.0	00	
3	AKP		2.0	L		40.0	-	120.0
4	GOT		0.5	L	U/L	9.1	-	49.0
5 TP 0.2 L g/L 61.0					-	83.0		
Report Date:2	Report Date:2007-08-11			Operator: 00	1		Che	ecker:

Remark: The results are only responsible for the current sample.

Economical

			URIT MEDICAL			Sar	nple ID:001
Nam	ne: Mike		Outpatient No.: 00	1		Sample Type: Serui	m
Sex	Male		Inpatient No.:			Test Date:2007-08-	11
Age	30		Department: interna	al medicine		Doctor: Lee	
No.	Item	Result	Reference(L-H)	No.	Item	Result	Reference
1	ALP	0.48 L	1.00-3.00 mg/l				
2	10000						

No.	Item	Result	Reference(L-H)	No.	Item	Result	Reference(L-H)
1	ALP	0.48 L	1.00-3.00 mg/l				
2	AST	0.70 L	1.00-3.00 mg/dl				
3	AKP	2.0 L	40.0-120.0				
4	GOT	0.5 L	9.1-49.0 U/L				
5	TP	0.2 L	61.0-83.0 g/L				

Report Date:2007-08-11 Checker: Operator: 001

Remark: The results are only responsible for the current sample.

Common

URIT MEDICAL Sample ID:001 Name: Mike No. Item Byname Result **Prompt** Unit Reference(L-H) Sex:Male 1 ALP 0.48 L 1.00 - 3.00 mg/l 1.00 - 3.00 **Age:** 30 0.70 2 L AST mg/dl Outpatient No.: 001 3 AKP 2.0 L 40.0 - 120.0 Inpatient No.: 4 GOT 0.5 L U/L 9.1 - 49.0 0.2 61.0 - 83.0 TP L g/L Sample Type: serum **Department:** internal medicine Doctor: Lee Test Date:2007-08-11 Report Date:2007-08-11 Operator: 001 Checker:

Remark: The results are only responsible for the current sample.





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