

# OPERATING MANUAL

## PKL PPC110 Chemistry Analyzer

Paramedical srl

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# Copyright and Declaration

Copyright : Paramedical srl

Thank you very much for your purchase of the PKL PPC110 chemistry analyzer.

All contents in this manual were strictly compiled according to the related laws and regulations in Italy, as well as the specific condition of PKL PPC110 chemistry analyzer, covering all the updated information before printing. Paramedical 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.

All the information included is protected by copyright. No any part of this document may be reproduced, stored or transmitted in any form, or by any means unless written authorization by Paramedical.

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

## Limitation of Liability

Paramedical 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.

Paramedical 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 Paramedical.
3. Failure due to operate not under the instructions described in the manual.
4. Replace accessories not specified by Paramedical, or after maintenance or repair by a service agent not approved or authorized by Paramedical.

### NOTE:

Paramedical 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 Paramedical.

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

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 document is the operating manual for PKL PPC110 Chemistry Analyzer. It describes in detail the structure, operation, maintenance and troubleshooting concerning the instrument. User should operate the instrument following the instructions in this manual.

## Markings

	Danger! High voltage		Power off
	Burn		Power on
	Caution		Grounded
	Biological Hazard		Recovery
	In vitro diagnostic		Serial number
	Manufacturer		
	Protect from heat and radioactive sources		
	Authorized representative in European Community		

## Safety Guidelines

Before using the instrument, be sure to read the precautions below. If they are neglected, human injury or instrument damage may be caused.



### CAUTION

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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.

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### Preventing electric shock



### CAUTION

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When the power supply is on, DO NOT open the instrument cover other than the authorized maintenance man.

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

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### Preventing eye injury



### CAUTION

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

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### Preventing chemical injury



### Biological Hazard

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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.

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 eyes accidentally, wash it off with water and consult an oculist.

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## Disposing waste solution



### Biological Hazard

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Discharge and disposal of reagent, control solution, calibration solution, detergent, and waste solution are regulated by certain standard provisions. Please observe the local regulation to discard waste or consult the reagent supplier or distributor.

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## Intended use



### CAUTION

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The instrument is mainly intended for quantitatively measuring the serum, plasma, urine and cerebrospinal fluid etc. If the instrument is to be used beyond this scope, consult Paramedical first.

Take clinical symptoms and other test results into consideration before making any clinical determinations.

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## Installation



### CAUTION

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Installation not complying with the specified requirement in this manual will cause erroneous test result or even damage to the instrument.

If relocation is necessary, contact Paramedical or your local distributor firstly.

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## Usage



### CAUTION

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- 1) Failing to operate the instrument as the instructions presented in the operating manual will cause erroneous result, or even damage to the instrument and injury to the operator.
  - 2) For the first time using the instrument, perform calibration and control tests before sample analyses.
  - 3) Control test should be done before sample analyses, or else, inexactly results may occur.
  - 4) Use the special connecting cable provided by Paramedical to connect the instrument with computer. Do not pull out the connecting cable before cutting off the power .
  - 5) DO NOT touch the LCD or keypad with wet or chemical-stuck hands.
-

# 1 General Description

The PKL PPC110 chemistry analyzer“ ( instrument for short) is intended for use in conjunction with certain reagents to quantitatively perform chemistry and immunology tests on a variety of clinical samples, such as serum, urine, cerebrospinal fluid and plasma. The instrument is only for professional, in vitro use in hospitals, clinics, and laboratories.

## 1.1 Capability

- ▼ Various assay methods: Endpoint, kinetics, two-point, dual-wavelength, absorbance, etc.
- ▼ Optional calculation methods: Reagent blank or sample blank is settable. Calculation methods include factor, single-point calibration and multi-point calibration, etc.
- ▼ Data bank: Test results, item parameters and item settings are stored in the memory permanently for further analysis and statistics.
- ▼ Powerful software: Item parameters are user-defined and can be saved permanently.
- ▼ User-friendly interface: Menu-led operation. All information, such as operating prompts, status indications, QC calculation, test results, etc., is displayed on the LCD. Data can be exported through the internal printer or via the RS 232 and parallel interfaces.
- ▼ Computer control: Computer control is available through relevant software.

## 1.2 Structure

The instrument is mainly composed of sampling system, cell system, MCU system, temperature control system, LCD, printer, and keypad, etc.

- ▼ Sampling system: Aspirates sample into cell and drains waste into waste bottle.
- ▼ Cell system: Includes light source, filter, cell, light signal sensor etc. Light signal is transformed into electric signal here.
- ▼ MCU system: Collects system signals, processes data, and controls light signals and temperature, etc.
- ▼ Temperature control system: Controls the temperature in the cell.
- ▼ LCD: Displays test results and operating information.
- ▼ Printer: Prints test results.
- ▼ keypad: Interaction tool for entering data and commands.

## 1.3 Specifications

- 1) Light Source: Halogen lamp, 6V/10W
- 2) Wavelengths: 300nm~800nm
- 3) Assay Methods: Endpoint, absorbance, kinetic, two-point, dual-wavelength, etc.
- 4) Measuring Range:  $-0.3\sim 3.0$  Abs
- 5) Resolution: 0.001 Abs (Display) , 0.0001 Abs (Internal calculation)
- 6) Drift:  $\leq 0.003$  Abs/20min
- 7) Flow Cell: 32  $\mu$  L quartz cell; Optical path: 10mm
- 8) Sampling Volume: 100  $\mu$  L~9999  $\mu$  L (auto-compensation), 500  $\mu$  L is recommended
- 9) Temperature Control: Room, 25°C; 30°C; 37°C;  $\pm 0.1$  °C
- 10) Cross-contamination:  $\leq 1\%$
- 11) Repeatability: CV  $\leq 1.0\%$
- 12) Memory: 0~999sec, variable
- 13) Memory: Up to 320 items and 20,000 test results
- 14) Export: Standard RS232 interface and parallel interface(LPT)
- 15) Software: The system management software includes control and statistic program, which can display item curves and control curves, and print the latter.
- 16) Power Dissipation: 130VA
- 17) Dimension: 392mm×375mm×205mm (length \* width \* height)
- 18) Weight: About 7.7Kg
- 19) Insulation Limit for External Circuit:  $\leq 0.1 \Omega$  (under single-fault condition)
- 20) Ambient:
  - Extreme Temperature: 5°C~40°C
  - Recommended Temperature: 10°C~30°C
  - RH:  $\leq 80\%$
- 21) Power Supply: AC 100~240V, 50/60Hz
- 22) Atmospheric Pressure: 75kPa~106kPa

## 1.4 Principle and Appearance

### 1.4.1 Principle

Beer's law:

When a parallel monochrome light beam goes through an light-absorbent object (gas, liquid or solid), some photons are absorbed and the light intensity decreases from  $I_0$  to  $I$ . The formula is:

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

K: Absorbance coefficient

L: Thickness of object

C: Concentration of object

$I_0$ : Intensity of shoot-in light

I: Intensity of shoot-out light

Measure  $I$ ,  $I_0$  and  $L$ , and then calculate  $C$  according to the formula above. Data conversion is outlined as below (Figure1):

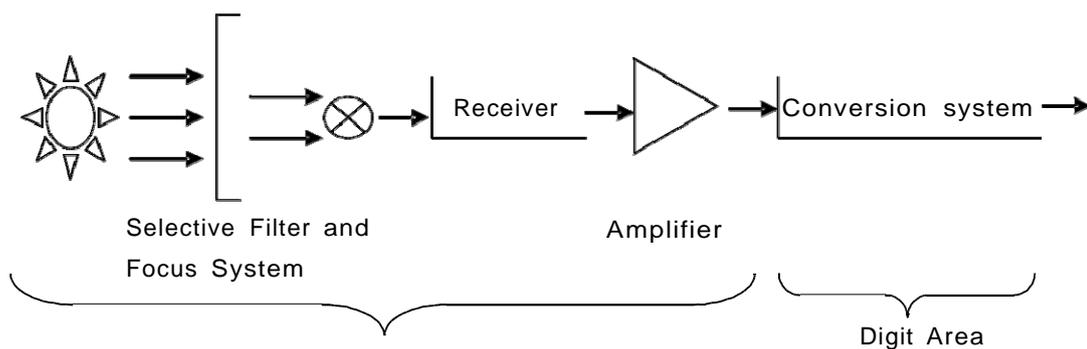


Figure 1

### 1.4.2 Appearance

Figure 2 and Figure 3 show the appearance of the instrument, front and rear.

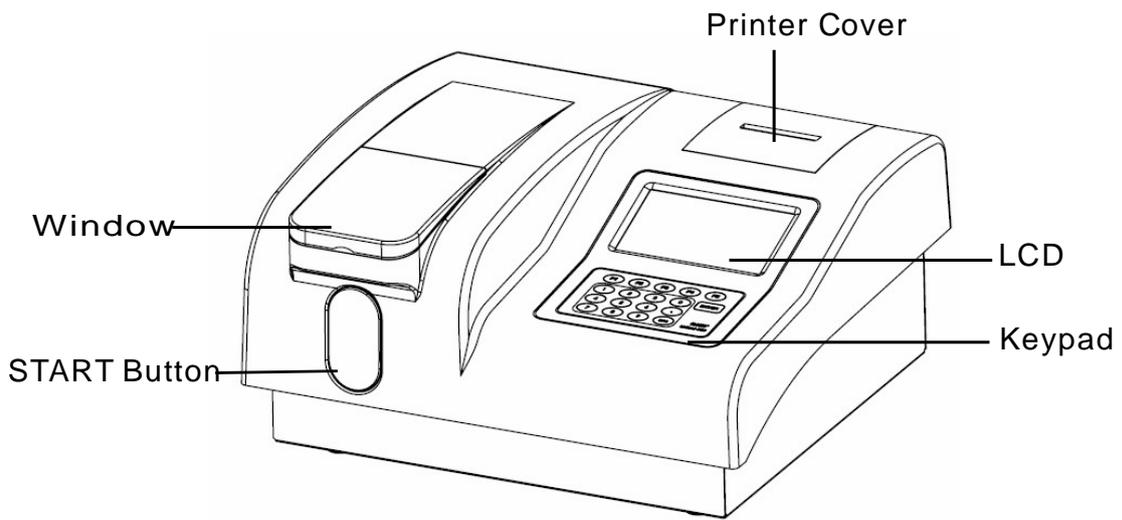


Figure 2

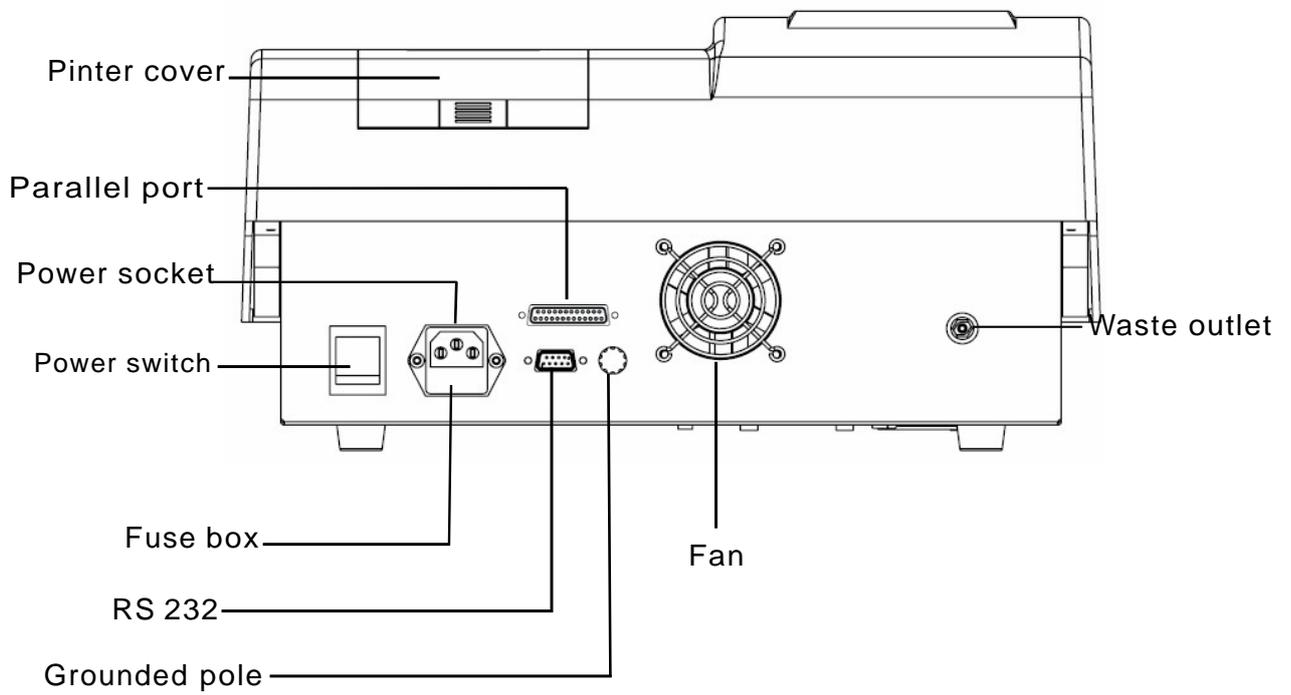


Figure 3

## 2 Unpacking and Installation



### CAUTION

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User shall not attempt installation of this instrument after its delivery. The 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.

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### 2.1 Unpacking

Please check the carton according to the following procedures:

- 1) Carefully unpack the package and take out the PKL PPC110 Chemistry Analyzer and the accessories.
- 2) Inspect the instrument and accessories for quantity and visible signs of damage according to the accompanying Packing List.
- 3) If any loss or damage exists, contact the distributor or manufacturer immediately.

### 2.2 Installation

#### 2.2.1 Requirements of installation

- 1) Only for room installation and use.
- 2) Worktable must be level, with gradient less than 1/200.
- 3) Good ventilation for the room.
- 4) Free from direct sunlight and dust.
- 5) Free from corrosive and flammable gas.
- 6) Free from hot and wind source.
- 7) No shake with the worktable.
- 8) Free from strong noise and electricity interference.
- 9) Keep away from brush-motor and the electric equipment that are turned on or off frequently.
- 10) Keep away from electromagnetic wave equipments, such as mobile phone, wireless transceiver, etc.
- 11) Power supply: AC 100~240V, 50~60Hz, three-core power cord, grounded.
- 12) A well-grounded power receptacle is required, and its maximum power consumption is 1kVA, zero to earth voltage is  $\leq 6V$ . The instrument should be connected with an exclusive cable, if possible.
- 13) The distance between electrical outlet and the instrument should be less than 5 meters.
- 14) Operating temperature should be within the range of  $5^{\circ}C \sim 40^{\circ}C$ ; with fluctuation  $< \underline{\underline{2}}^{\circ}C/H$ .
- 15) Relative humidity is 35%~80%, no coagulation.

### 2.2.2 Procedures of installation

- 1) Take out the instrument and place it on the level, stable worktable. For heat dispersion, the rear of the instrument should keep away from wall or obstacles at least 20cm. The bottom of the instrument should keep good air circulation.
- 2) Connect the power cord to the power socket on the rear of the instrument.
- 3) Connect the joint end of the waste tube to the waste outlet, and the other end to the waste flask.
- 4) Before initial running, check the waste tube for bend and jam, and make sure the waste solution can be discharged into the waste flask smoothly.
- 5) Before operation, warm up the instrument for 20~30 minutes until the temperature is balanced and the light source is stable.

## 3 Operation Brief



### Biological Hazard

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

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To avoid unnecessary damage to the instrument, please read the Operating Manual carefully before operation.

### 3.1 Explanation for Keypad

The keypad is shown as Figure 4, for example:

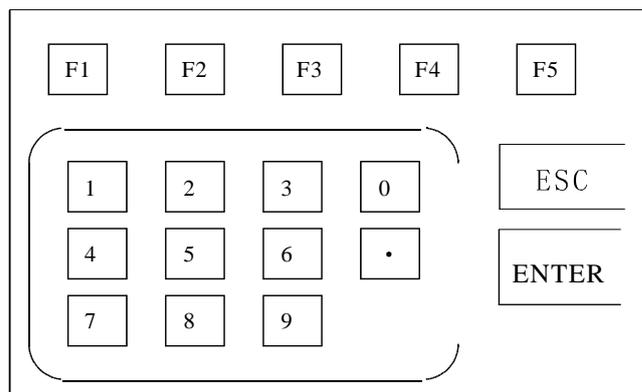


Figure 4

- 1) Digit keys (0~9): For entering digits .
- 2) Radix point key (.): For entering radix point.
- 3) ENTER key: For entering into edit status and confirming edit.
- 4) ESC key: Exits the current status, returns to the last screen.
- 5) Function keys (F1~F5) : Corresponds with the operation prompts displayed on the lower of the screen. There are some operation prompts displayed in different screens but in common use:
  - ▼ WASH: Washes the cell with distilled water or detergent.
  - ▼ PgDn/PgUp: Turns page to display the next screen for reviewing the continuing content.
  - ▼ PUMP: Aspirates sample.
  - ▼ RUN: Starts testing.
  - ▼ REPT: Repeats testing.
  - ▼ QC: Performs control analysis.
  - ▼ DEL: Deletes selected item.
  - ▼ ↑ : Moves cursor up.
  - ▼ ↓ : Moves cursor down.

## 3.2 Startup

Turn on or off the instrument by pressing the power switch on the rear of the instrument. “I” denotes ON, “O” denotes OFF.

## 3.3 Preparations

- 1) Check if the waste bottle is full and, if so, empty the waste bottle, then prepare enough distilled water.
- 2) Rinse the instrument with distilled water by executing the WASH function from the Main Menu screen. The instrument then goes into standby status.
- 3) Keep standby status for 30 minutes until the light source is stable and the temperature reaches the expected level.
- 4) Clean the instrument with distilled water by executing WASH five times.
- 5) Select “MAINTENANCE” from the Main Menu screen to enter the Maintenance screen. Then, select “A/D ADJUST” to enter the A/D screen. Press F5 [ADJ] to automatically adjust the A/D. After adjustment, a short tone is heard and the adjusted A/D value is saved automatically. If problems occur during the adjustment, refer to “Troubleshooting”.

## 3.4 Setup of Item Parameters

Press “1” or “2” from the Main Menu to enter the Item Screen. Each item is marked with a number (Item ID) ahead. Enter the number of desired item then press the [ENTER] key to display the relative Item Parameter screen. Refer to chapter “4.1.1” for details. Refer to Appendix B for item sequence and abbreviation.

## 3.5 Item Test

Press the F1 [RUN] from the Item Parameter screen.

Place the sample under the probe, then press the START button on the instrument. The instrument will automatically aspirate sample and measure it according to the set parameters. If you need to abort the measuring process, press the [ESC] key.

## 3.6 Print and Review

After measurement, return to the Main Menu. Press 4 [RESULT DATA] to enter the Review screen. The latest test results are displayed first, and other results can be reviewed by pressing the [↑] or [↓].

Pressing the [OUT] key will print all test results that are subject to the date displayed on the current screen.

If you just want to print the result of a specified sample, press the [ID] key first to enter the desired sample ID, then press the [OUT] key.

### 3.7 Ending

Follow below steps after daily work:

- 1) Put reagent into icebox.
- 2) Dispose of used serum cuvettes according to relevant regulations.
- 3) Clean instrument 7-20 times.
- 4) Cut off powersupply
- 5) Clean worktable with soft cloth.

## 4 Operation Details

The Main Menu includes following six submenus: Item Test, Curve Test, ABS Test, Result Data, QC Date and Maintenance. Following is the detailed description.

### 4.1 Item Test

#### 4.1.1 Setup of Item Parameters

Setting item parameters is an essential step for item measurement. Proper item parameters can ensure the measurement accuracy.

You can select item parameters by moving the cursor [ ↓ ], turn to other pages by pressing [PgDn].

When selecting an item parameter, press [ENTER] to edit.

After edit, Press [ENTER] to save, [ESC] to cancel and return.

#### 1) Item Name

The item name can be entered using the cursor and numeric keyboard displayed on the screen.

#### 2) Test Method

Four methods are available: Endpoint, kinetic, Twopoint and Bichwave (Dual-wavelength).

#### 3) Wavelength 1 and wavelength 2

Both wavelength 1 and wavelength 2 has the range of 300nm~800 nm. Wavelength 2 is available when Dual-wavelength method is active.

#### 4)Time

DELAY(s): For endpoint and dual-wavelength, delay time is the length from the moment the sample is pipetted into cell to the beginning of measurement; for kinetic and twopoint, delay time is the length from the moment the sample is pipetted into cell to the beginning of the first point measurement.

MEAS TIME(s): The measurement time, only applied to kinetic and twopoint, is the length from the first point being measured to the last point being measured.

#### 5) Blank

Blank mediums include reagent, distilled water and sample. Accordingly, blank methods include reagent blank, water blank and sample blank.

#### 6) Volume

The volume of reaction solution to be pipetted.

## 7) Units

Units for test results

## 8) Temperature

Temperature choices include: --(Room), 25DC, 30DC, and 30DC.

## 9) Print

Turns on or off the printer. Selecting ON, test results will be printed out following each measurement; Selecting OFF, the printer will not work.

NOTE: In RESULT DATA, press [ID ] will print the comprehensive report. See chapter "4.4.2" for details.

## 10) Standard

Standard concentration used for calculating K value.

## 11) Factor

Factor is the K value. It can be entered manually or calculated automatically by the system after a standard test. For the latter, when the standard concentration has been entered and the K value is 0, a standard test is required by the system before sample test is done. After the standard test, the system will calculate the K value automatically.

NOTE: Factor method is available.

After completion of parameters setup, you can select following operation:

[RUN]: Starts testing current item.

[WASH]: Rinses the liquid path with water or detergent.

[ESC]: Returns to Main Menu.

### 4.1.2 Process of Item Test

Press the FI [RUN] to enter the Testing screen. Place the sample under the probe, then press the START button, the instrument then automatically perform measurement according to set item parameters.

If there are more than one test to be done, the tests will be processed following the sequence: blank , standard, samples (If blank and standard parameters are set up in advance ).

[REPT]: If you have doubt in test result, press F4 [REPT] to retest the sample. The retest result will replace the previous one.

[PLOT]: Press F2 [PLOT] to enter the Reaction Curve screen, where the reaction curves are presented in real time for convenient observation.

[ ID ]: You can edit sample ID by pressing F1[ID]. After edit, press [ENTER] to save, or [ESC] to cancel. The sample ID will automatically add 1 each time a sample is tested.

[QC]: Pressing F5[QC], the system prompts to perform control test and saves the control results. Refer to Chapter 5 for details.

## 4.2 Curve Test

Press “2” from the Main Menu screen to enter the Curve Item screen. This function is mainly used for testing samples that need 2~5 standards to calibrate.

### 4.2.1 Setup of Standard Curve

Up to 20 standard curves for 20 items can be created and the item parameters are user-defined. The minimum of two standard samples (Maximum five) are available. Standard concentrations should be entered in ascending order. If you pre-define the ABS, just enter it. So far the curves are created.

If you do not know the ABS or if you want to recalibrate, just enter the standard concentrations, then set the ABS to “0.0000”. The system will prompt to perform standard test before sample test. The standard results will be saved and standard curves are created.

### 4.2.2 Process of Curve Test

After setup of parameters, press F5[RUN] from Curve Parameter screen to start testing. System prompt will be displayed if parameters are inadequate. In this case, press [ESC] to return and complete the parameters entry. Test result will be displayed after testing.

[REPT]: If you have doubt in test result, press F4 [REPT] to retest the sample. The retest result will replace the previous one.

[PLOT]: Press F2[PLOT] to enter the Reaction Curve screen, where the reaction curves are presented in real time for convenient observation.

[ ID ]: You can edit sample ID by pressing F1[ID]. After edit, press [ENTER] to save, or [ESC] to cancel. The sample ID will automatically add 1 each time a sample is tested.

[ . ]: Pressing the radix point key on the keypad will compulsorily print the current test result even when the printer is set OFF.

## 4.3 ABS Test

Press “3” from the Main Menu screen to enter the ABS Parameter screen.

### 4.3.1 Setup of Parameters

#### 1) Test Method

ABS---- Absorbance of sample

TIME-----Change rate of absorbance

#### 2) Delay

For ABS method, the delay time is the length from the moment the sample is aspirated into cell to the beginning of measurement

For TIME method, the delay time is the length from the moment the sample is aspirated into cell to the beginning of first point measurement.

#### 3) Meas time (measuring time)

The measuring time, only applied to TIME method, is the length from the first point being measured to the last point being measured.

Other parameters setup are the same as "4.1.1 Setup of Item parameters".

### 4.3.2 Process of ABS test

Press F3[**RUN**] from the ABS Parameter screen to start testing. The system will prompt to pump water and test the absorbency of water before the sample absorbency test.

[**ZERO**]: Zeros the water blank or reagent blank.

[**REPT**]: Repeat the test.

[**OUT**]: Prints test result.

## 4.4 Result Data

### 4.4.1 Result Review

Press "4" from the Main Menu screen to enter the Review screen. The latest result will be displayed at first, including sample ID, item name, test result, unit, prompt and measuring date.

↑[ ]: Displays the previous stored result. [

↓ ]: Displays the next stored result . [OUT]:

Prints test result.

[ID]: Enters sample ID to print specified test result.

### 4.4.2 Result Print

Pressing F3[**OUT**] from the Review screen, all test results that are subject to the displayed measuring date will be printed. Or you can just print the specified results by pressing [ID] to enter the desired sample ID following by pressing [OUT].

## 4.5 QC Data

QC data of 300 items can be stored in memory for 2 months. Press “5” from the Main Menu screen to enter the QC Item screen. Select an item by entering the number ahead of each item then press the [ENTER] key to show the QC screen.

If you pre-define the target value and SD value, the QC chart will be plot using those entered values; if not, the QC chart will be plot using the mean value and SD automatically calculated by system.

MEAN: The automatically calculated mean value or the manually entered target value; the latter has the priority of display.

SD: The automatically calculated SD value or the manually entered SD value. The latter has the priority of display.

CV: CV of QC data.

QT.(QUANTITY): the quantity of current QC data.

[ ↓ ]: Turns to QC data of another month.

[DEL]: Deletes QC data.

[PLOT]: Displays QC chart.

[OUT]: Prints QC data.

[IN]: Enters QC target and SD values.

## 4.6 Maintenance

This function is intended for instrument maintenance and debugging. Press “6” from the Main Menu screen to enter the Maintenance Submenu screen.

### 4.6.1 A/D Adjust

The A/D initial value of the instrument has been adjusted before leaving factory. The gain, A/D and dark level values vary with different filters. Generally, the gain is 3 or 4, the A/D is about 34000 and the dark level is within 70~130(never 0); this profile is the optimum initial values.

Pressing F5 [ADJ], the system will automatically adjust the gain and dark level for different filters. After adjustment, the buzzer rings and the adjusted values are saved as reference for future adjustment.

NOTE: Press F4 [PUMP] to fill the cell with water before adjustment.

[SET]: This function is only for factory debugging use.

[TEST]: This function is only for factory debugging use.

It is suggested to adjust initial value under following situations:

When installing the instrument

- ▼ After long-distance delivery
- ▼ When replacing a halogen lamp
- ▼ When replacing a cell
- ▼ When filter has deteriorated
- ▼ Whenever test results show abnormal fluctuation.

#### 4.6.2 Pump Adjust

This function is for adjusting the parameters of peristaltic pump. It is not necessary to change the parameters in general circumstances as they have been set up to optimum condition by the factory.

##### 1) Volume

Liquid volume, usually 500 uL, pumped once a moving. If the volume is 1000uL, the pump needs to move twice.

##### 2) Speed

The speed of pump motor

##### 3) Step

The moving step for pump motor

##### 4) Wash times

The times for washing liquid path.

#### 4.6.3 Temperature

Only for factory debugging use.

#### 4.6.4 System

##### 1) LCD Contrast

Move cursor to SYSTEM then press [ENTER] to enter the Contrast screen .

[ + ]: Increases the LCD contrast.

[ - ]: Decreases the LCD contrast.

[SAVE]: Saves the adjustment

[ESC]: Cancels and exits the current screen.

##### 2) Language

Select language for user interface. English is default.

### 3) PC Control

Moving cursor to PC CONTROL and pressing [ENTER], the instrument then is controlled by PC. Pressing [ESC] cancel the pc control.

### 4) Printer

Move cursor to PRINTER and press [ENTER] to change the selection between ON and OFF.

### 5) RS232 (Serial Port)

Move cursor to RS232 and press [ENTER] to change the selection between ON and OFF.

### 6) LPT (Parallel Port)

Move cursor to LPT and press [ENTER] to change the selection between ON and OFF.

#### 4.6.5 Date&Time

Move cursor to DATE TIME and press [ENTER] to enter the Date&Time screen. Move the cursor to the appropriate digit that needs to be changed. Then, enter the appropriate digits by pressing the proper numeric keys.

#### 4.6.6 Calibration

Only for factory debugging use.

### 4.7 Tube Wash

Washing tube frequently can keep the tube and cell clean and reduce cross-contamination. Place water or detergent under the probe, then press the [WASH] key, which is displayed on various screen. The instrument will then automatically wash the tube.

It is recommended to wash tube in the following situations:

- ▶ At the start of day's run.
- ▶ At the end of day's run.
- ▶ After testing high concentration solution.
- ▶ A long time for disuse.
- ▶ Abnormal A/D values.



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For the air bubble or foreign body that is difficult to wash off from the cell, try to use the absolute alcohol or detergent recommended by Paramedical.

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## QC Analysis and Calibration

### 5.1 General Information

The reliability of test results depends on two aspects: One is precision, i.e. the repeatability of test results, which mainly aims at eliminating or minimizing the influence caused by random error and depends on the sound 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 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

To minimize 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 and absence of measurement value.

You can select one kind of control sample listed 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 in the same condition as 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 the following methods:

- Setup of temporary target value: Test a new lot of control sample. Obtain the results of at least 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: A new lot of control sample is required to confirm the control limit that is usually denoted with the multiple of SD. The control limit of different items (quantitative test) depends on their QC regulations.

#### 5.2.4 Control Procedure

In "Item Test", press F5[QC] from the Testing screen to test the control sample. The QC results will be stored automatically in memory for further analysis.

### 5.3 Analysis of QC Results

#### 5.3.1 Entry of QC Target and SD

In "QC Data", press F2 [IN] from the QC screen to enter target and SD value.

#### 5.3.2 Analysis of QC Chart

Press F5[PLOT] from the QC screen to display the QC chart.

In the QC chart, the middle line denotes the target value, while the lines up and down denote +1SD、+2SD、 and +3SD.

#### 5.3.3 Normal Distribution

- About 95% data are within  $X \pm 2SD$ .
- 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  $X \pm 2SD$  are not allowed.
- Points outside  $X \pm 3SD$  are not allowed.

#### 5.3.4 Abnormality

- Drift: System error exists
- 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.

- 1) Fill in abnormality report and report to your lab manager.
- 2) Simply and quickly review the operation process to find out the possible cause.
- 3) If no evident error is found, take the following steps.

- ❗ Retest the same control sample strictly as the operation procedures. If the retest results are normal, it means that personal error or random error existed in previous testing; If the retest results still fall outside the allowable range, proceed to the next step.
- ❗ Test a new bottle of control sample. If the test results are normal, the previous bottle of control sample has expired or been contaminated; if the test results still fall outside the allowable range, proceed to the next step.
- ❗ Test a new lot of control sample. If the test results are normal, the previous lot of control sample has problem. Inspect the storage environment and expiration date for possible cause. If the test result still fall outside the allowable range, proceed to the next step.
- ❗ Maintain the instrument. Inspect the instrument status and check whether it is necessary to replace the light source and filter, clean cell or change reagents. Test control sample after maintenance. If the test result still fall outside the allowable range, proceed to the next step.
- ❗ Perform recalibration. Recalibrate the instrument with new calibration solution. If the test result sill fall outside the allowable range, proceed to the next step.
- ❗ Obtain help from technician. If the test result still falls outside the allowable range after the five steps above, the instrument or reagent may be to blame. Contact Paramedical or reagent manufacturer to get more technical help.

## 5.5 Calibration

The calibration sample is to minimize or eliminate the system error caused by instrument or reagent. It is recommended than human serum matrix be used to reduce the matrix error.

### 5.5.1 When to Calibrate

It is suggested that calibration be carried out every six months or under the following conditions:

- 1) When initially installing and running the instrument.
- 2) When changing the reagent type or lot, unless otherwise specified by the laboratory that the change will not influence the precision.
- 3) When carrying out a protective maintenance or replacing an important component , which may influence the instrument capability.
- 4) When QC chart reflects abnormal tendency and drift, or exceeds the allowable range and it can not be corrected by routine steps.

### 5.5.2 Calibration Procedure

In “Item Test ”, enter the concentration value given by the calibration sample supplier into the STANDARD field. Save and exit. The calibration will be automatically carried out before testing sample, and the result will be stored as reference for the next calibration.

It is suggested that all calibration or validation work should be written down and compiled into documents. What should be emphasized is that the fix-value serum should never be used as calibration sample because the huge difference between.

## 6 Reagent, Sample and Waste

### 6.1 Reagent

The reagent parameters are customized

Only the certified and qualified reagents can be used.

Carefully read the instructions provided by reagent supplier before using.

### 6.2 Detergent

The detergent that the instrument employs is optional.

### 6.3 Precautions

- 1) When performing tests and daily maintenance, be sure to obey the operation procedures, and avoid contacting the sample directly.
- 2) All clinic samples should be handled according to the operation regulations, as they may carry potential infectious disease. Put on protective clothes, gloves and goggles . No smoking and eating in working area. Do not blow or suck the tubes.
- 3) Carefully dispose of wastes as they may carry potential contaminations and cause biologic and chemical hazard. Obey local regulations to dispose and drain the waste solution.
- 4) Store reagents according to the instructions offered by reagent supplier. User should establish and maintain the keeping- and- using system for reagents, to avoid using expired reagent. Storage should keep away from extremely hot or cold environment.

