Automatic Coagulation Analyzer LMCA-B100

Operation Manual

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Index

1. Safety Measures

Biohazard

In Vitro Diagnosis

Protective Ground

"I"

"On"

"O"

"Off"

Warning: If the users ignore the tags and misuse them, it may cause serious injury and property damage.
Notice: If the users ignore the tags and misuse, it may cause serious injury, output error, and property damage.

1.1 Precaution for use

- This product is an in-vitro diagnosis medical device for clinical assays. The clinical diagnosis based on this assay should be performed by the physician and be confirmed according to the clinical symptoms and other assay results.
- This product is only for in-vitro diagnosis. Kindly read carefully and follow the notices below before use.
- The operators should have the basic knowledge of performing clinical coagulation assay.
- In the environment of home-use, this device may cause radiation interference. Protection is required.

1.2 Warning

1) Do not use this device nearby substantial radiation sources (e.g. unshielded radio sources). Otherwise, it may cause problems for this device to work normally.
2) Before using this device, kindly check the radiation environment to ensure that the electromagnetic compatibility environment meets the requirement for this device to work normally.
3) If there is an abnormal smell of smoke, turn the power off Immediately, and unplug the device. If anyone continues using the device in this situation, it may cause fire, electric shock, and serious injury.
4) Do not spill blood or reagent into the device or drop metal pieces (e.g. staples) into the device. Otherwise, it may cause short circuits, smoke, or fire.
5) If any abnormal situation happens, kindly turn the power off and unplug this device Immediately.
6) The operators should not touch the electronic circuit inside this device. It may cause electric shock, especially when the hands are wet.

7) Kindly wear rubber gloves and use the regulated tools and parts when maintenance or repairing this device. After maintenance or repairing, Kindly wash hands using disinfectants. Otherwise, it may cause infection of the skin touching the blood, electric shock, and burn.
8) Be careful when processing the samples. Kindly wear rubber gloves, otherwise it may cause infection. If the sample gets into the eyes or wounds, wash it with a large amount of water, and ask physicians for professional medical advice immediately.
9) If parts replacement is needed when the device breaks down, all parts and components must be provided or checked by the professional personnel
10) Before replacing fuses, users must turn off the system and unplug the power cable. Only specified fuses can be used according to the specification printed near the fuse holder, which is 5*20mm glass tube fuse F2.5AL 250V AC.
11) The protective insulation wire is ground wire, colored green, yellow.

1.3 Safety notices

Use of Reagent

1) If the reagent gets into the eye accidentally, wash it with a large amount of clean water, and ask physicians for professional medical advice immediately.
2) If someone drinks the reagent they ask physicians for professional medical advice immediately. Drink a large amount of water until emesis.
3) If the reagent touches the hands or skin, wash it away with clean water immediately.
4) Used cuvettes, medical consumables, and wastes should be disposed properly as medical wastes or infectious wastes. If the hands touch the blood, it may cause infection by pathogen.

Power voltage, connection, and grounding

1) Do not plug this device into the voltage other than AC 220V. Otherwise, it may cause fire or electric shock.
2) When installation, Kindly place this device where the operator can easily reach the power switch. You must use the three-core cable given in the package and check the effectiveness of grounding. Otherwise, it may cause fire or electrical shock.
3) Do not damage the insulation sheath of the cable. Do not pull the cable or put heavy objects on it. Otherwise, it may cause short circuits or open circuits and cause electric shock and fire.
4) When connecting to peripheral equipment, you must keep the power off. Otherwise, it may cause electric shock and device failure.
5) When the device is working, kindly keep the power on. Otherwise, it may damage the memory. Uninterruptible Power Supply is recommended.

2. Introduction

Automatic Coagulation Analyzer LMCA-B100 is designed to assess and monitor the coagulation profile of a patient's blood by employing Optical coagulation assay and immunoassay methodologies. The coagulation analyzer features four test channels, and 40 cuvettes, and accommodates 10 positions each for sample and reagent containers. It offers a range of automated functions, including sample probe cleaning, sampling procedures, measurements, data analysis, and re-testing of abnormal samples, complete with error reporting.

3. Features

- Compact and benchtop design
- Incorporates bar-code and QR code scanning for efficient sample and reagent identification
- Equipped with an LCD display and remote control capability
- Stores calibration curves and test results with a data memory capacity exceeding 50 million pieces
- Provides continuous operation for up to 24 hours
- Features system maintenance settings, including motor frequency and motion accuracy adjustments
- Includes self-testing and editable settings for calibrations, quality control, and test procedures
- Equipped with an emergency sample setting function, featuring liquid-level detection
- Generates comprehensive analysis reports in an international standard format
- Work with high efficiency, stability, and reliability
- Offers user-friendly operation and consistent performance

4. Specifications

Model No	LMCA-B100
Method	Optical coagulation assay, and immunoassay
Test Channels	4
Test Methods	Automatic or manual test mode
Sample Position	10
Reagent Container Position	10
Cuvette	40
Test Timing Range	0 to 300 s
Test Speed	PT - 300 Tests/h,APTT - 250 Tests/h,TT - 300 Tests/h,FIB – 300 Tests/h
Reagent Volume	5 to 200 μL
Sample Volume	5 to 100 μL
Preheating Time	>30 mins (after start-up)
Constant Temperature	Detector: 37°C ± 1°C,Reagent and Sample disk: 37°C ± 1°C
Test Items	Prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB), coagulation factors II-XII, D-dimer, reptilase time (RT), lupus anticoagulant (LA), heparin (HEP), protein C (PC), etc.
Temperature Control	Test module and preheating system: 37°C ± 1°C (constant temperature control)Reagent cooling temperature control: >16°C
Repeatability	CVPT ≤ 2%CVAPTT ≤ 2.5%CVTT ≤ 3%CVFIB≤5%CV D-Dimer ≤ 6%
Relative Bias	FIB relative bias ≤ ±10.0%,D-dimer relative bias ≤ ±10.0%
Linearity	FIB linearity r ≥ 0.975D-dimer linearity r ≥ 0.975
Sample Carryover Rate	FIB carryover rate ≤10%
Continuous Working Time	≥ 24 h
Display	LCD display or touchscreen
Storage	More than 50 million pieces of data
Power Supply	AC 220 ± 22 V AC, 50 ± 1 Hz
Power	≤ 320 VA
Packaging Dimension (W×D×H)	820 × 730 × 740 mm
Net Weight	39 kg
Gross Weight	75 kg

5. Applications

Automatic Coagulation Analyzer LMCA-B100 evaluates blood coagulation factors and helps in diagnosis and monitoring of diseased conditions.

6. Instrument Introduction

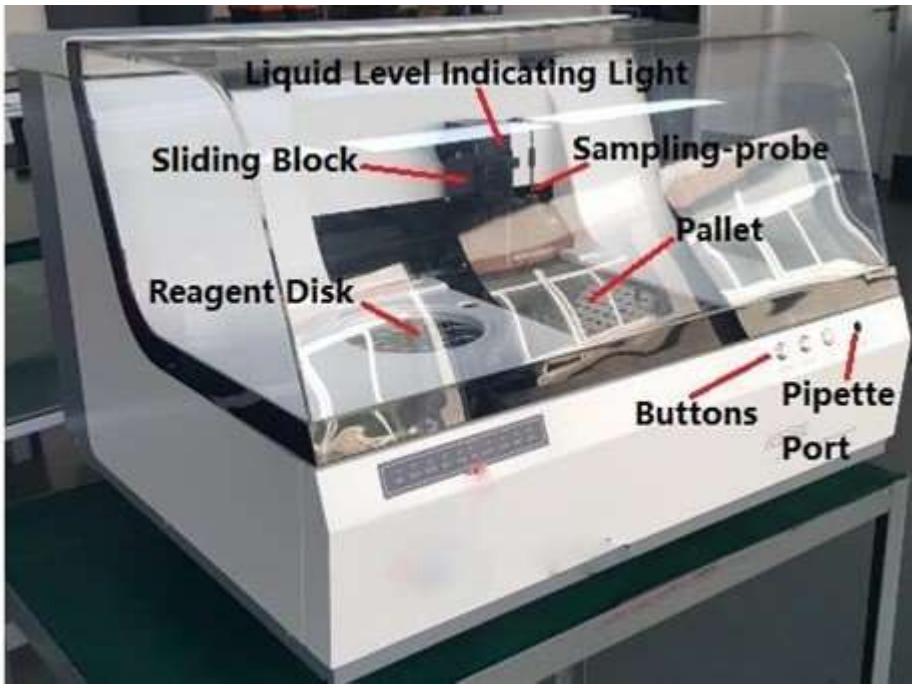

Figure-1

6.1 Liquid level indicating light

When the Sampling-probe touches liquid surface of the sample or reagent, this light will turn off. Otherwise, the light will turn on.

6.2 Sampling Pipette Socket

When operating in manual mode, this socket is designed for connecting specialized sampling pipettes to dispense samples or reagent into the colorimetric cuvette manually.

6.3 Reagent Disk

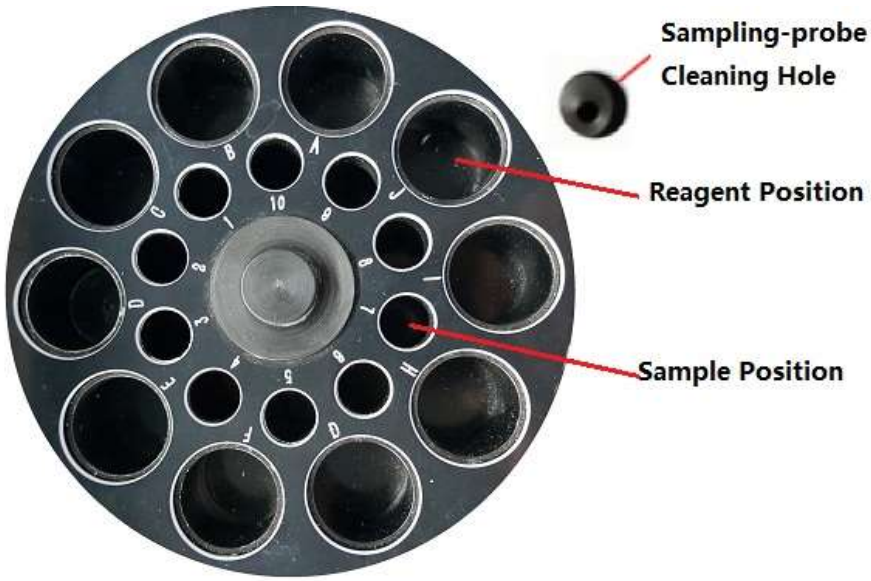

Figure-2

- **Sampling-probe Cleaning Hole:**
  When cleaning the sampling-probe, the system automatically moves the sliding block to this location for cleaning procedure. After cleaning, liquid waste is drained from the cleaning hole to the liquid waste container.
  Reagent disk is usually divided into 2 circular areas, noted as the sample position and the reagent position.
- **Reagent Position:**
  Reagent positions are the larger holes labeled in upper-case alphabet letters A-J, as it shows in the figure above.
- Positions D and F remain constant temperature for the reagent that needs preheated.
- **Sample Position:**
  Sample positions are the smaller holes labeled in Arabic numbers 1-10, as is shown in the figure above.

6.4 Pallet

Pallet is for putting the colorimetric cuvettes. The colorimetric cuvettes are placed in small holes. The pallet has 10 rows (downward from the top) and 6 columns (left to right).

For changing the cuvette, grab the handles from both sides of the pallet; lift the handles upward to take the pallet. Insert unused cuvettes into the testing holes and restore the pallet into the original position. When finishing testing for each row, the pallet moves automatically to the next row. If finishing testing all rows of cuvettes, the system will pop up a notice “No cuvette for use”, and new cuvettes need to be changed.

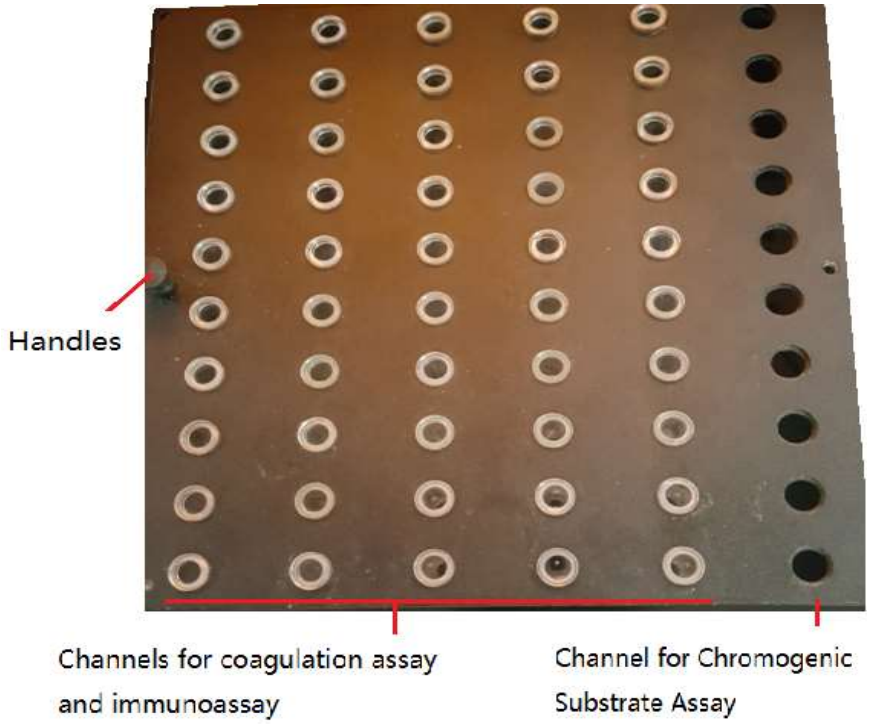

Figure-3

6.5 Panel Lights

Figure-4

1) **Liquid Waste**: This light turns on when the liquid level in liquid waste container is high. Or when operating in manual testing mode, this light is used for indicating the signal of sampling pipette.
2) **Distilled Water:** This light is off when the liquid level is low in distilled water container.
3) **Cleaning Liquid:** This light is off when the liquid level is low in cleaning liquid container.
4) **Sampling**: This light turns on when the sampling-probe is at zero.
5) **Proportioner:** This light turns on when proportioner is at zero.
6) **X Cleaning Liquid:** This light turns on when indicating deceleration of the sliding block approaching zero.
7) **Detect**: This light turns on when the detector is at zero.
8) **Reagent Disk:** This light is off when the reagent disk is at zero position.
9) **X Zero:** This light turns on when the sliding block is at zero.
10) **Pallet:** This light turns on when the pallet is at zero position.

6.6 Panel Buttons

Figure-5

Cooling Switch: Push the button when the reagent disk needs cooling.
Note:
Do not push this button when operating the test.
Emergency Button: Push this button to stop operation when emergency.
Power: Push this button to power on this device.

6.7 Rear Panel

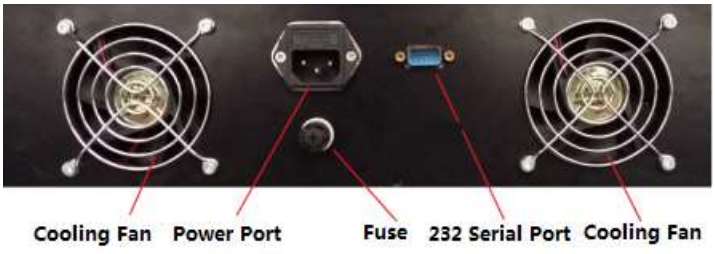

Figure-6

232 Communication Interface: This is a data transmission interface connecting to the main computer unit.

6.8 Main systems

6.8.1 Cleaning System

- Cleaning system is mainly designed to rinse the inner and outer walls of sampling-probe to prevent cross contamination of sample and reagent. The cleaning system mainly consists of wriggle pump, three-way solenoid valve, cleaning tank, sampling-probe, and pipeline, as it shows in the figure below.
- Switch the selection valve to choose the liquid for cleaning. The sampling-probe lifts for a small distance. When the three-way solenoid valve opens, the cleaning liquid (or distilled water) runs into outlet 1, and then runs through the sampling-probe to the cleaning tank for cleaning the inner wall. The sampling-probe drops for a small distance. The three-way solenoid valve closes. And the wriggle pump turns on. The cleaning liquid (or distilled water) runs into outlet 2 and fills the cleaning tank. The sampling-probe drops into the cleaning tank for cleaning the outer wall. At the same time, the pump remains working to drain the liquid waste to the liquid waste container when cleaning the inner and outer wall of sampling-probe.

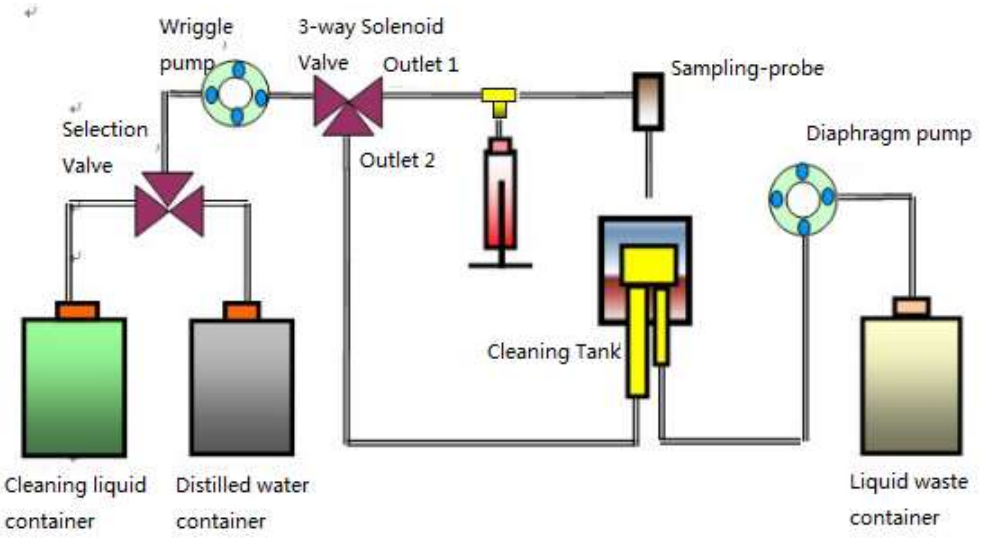

Figure-7

6.8.2 Sampling System

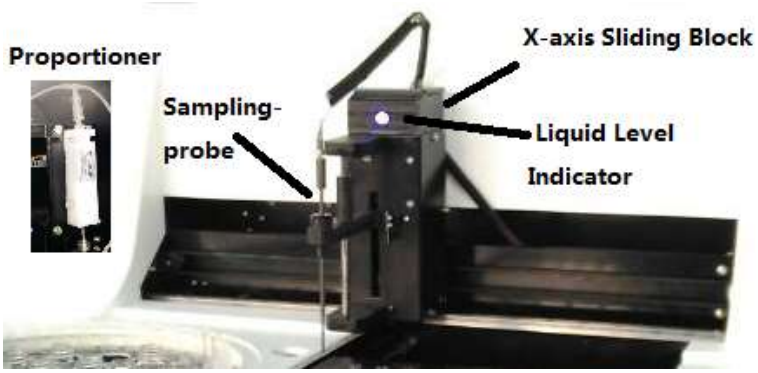

Figure-8

- Sampling system mainly consists of X axis sliding block, sampling-probe, proportioner, and liquid level indicator. The main function of this system is to dispense sample and reagent into the cuvettes by designed proportion.
- Sampling procedures are as follows:
- The sliding block moves to the reagent or sample position.
- Reagent disk rotates. The sampling-probe moves to the reagent or sample position.
- Sampling-probe takes in a small portion of air for isolation.
- Insert the sampling-probe into reagent or sample container, take in a certain amount of reagent or sample.
- The sliding block moves to specified cuvette position.
- Sampling probe drops to the cuvette opening and dispenses all the intake liquid.
- Sampling-probe moves to the cleaning position. Cleaning system starts to rinse the inner and outer wall of sampling-probe.

6.8.3 Test System

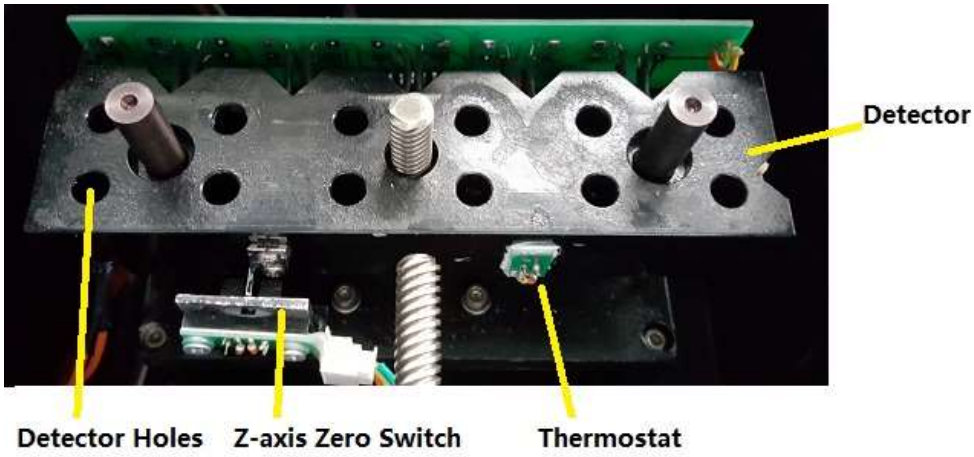

Figure-9

The test system consists of a detector, temperature sensor, preheating and constant temperature system, Z axis indicator, and pallet transmission system, which contains the core modules of this device. The detector is below the pallet. There are two rows of holes on the detector. The first row is testing holes for sample testing. The second rows are preheating holes. There are 6 holes in each row, corresponding to 6 channels. The first 5 holes are for coagulation assay, immunoassay (prothrombin time, PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen content (FIB), D-Dimer, coagulation factor, etc. The 6th channel is for chromogenic substrate assay (antithrombin Ⅲ, AT-Ⅲ).

6.8.4 Temperature Control System

- Temperature control system is designed to be installed in the detector and the reagent disk, which is the thermostat to control the needed temperature.
- Temperature control system is required to keep the temperature in range of 37℃±1℃. When booting the software system, temperature control system starts to work. The software can monitor and control the temperature change until the software system turns off.
- Temperature control system consists of heating system and cooling system. The heating system has two sets of modules: one is for sample heating, the other one is for position locating (reagent position D and E), controlling the temperature to be in range of 37℃±1℃. When booting the software system, temperature control system starts to work, and the software starts to monitor temperature change until the software system turns off. The cooling system is designed for cooling all reagent positions. The temperature is controlled to remain ≤16℃. When the cooling system starts, the software starts to monitor temperature change until the software system turns off.

Warning: Do not turn on the cooling system when test starts or reagent disk is in operation.

6.8.5 Liquid Level Detecting System

- The **sampling probe** is equipped with a function to detect and indicate the liquid level. During sample intake, the probe tip lowers into the liquid container. Once the probe touches the surface of the liquid, the liquid level indicator light turns off. At this point, the probe stops descending and begins to draw in the sample. If the probe reaches its lowest point without detecting the liquid, the system will display a notice indicating that the liquid container is empty.
- The **cleaning system**, which includes both a cleaning liquid container and a liquid waste container, also features liquid level detection. When the **cleaning liquid container** is empty, the detecting rod fails to contact the liquid, triggering a signal to the system that prompts a notice alerting the user. In contrast, when the **liquid waste container** becomes full, the detecting rod becomes immersed in the waste liquid. This change also sends a signal to the system, which then displays a notice informing the operator that the waste container is full.

6.8.6 Device Controlling System

Device controlling system consists of external computer unit, I/O panel, simulation panel, amplifier panel, monitor, and system software, etc, which is the human-machine interface interacting with the operator. Device controlling system controls the device movements and data memory. Computer unit, monitor, keyboard, mouse, and printer is external parts for the operator. The other units are installed inside the device.

6.9 Parameter

1) **Methodology:** Optical coagulation assay, immunoassay, and chromogenic substrate assay.
2) Test items：
   - Prothrombin Time（PT）
   - Activated Partial Thromboplastin Time（APTT）
   - Thrombin Time（TT）
   - Fibrinogen Content（FIB）
   - Antithrombin Ⅲ （AT-Ⅲ）
   - D-Dimer
   - Ⅱ～Ⅻ Endogenous or Exogenous Coagulation Factors
   - Reptilase time (RT)
   - Lupus anticoagulant (LA)
   - Heparin (HEP)
   - Protein C (PC)
3) **Test Channels**: 6
4) **Reagent Position**： 10
5) **Sample Position**： 10 (Any one of these can be set for emergency diagnosis)
6) **Assay Position (Colorimetric Cuvette)**: 60
7) Constant Temperature Features：
   - Detector: 37℃±1℃
   - Sample and Reagent Disk: 37℃±1℃

8) Reagent Volume PT, APTT, TT, FIB 5～200μL
9) Sample Volume PT, APTT, TT, FIB 5～100μL
10) **Test Timing Range**: 0s～300s
11) **Sample Carryover Rate:** FIB carryover rate ≤10%
12) Test Speed：
    - PT 350/h,
    - APTT 300/h,
    - TT350/h,
    - FIB 350/h
13) Accuracy：
    - CVPT≤2%
    - CVAPTT≤2.5%
    - CVTT≤3%
    - CVFIB≤5%
    - CVAT-Ⅲ≤10%
    - CVD-Dimer≤6%
14) **Display**: Color LCD (or touch screen for optional purchase)
15) **Environmental Temperature:** 15℃～30℃
16) **Preheating Time:** <30min after start-up
17) **Relative Humidity：** ≤85%
18) **Atmospheric Pressure：** 86kPa～106kPa
19) **Power：** Voltage 220V±22V（AC），Frequency 50Hz±1Hz
20) **Power Consumption：** ≤320VA
21) **Net Weight：** 65KG
22) **Size:** 720×620×520mm

7. Installation

7.1 Working Conditions

- Environment Temperature - 18℃～30℃
- Relative Humidity - ≤85%
- Atmospheric Pressure - 86KPA～106KPA
- Power - Voltage 220V±22V（AC） Frequency 50HZ±1HZ
- Preheating Time - 30 minutes

7.2 Transport and Storage Conditions

- **Ambient Temperature Range**: -40℃～55℃.
- **Relative Humidity Range**: 95%.
- **Atmospheric Pressure Range**: 500hPa～1060hPa.
- This device can be transported by common transportation vehicles. Kindly avoid vibration, impact, rainfall, and snow erosion. The device is fragile. Kindly keep it up-right when transporting. DO NOT turn it over or upside down.

7.3 Unpacking

Unpackage the box and remove the materials for transport. Kindly keep the packaging box and the materials for repacking in the future. The device is put in plastic bags and covered with polyethylene foamed sheets, placed in the wooden box.

1) Take the device out of the box
2) Place the device in a proper location
3) Kindly check the material in the box.

7.4 Electronic Circuit Wiring

Before connecting to the power, Kindly check and make sure the power switch of electrical equipment is off.

Connect the Device to the Power

Plug one end of the power cable to the power line interface, and the other end to 220V AC socket.

Connect the Monitor

Connect one end of the monitor cable to the display interface behind the monitor.
Connect the other end to the computer display interface.

Connect Mouse and Keyboard

Connect the mouse to the USB interface on the computer, and the keyboard to the keyboard interface on the computer.

Connect to the External Printer

Connect one end of the printer cable to the printer interface on the printer.
Connect the other end to the USB interface on the computer.
Plug the printer power cable to AC power.

7.5 Pipeline Connection

- **Cleaning Pipe**
  Connect one end of the pipe to the inlet of the cleaning liquid behind the device, and the other end to the cleaning liquid container.
- **Distilled Water Pipe**
  Connect one end of the pipe to the inlet of distilled water behind the device, and the other end to the distilled water container.
- **Liquid Waste Pipe**
  Connect one end of the pipe to the outlet of the liquid waste behind the device, and the other end to the liquid waste container.

8. Software Installation

Running Environment
The operating system is Windows 10. The optimal display resolution is 1024*900.
System Installation
The system is installed by the manufacturer before leaving the factory.

9. Operations

9.1 Power On

Ensure all electric cables are wired correctly before turning on the power.

- Push the power button on the display to turn on the monitor
- Push the power button on the printer to turn on the printer
- Push the power button on the coagulation analyzer
- Push the power button on the computer to turn on the computer.
- System starts to log in normally.

9.2 System Log-In

Double-click Automatic Analyzing System icon, the software starts logging in and entering self-check procedures.

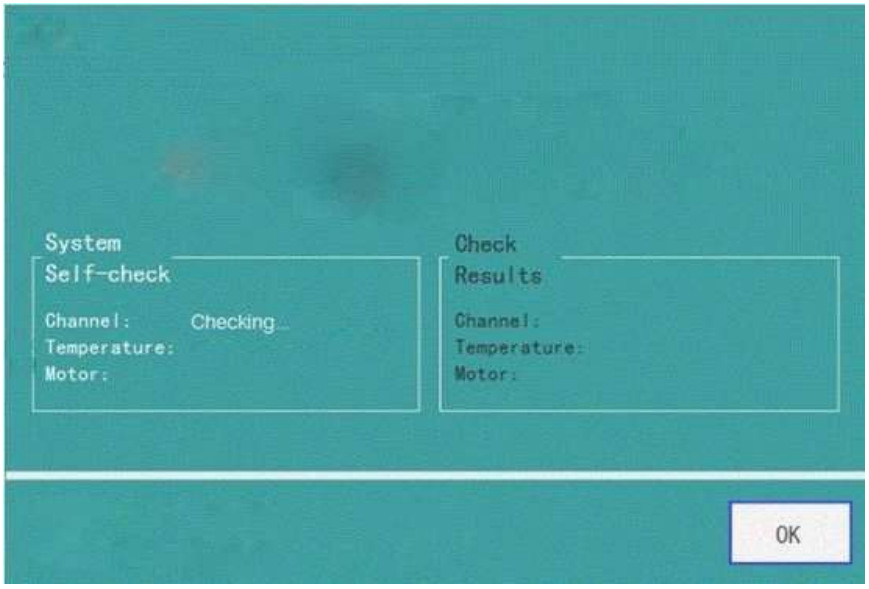

Figure-10

System self-check procedures check whether components and systems work normally.

Self-check procedures include：

- Checking components movements.
- Checking channel operation capability.
- Checking temperature control.
- Display self-check results.
- If abnormal, system notice pops up.
- If normal, the system enters the operation interface automatically and starts to remove bubbles.

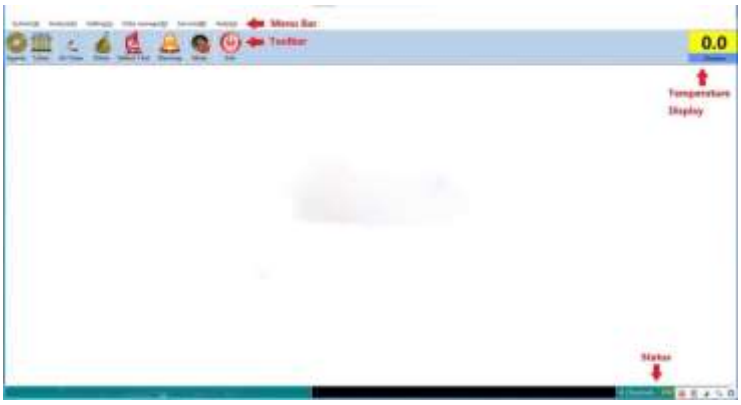

Figure-11

9.3 System operation

Enter Menu

Select the icons in the menu bar to enter the window.

System

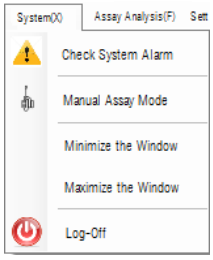

Figure-12

Assay Analysis

Figure-13

Settings

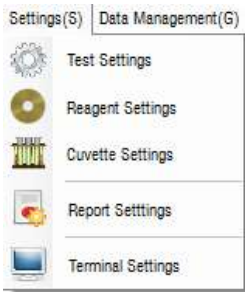

Figure-14

Data Management

Figure-15

System Maintenance

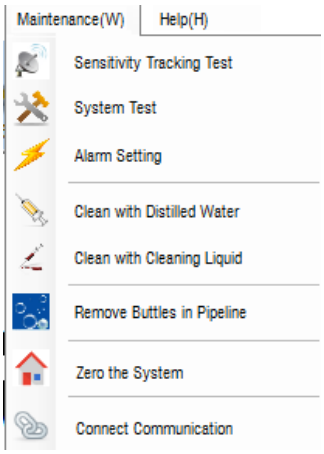

Figure-16

Help

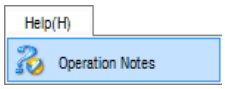

Figure-17

Toolbar

Commonly used icons are in the toolbar, as it shows in the figure below.

Figure-18

Dimmed icon means it is not currently functioning.

9.4 Initial Setup

For the first time entering the system, initial setup is needed.

- Setup hospital information. When entering patients' information, the hospital information is available for selection in pull-down list.
- Setup testing mode.
- Setup calibration.
- Setup sensitivity.
- Setup reference range.
- Set up sampling time for each essay.

Note: For those who use reagent from different producers, when changing new reagent, the user Must reset testing mode, calibration, and sensitivity.

9.5 Log-off

Click [**Log-Off**] under [System] menu. Prompt window pops up for ensuring log-off.

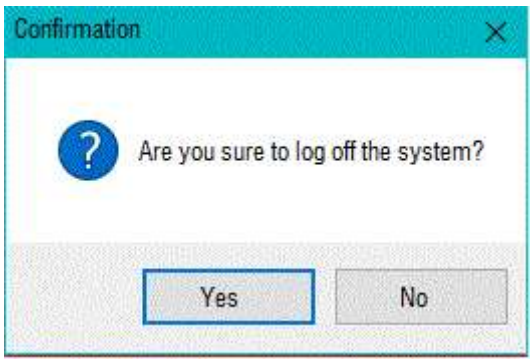

Figure-19

- Click [**Yes**] to log off
- Click [**No**] to cancel log-off
- Select Log-Off in Start Menu at lower left corner for Windows system to log off the computer.
- Turn off the power for display
- Turn off the power for printer
- Push [**Power**] button on the front panel of analyzer to turn off the power.

Note:

- Kindly follow the steps to log off the device for data safety. Otherwise, the data might be lost.
- If the program shuts down abnormally, the temperature control system does not turn off automatically. The operator needs to turn off the power to prevent overheating due to temperature control system failure.

9.6 Parameter Setting

9.6.1 Cuvette Setting

Click **[Cuvette Setting]** icon in the toolbar. The cuvette setting window prompts, as it shows in the figure below.

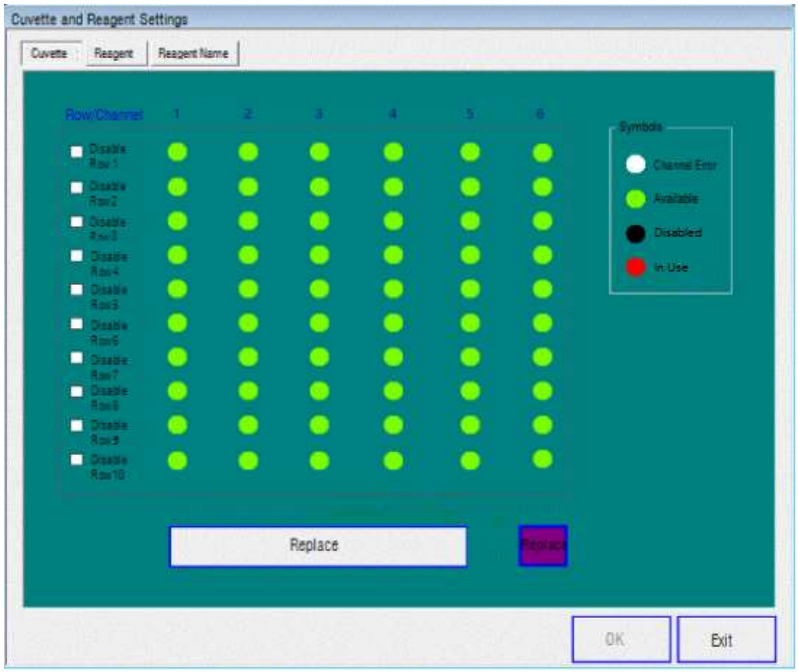

Figure-20

Circles correspond to the cuvette's position in the pallet. The color of each circle corresponds to the current state of the cuvette.

Colors:

- **White:** Channel Error. Not functioning.
- **Green**: Cuvette is available.
- **Black:** This row of cuvettes is not functioning.
- **Red**: Cuvette is not available. Click the [**Replace**] button for switching to green available state.

When sampling, the sampling system indicates the cuvette position that needs sampling by checking states and settings. When changing cuvettes, change the setting of cuvettes for matching the monitored cuvettes states with the pallet.

Click the grey colored [**Replace**] button to change the states of channels other than the last channel; Click the purple colored [**Replace**] button to change the states of the last channel. Click [**OK**] to save and exit. Click [**Exit**] to exit without saving.

Click [**Disable this Row**] for system to ignore the row. The disabled row is not tested.

Note

- Before testing, kindly make sure the cuvettes states in the monitor match the actual cuvette position in the pallet.
- The last channel is Only for chromogenic substrate assay.

9.6.2 Reagent Disk Setting

Click [**Reagent Disk**] icon in the toolbar. The reagent disk setting window prompts, as it shows in the figure below.

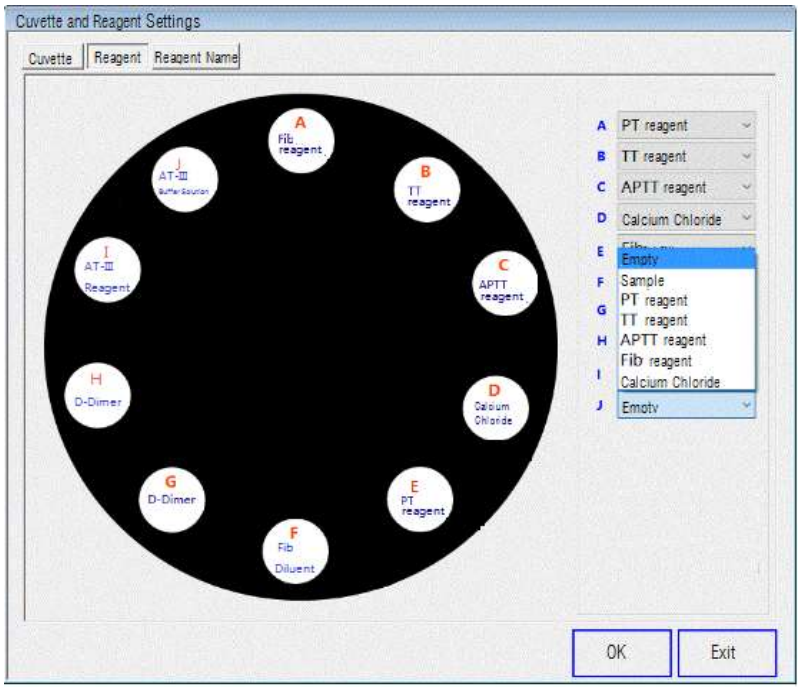

Figure-21

1) In the reagent setting window, there are 10 circles corresponding to the reagent position in the disk.
2) After inserting reagent container into the disk, select the [Reagent Setting] panel in [Cuvette and Reagent Setting] window. Select the reagent for each reagent position by clicking the reagent types in the pull-down list.
3) When finished, click [**OK**] to save the settings.
4) The user Must check the actual reagent positions match the settings of [Reagent Setting] panel in [Cuvette and Reagent Setting] window. When sampling, the system follows the settings of [Reagent Setting] panel in [Cuvette and Reagent Setting] window.

Note: Before starting test, Kindly check whether the actual reagent positions match the settings of [Reagent Setting] panel in [Cuvette and Reagent Setting] window.

9.6.3 Reagent Name setting

Click [**Reagent Name Setting**] under [**Data Management**] to open the reagent name setting window.

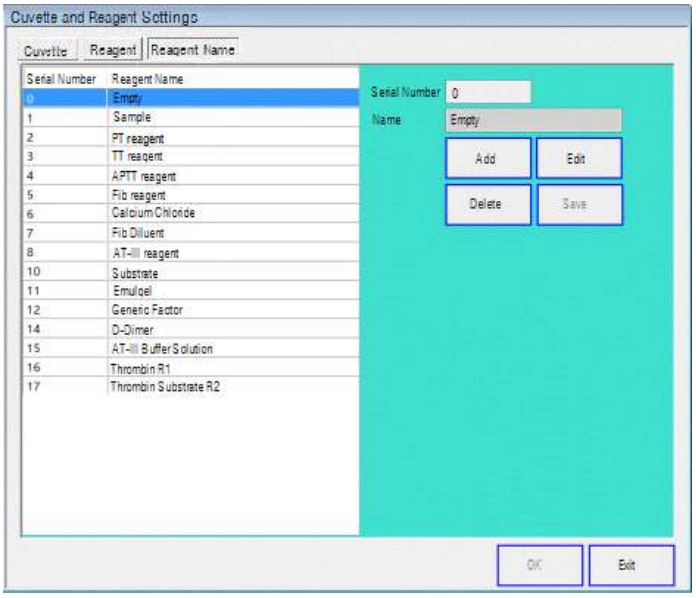

Figure-22

【Add】: Add a new reagent name.
【Edit】: Edit the name of selected reagent.
【Delete】: Delete the name of selected reagent.
【Save】: After finishing settings, click this button to save the data in the database.
Note:
For operators, do not change the reagent name. Otherwise, the program cannot find the reagent for dilution, assay, quality control analysis, and calibration.
If the reagent name is changed, Kindly check reagent disk settings and test settings to make sure the reagent names are consistent.

9.6.4 Current Calibration

In test setting window, select **[Current Calibration]** option. Select needed calibration setting of each patient sample in the pull-down list for different assay types under the current calibration. Then click **[Save Calibration]** to save.

Sensitivity setting

System has 4 selections of sensitivity: Sensitivity 1, Sensitivity 2, Sensitivity 3, and Sensitivity 4.

- PT tests often use sensitivity 1.
- TT test uses sensitivity 1.
- APTT test uses sensitivity 1.
- Fib test uses sensitivity 3.
- D-Dimer test uses sensitivity 1.

If the test result does not make sense, and reaction curve varies rapidly, select lower sensitivity; otherwise, if the reaction curve varies in a very small range, select higher sensitivity.

Reference Point: Select numbers from 0 to 1.

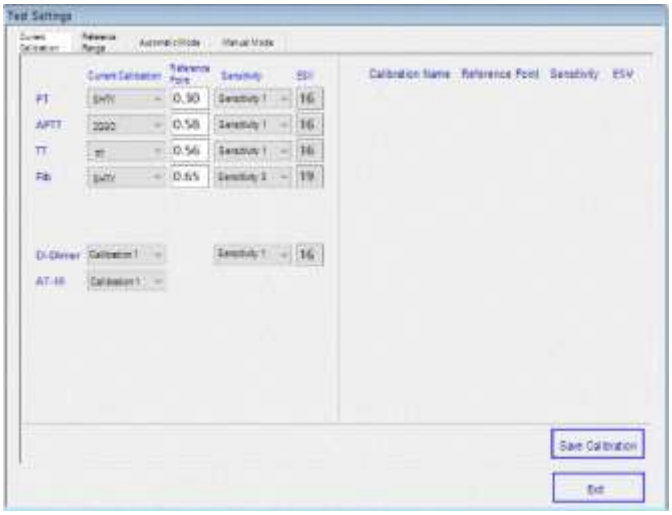

Figure-23

Note:

- After the calibration type is selected, the reference point and sensitivity are automatically selected according to the calibration type.
- For the same batch of reagents, after finish setting sensitivity and reference point, the user usually does not need to change the sensitivity and reference point during the assay.

9.6.5 Reference range

When users select the reagent from a producer, the reference range for the reagent is usually given in the instruction book.

After setting reference range, system can determine automatically whether the result is in the normal range according to the assay result. If the result is not in the normal range, system will prompt an alarm signal.

To set reference range, select [Reference Range] option in test setting window. Input reference lower limits in the left column and upper limits in the right column, corresponding to the assay types. After finishing setting, click [**Save Reference Range**] to save setting. The window is shown as follows.

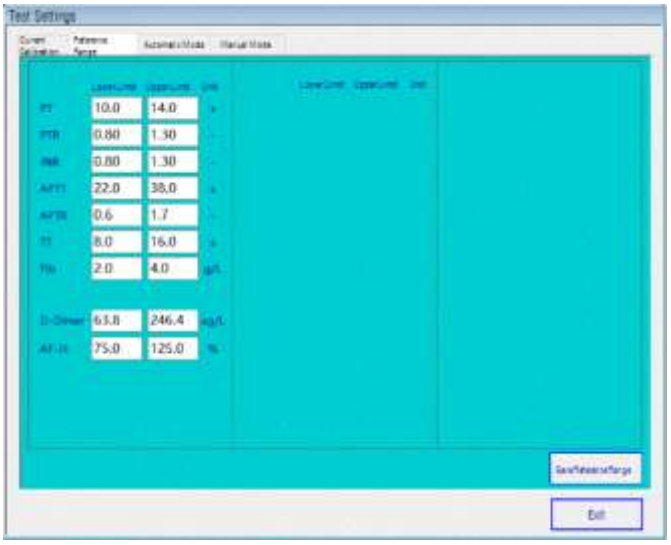

Figure-24

9.6.6 Assay mode

- For reagent from different producers, test procedures may vary.
- After selecting the reagent, kindly read the reagent instruction book carefully. Understand the test procedures of the reagent. Then set assay mode.
- Assay mode panel is for setting assay procedures. The system follows the set procedures to perform intake and sampling during operating assays.
- Assay mode includes automatic mode and manual mode. Manual mode is Only for perform assay manually.

Automatic Assay mode Setting window

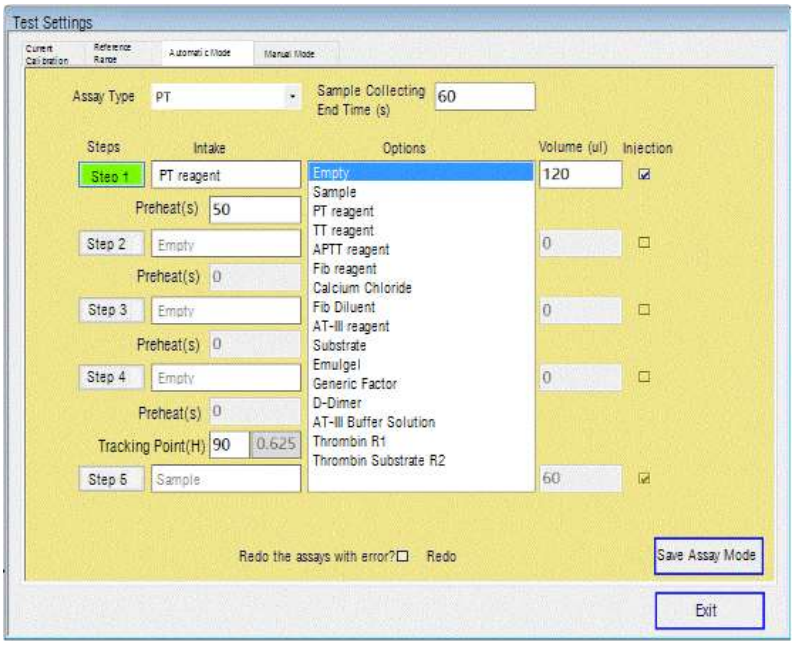

Figure-25

1) Select [**Test Setting**] under the menu bar to open the window.
2) Click the [**Automatic Assay Mode**] option to see automatic mode settings.
3) Select an assay type in the pull-down list of assay type.
4) Click the operating procedure buttons.
5) Intake blank shows the types of samples or reagent for this procedure. Select one of them from the list.
6) Input intake volume in the Intake Volume blank. Inputs must be numbers that are multiples of 5 or 10 (refer to different devices). The summation of total volume for different procedures Cannot exceed 400μl.
7) If the injection selection is checked, the intake volume in this procedure will be injected into the cuvette. If not checked, the system will do the next step of intake.
8) Set preheating according to the requirement of reagent instruction book. The unit is second.
9) Set tracking point between 30~A0. Tracking point is usually set to be 60H. Tracking point MUST be set before assay.
10) Sampling End Time is the maximum testing time. If the device does not get results at the end, there is an error in this assay.
11) When finishing setting, click [**Save Assay Mode**] to save the settings.

12) Recheck selection: if checked, when there is an error during test, system will redo the assay type of samples with errors automatically after finishing all rows of assays.

Manual assay Mode Setting Window

Figure-26

1) Click **[Manual Assay Mode]** option.
2) Select one assay type in the pull-down list.
3) Apart from Fib assays, all test procedures, time, and tracking points are the same as in automatic assay mode. For manual mode, only change the intake volume and preheating time if needed.
4) Input intake volume in the Intake Volume blank. Inputs must be numbers that are multiples of minimum scale in sampling pipette. The summation of total volume for different procedures Cannot exceed 400μl.
5) When finishing setting, click **[Save Assay Mode]** to save the settings.

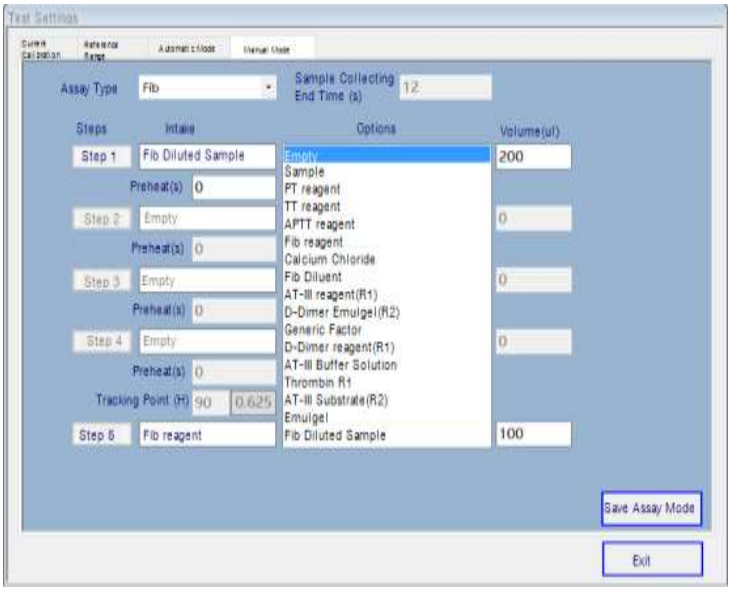

Figure-27

For Fib Assays：

Step 1: Select one of the selections and change the corresponding preheating time and intake volume.

Step 5: Select one of the selections and change the corresponding preheating time and intake volume.

Input intake volume in the Intake Volume blank. Inputs must be numbers that are multiples of minimum scale in sampling pipette. The summation of total volume for different procedures Cannot exceed 400μl.

Other settings such as sampling time and tracking point are the same as in automatic assay mode.

When finishing setting, click **[Save Assay Mode]** to save the settings.

9.7 Normal Operations

9.7.4 Sampling and Processing

1) Sampling

- Venous blood sampling. Be aware of avoiding collecting samples at or near the puncture site of the vein.
- Puncture should succeed at the first attempt to avoid blood congestion, bubbles, hemolysis, and interstitial fluid carryover.
- If using vacuum tube, select the second or the third tube of sample for better quality.
- If using sampler tube, rinse the tube with saline solution first. The first 5ml sample is unusable.
- Collected samples should be fully mixed with anticoagulants and delivered to the laboratory Immediately.
- Sample volume must be accurate. If sample volume is less than 90% of designed volume, the sample is unusable.

2) Sample Processing

- Use 3.8% or 3.2% (WN) Sodium Citrate solution as anticoagulant. Sample to anticoagulant ratio is 9:1. If hematocrit is less than 20% or larger than 55%,, the ratio has to be modified as following formula: 0.00815×Blood Sample（ml）×（100-Hematocrit）= Anticoagulant（ml）
- Plasmapheresis (if the sample cannot be tested immediately, do plasmapheresis as soon as possible.): Centrifugal Velocity 300 RPM, within 60min after sampling.
- Sampling containers should be covered to prevent pH change.
- Sample preservation temperature is 2℃～8℃. The sample should NOT be stored for too long time. Effective time for different temperature is shown in the table below.

Temp. Effective Time	Temp. Effective Time
Room Temp. ≤2h 2-8℃ ≤4h	-20℃ ≤2 weeks -70℃ ≤6 months

- Low temperature stored samples need to be rapidly defrosted at 37℃ and be tested immediately for decreasing the consumption of coagulation factors.

- All containers that touch the sample (injectors, sampling tubes, and cuvettes) must be made of plastic or silica glasses.
- All instruments should not be stained with detergent or cleaning liquid.

Device Preparation

1) Check the cleaning liquid.
2) Check if the liquid waste container is full. Empty the container.
3) Check the pallet to see whether there is an empty cuvette. And check if the actual states match the states in the cuvette setting window.
4) Check calibration, sensitivity, reference range, and assay mode settings.
5) Check the detector temperature whether it reaches 37°C.
6) Start the assays after completing preparation.

9.7.5 Dilution

For some assay types, e.g. FIB, samples need dilution. Operators can use dilution program for diluting the samples with diluent by designed proportion.

Click **[Dilution]** in the toolbar to open the dilution window, as it shows in the following figure.

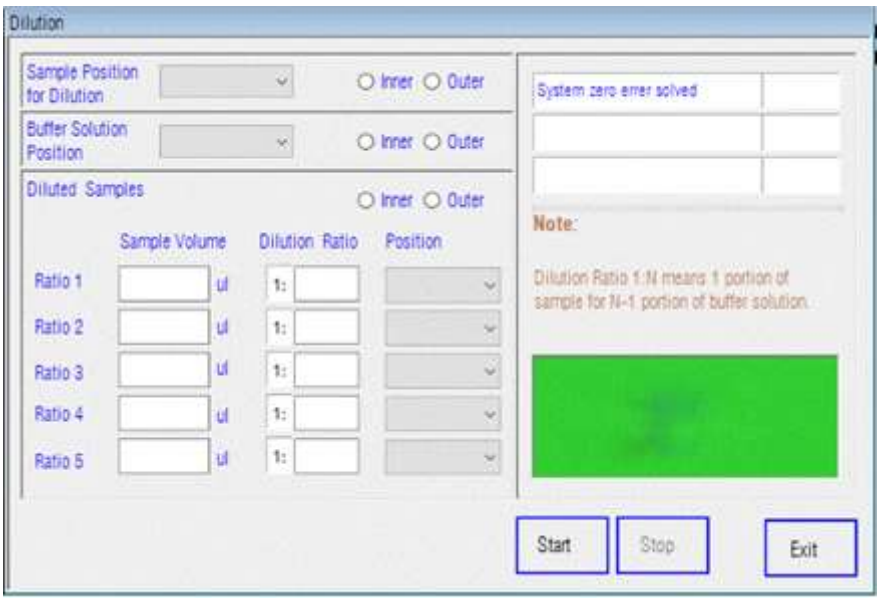

Figure-28

Settings for user's need

1) Sample position for dilution
2) Buffer solution position
3) Sample volume for dilution
4) Dilution Ratio
5) Sample position after dilution

Note

1) "Inner" means the position locates at the inner position of the reagent disk. "Outer" means the position locates at the outer position of the reagent disk.
2) If the dilution ratio is 1:10, it will take in 1 portion of sample and 9 portion of diluent for mixture. The diluent volume is automatically calculated according to the sample volume of the user's setting.

3) After finishing all settings, click [**Start**]. The processing bar shows the real-time dilution procedures of the system. No operation is needed for users until the system notices "**Dilution Complete".**
4) When diluting, if running out of samples or diluent, the system turns on the buzzer and prompts a notice window.
【**Mute**】: To mute the buzzer
【**Continue**】: To continue dilution after finishing processing settings.

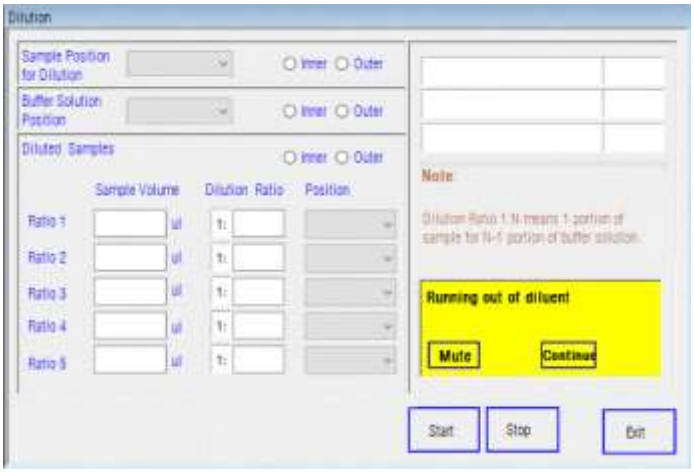

Figure-29

During dilution, if there is an error in the setting, the system will pop up a notice at the bottom of the window, as it shows in the following figure.

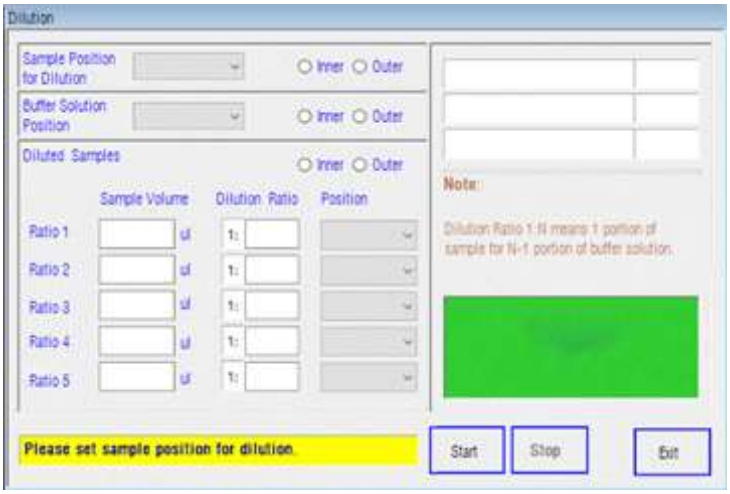

Figure-30

9.7.6 Cleaning Sampling Probe

Click [**Clean with Distilled Water**] or [**Clean with Cleaning Liquid**] in the toolbar to start the cleaning process automatically.
Cleaning procedures include cleaning inner wall and outer wall.
1) Sampling-probe moves to cleaning position.
2) Distilled water or cleaning liquid flows from inner wall of sampling-probe to rinse the inner wall.

3) Distilled water or cleaning liquid fills the cleaning hole to clean the outer wall.
4) After completing the cleaning process, click [**Exit**] to close the window.

During the assays, after the sampling procedure, the sampling-probe starts cleaning procedure automatically, but the window for cleaning does not show up.

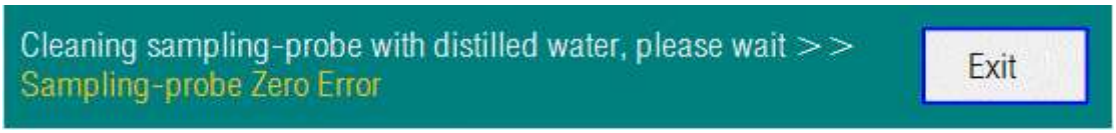

Figure-31

9.7.7 Zero the system

Click [**Zero the System**] under [**System Maintenance**] menu to open the window and start the zero procedure automatically.

Figure-32

Zero Procedures are:

1) Sliding block returns to cleaning position.
2) Proportioner returns to zero.
3) Sampling-probe returns to zero.
4) The detector returns to zero.
5) Pallet returns to zero position.
6) Reagent disk returns to zero position.

9.7.8 Removal Of bubbles in pipeline

Click [**Remove Bubbles in Pipeline**] under [**System Maintenance**] to open the window and start to remove the bubbles automatically.

Figure-33

9.7.9 Patient Assay

Patient assay is to start the assay procedures of patient samples.

There are two assay modes: Automatic assay mode (for normal operation) and manual assay mode (for emergency situations of motor errors).

- Automatic Assay Mode：
  Click [**Patient Assay**] under [**Assay Analysis**] menu or click [Patient Assay] in the toolbar to enter the automatic assay panel.
- Manual Assay Mode：
  Click [**Manual Assay Mode**] under [**System**] menu to enter the manual assay panel. See details in instruction of software for manual assay mode.

Figure-34

Notes:

1) If the channel tag is in red, the channel is not currently functioning, as it shows in channel 3 of the figure above.
2) When preheating of the detector is needed during the assays (according to detector settings), the "System is preheating. Kindly wait..." window prompts as it shows in the figure above. It shows the total preheating time and remaining time.
3) If one of the channels is in use for any assay of any sample, the headline of the channel block will show the sample number and corresponding assay type. As it shows in the figure above, the sample number is 1610260004 for assay type of PT, using channel 4.
4) Information Block

Figure-35

State Info: To show the operation states.
Emergency Diagnosis Info: If you add samples for emergency diagnosis, the emergency diagnosis information is given here.
Info Notice: When running out of cuvettes, reagent, samples, or adding samples for emergency diagnosis, information and operation commands are given here. Alarm prompts at the same time, as it shows in the following figure.

Figure-36

- **Placement Of Sample and Reagent**
  1) Place patient samples for assays in sample position of the reagent disk (smaller holes). Diluted samples are also placed in the sample position (smaller holes) if the sample needs dilution.
  2) Place all needed reagent in reagent position of the reagent disk (larger holes). And set the reagent position in the reagent setting window.
  3) After placing the samples and reagent in the disk, wait for about 10 minutes. When the temperature of samples and reagent meets requirements, tests start.
- **Enter Patient Information**

  Click [**Add Sample**] to open the panel for entering normal patient information and input the information of normal patients.

  Click [**Add Sample for Emergency**] to open the panel for entering emergency patient information and input the information of emergency patients. Only add samples for emergency diagnosis After adding normal samples.

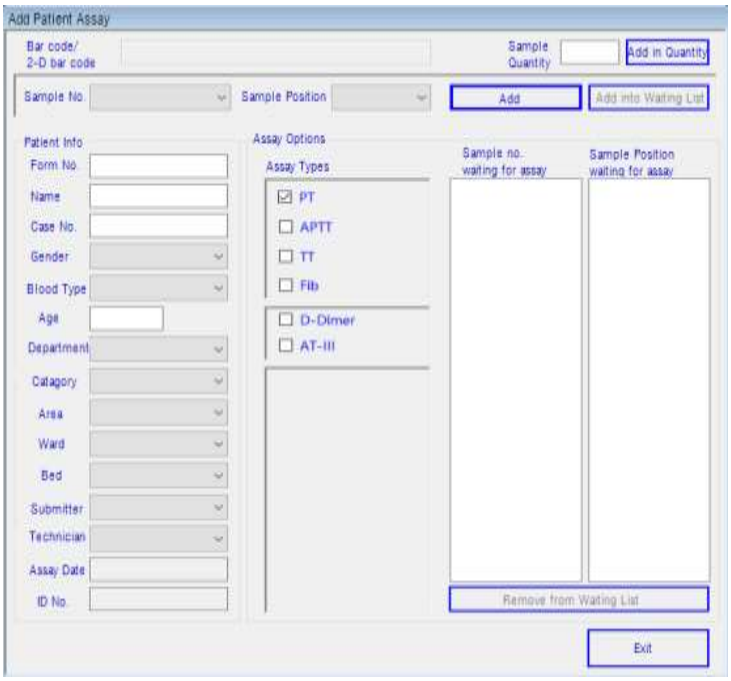

Figure-37

There are 2 ways to enter normal patient sample information.

Add info one by one：

1) Select assay types for the patient in the assay types of blocks
2) Click [**Add**] to add a new sample number. Sample number is generated by the system automatically.
   - Normal patient sample number: First 6 digits are date. Next 4 digits counts from 0001.
   - The number of samples cannot exceed 9999 every day.
3) Select patient sample position in the pull-down list of sample position.

4) Enter patient information.
5) Click [**Add into Waiting List**]. The patient sample shows up in the list of samples waiting for assays. The patient sample position shows up in the list of sample positions waiting for assays.
   - Select sample numbers in the list of samples waiting for assays to check corresponding patient information and assay type.
   - Select sample numbers in the list of samples waiting for assays and click [**Remove from Waiting List**] to remove the sample from the waiting list.
6) After finishing settings, click [**Exit**] to return to patient assay window.
7) For entering bar code or QR code of samples, select the bar code/ QR code textbox, and scan the bar code or QR code with scanning instrument by pushing the scanning button. Then information is inputted automatically into the textbox.

Add info in quantity

1) Select assay types for patients in the assay types of blocks.
2) Enter sample quantity in the sample quantity textbox.
3) Select the initial sample position in the pull-down list of sample position.
4) Select assay types in the assay types of blocks.
5) Click **[Add in Quantity]** to add sample information automatically from selected initial sample position in entered quantity.
   Note: Adding info in quantity does not allow entering bar code/ QR code.
6) After completing settings, click [**Exit**] to return to patient assay window.

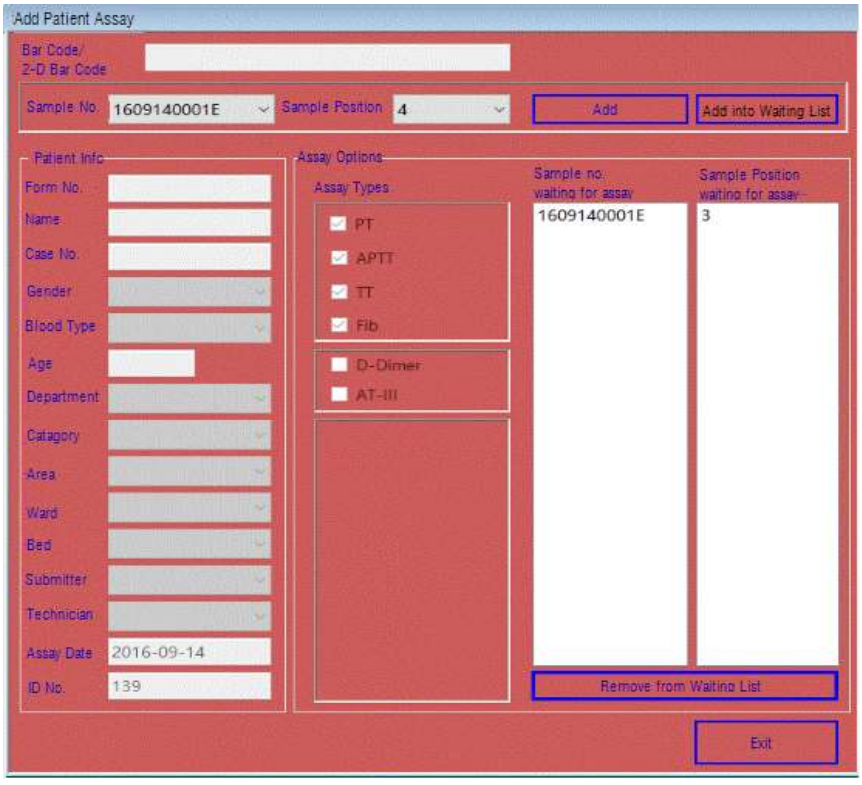

Figure-38

Entering information for emergency patients

1) Select assay type for the patient in the assay types of blocks.
2) Click **[Add]** to add a new sample number. Sample number is generated by the system automatically.
   - Emergency patient sample number: First 6 digits are date. Next 4 digits counts from 0001. The last digit is alphabet E.
   - The number of samples cannot exceed 9999 every day.
3) Select patient sample position in the pull-down list of sample position.
4) Enter patient information.
   Click **[Add into Waiting List]**. The patient sample shows up in the list of samples waiting for assays. The patient sample position shows up in the list of sample positions waiting for assays.
   - Select sample numbers in the list of samples waiting for assays to check corresponding patient information and assay type.
   - Select sample numbers in the list of samples waiting for assays and click **[Remove from Waiting List]** to remove the sample from the waiting list.
5) After finishing settings, click **[Exit]** to return to patient assay window.
6) For entering bar code or QR code of samples, select the bar code/ QR code textbox, and scan the bar code or QR code with scanning instrument by pushing the scanning button. Then information is inputted automatically into the textbox.

Note: System Date must match the actual date. System Date follows the short form as it shows in the following figure.

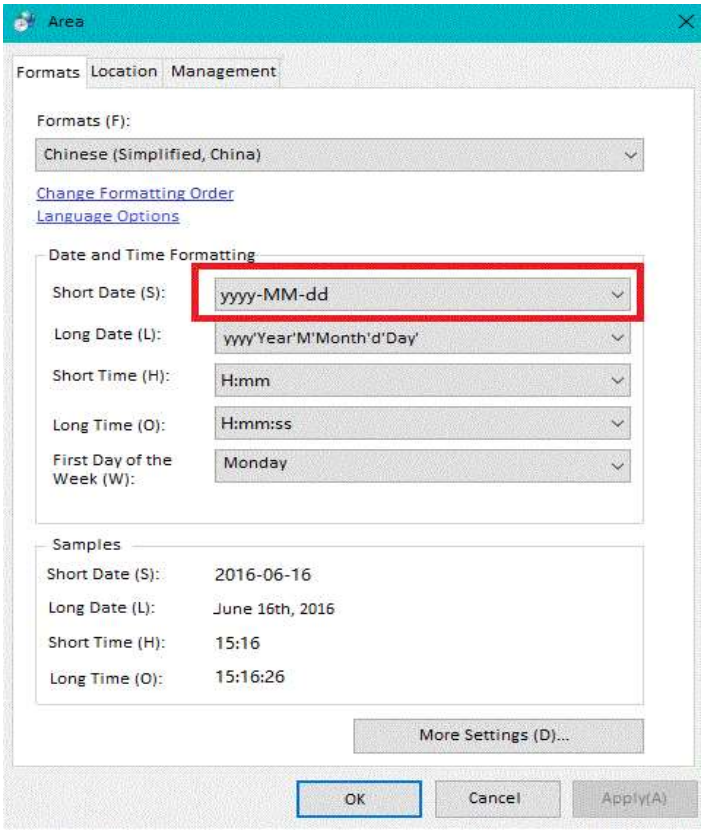

Figure-39

- **Notes of Channel Monitoring Block**
  Channel monitoring blocks in the patient assay window correspond to the channels in the detector. One of the monitoring blocks is shown in the following figure.

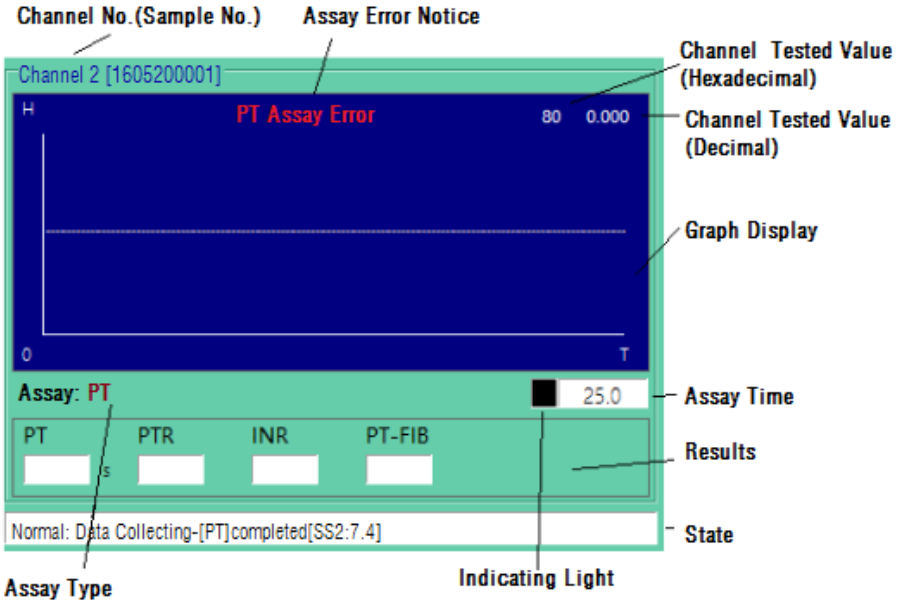

Figure-40

- **Start Assay**
  Note
  Before start, check if the temperature of detector reaches 37℃.
  1) Select [Start Assay]. The system starts with zero procedures. Then operation starts according to selected assay mode.
     After sampling one channel, the corresponding channel color turns green in the monitoring window. A sample number appears next to the corresponding channel at the same time.
  2) During assay, click [**Stop Assays**] to stop assay operations.
     During assay, if "Running out of cuvette" notice prompts at lower right corner of the window, as it shows in the figure below,

Figure-41

Operator should change used cuvettes with empty ones, then click [**Cuvette Setting**] in the toolbar. Click [**Replace**] in the setting window to change cuvette. (White [Replace] button for changing cuvettes other than AT-III; Purple [Replaces] button for changing AT-III channel. The last

channel is often for AT-III assays.) Click [**Continue**] in the information block to continue the assays.

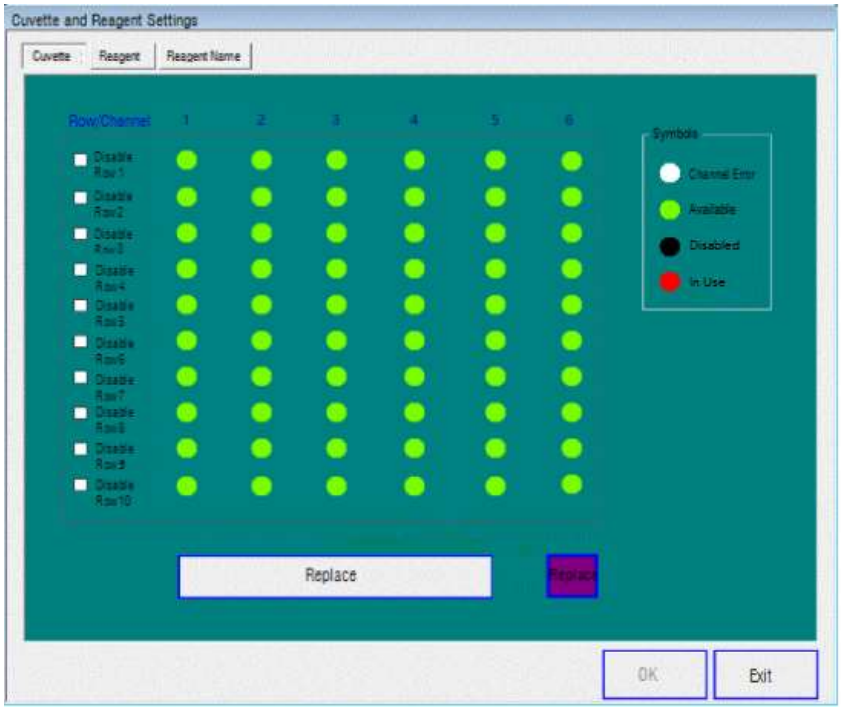

Figure-42

Note

If emergency samples are currently in the test, do not add new emergency samples.

- After adding emergency samples, notice prompts in the emergency sample information block. When completing the current assay before starting an emergency assay, the system prompts a dialog box as in the figure below. Operator needs to follow the steps to add emergency samples in the sample position of the reagent disk, as position 1 is shown in the figure. Then click [Start] to start emergency assays. Click [**Exit**] to exit emergency assays.

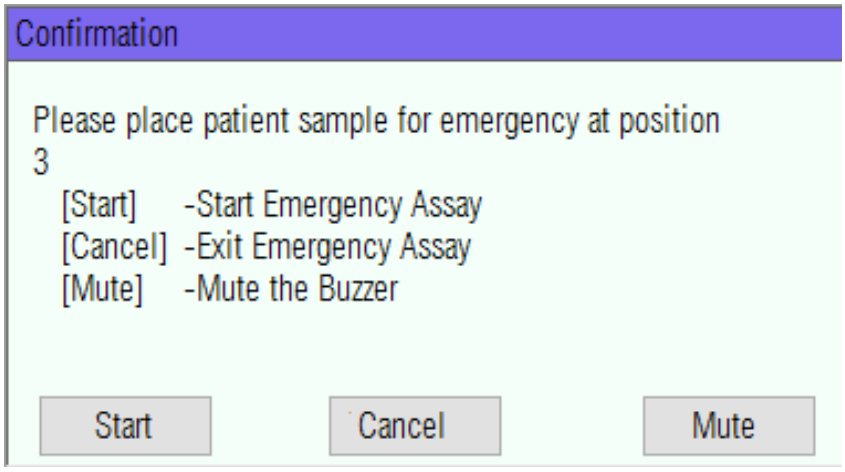

Figure-43

3) After completing the last step of assay, graph monitoring box generates graphical changing process. And detector indicating light turns green. After the reaction, the detector indicating light turns black.
4) System saves assay results in corresponding patient results and determines whether the result is in normal reference range.
5) For results not in normal reference range, alarm shows up in the result.
6) Print the report
   - [Print] is available after completing all assays for normal samples. Click to open print window for normal patient assay results.
   - [Print for Emergency] is available after completing all assays for emergency samples. Click to open print window for emergency patient assay results.

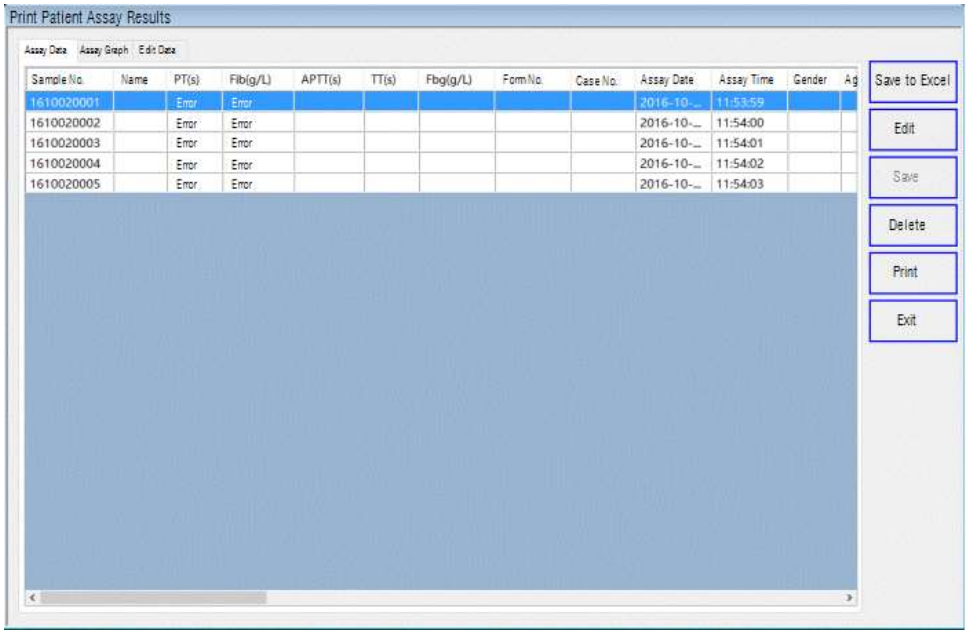

Figure-44

Note : All tested samples for this day are listed in this window. Operations are as follows.

【Assay Data】Option : To observe patient assay data, as in the figure above.

【Assay Graphs】Option: To observe patient assay graphs, as in the figure below.

Select assay type in the assay type list, e.g. PT

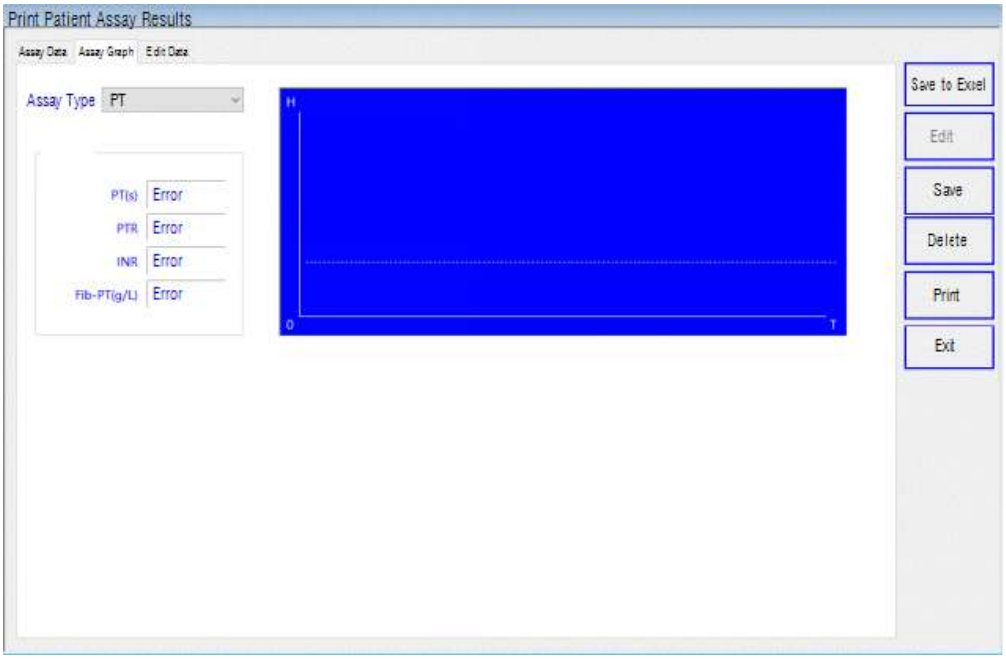

Figure-45

【Editing Data】Option：To edit selected data of patient sample, as in the figure below.

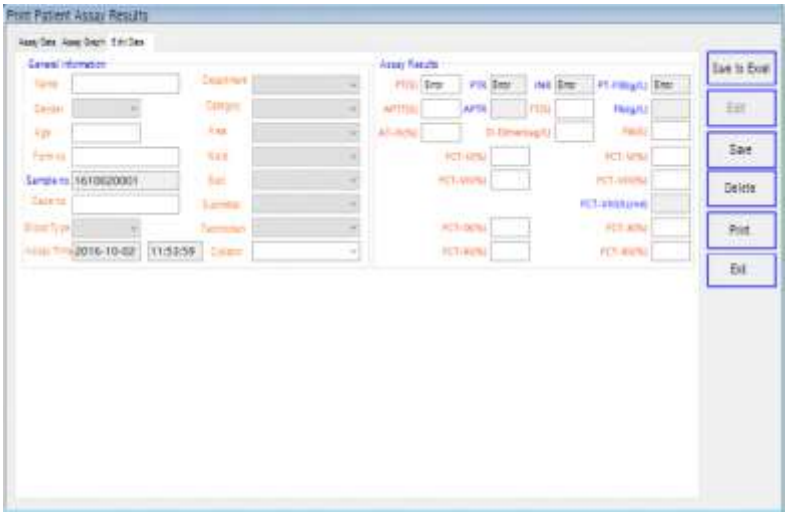

Figure-46

Click **【Edit】**, content in orange tagged textbox is editable. Content in blue tagged textbox CANNOT be changed. However, for PTR, INR, PT-FIB, APTR, Fib, FCT-VIII（U/ml), the system automatically recalculates the result according to data input.

【Save to Excel】：To save data in Excel format.

【Print】：To enter print window, and select patient sample assay report for printing by clicking navigation buttons.

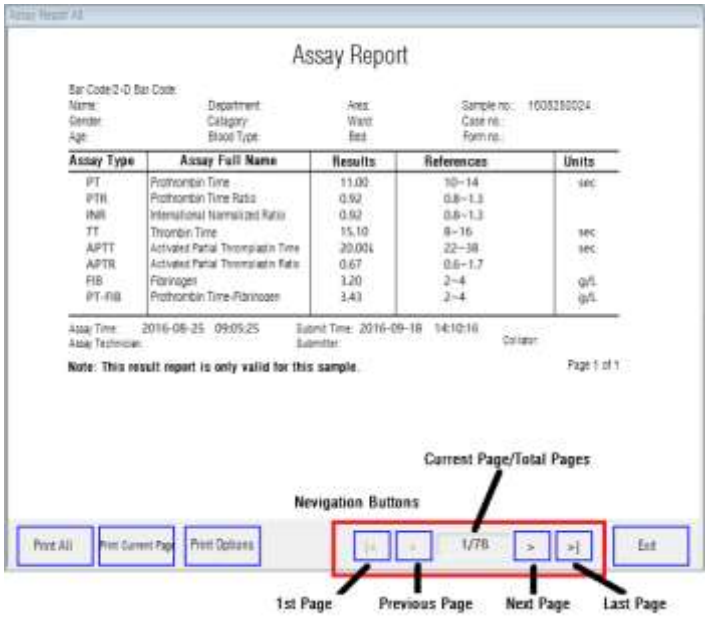

Figure-47

Note:

Do not print reports when the device is collecting data; otherwise, data may be partially lost. During assays, users can enter patient information. However, other operations are Not allowed to avoid system busyness or breakdown.

【Exit】： To return to patient assay window.

9.7.10 Quality Control

Quality control test is for analyzing repeatability and checking assay data accuracy, when system repetitively performs same assay for multiple times.

Figure-48

1) In the pull-down list of [**Assay Analysis**], select [**Quality Control Analysis**] to enter quality control test window.
2) Select assay type for quality control test.
3) Select "inner" or "outer" for sample position. "Inner" means the sample is placed in the inner circle of reagent disk; "outer" means the sample is placed in the outer circle of reagent disk.
4) Select number of testings, usually between 1~20.
5) Enter reagent lot number. When inputting bar code or QR code, select bar code/ QR code textbox, and then scan the code with scanning instrument.
6) When detector temperature reaches 37°Cclick [**Start Test**] to start operation according to assay procedure settings.
   If the setting is incorrect, the background of states information block at the bottom turns yellow for notice.
   During the assay, if running out of reagent or sample, the system will prompt alarm in the alarm block at lower right corner of the window and turns on the buzzer.
7) Click [**Stop Test**] to stop the test.
8) After the test is complete, test results and reaction curve show up in the window.
9) Click [**Quality Control Report**] to enter the quality control data window. Click [Statistical Analysis] to calculate mean, mean square deviation, and variation coefficient of test results.
10) See quality control data window for details of processing quality control data.

Note: Results with errors are not calculated in the statistical analysis.

9.7.11 Calibration Test

In calibration test window, users can check saved calibration parameters and perform calibration test.

Click [**Calibration Test**] under menu [Assay Analysis] to open calibration test window.

Notes: Fib D-Dimer, AT-III calibration curves are linear straight line, as in the figure below.

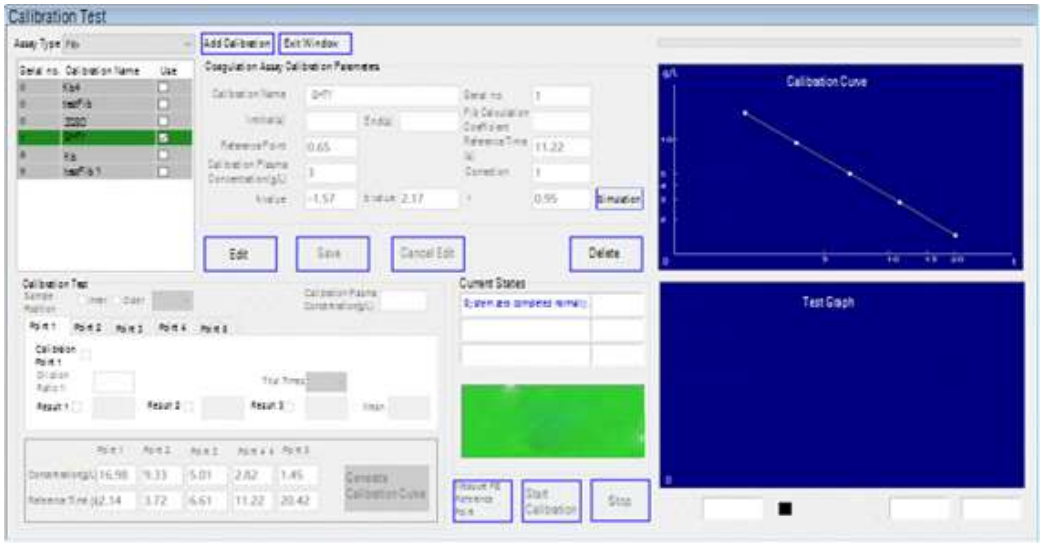

Figure-49

PT, APTT, TT calibration curves are shown in the figure below.

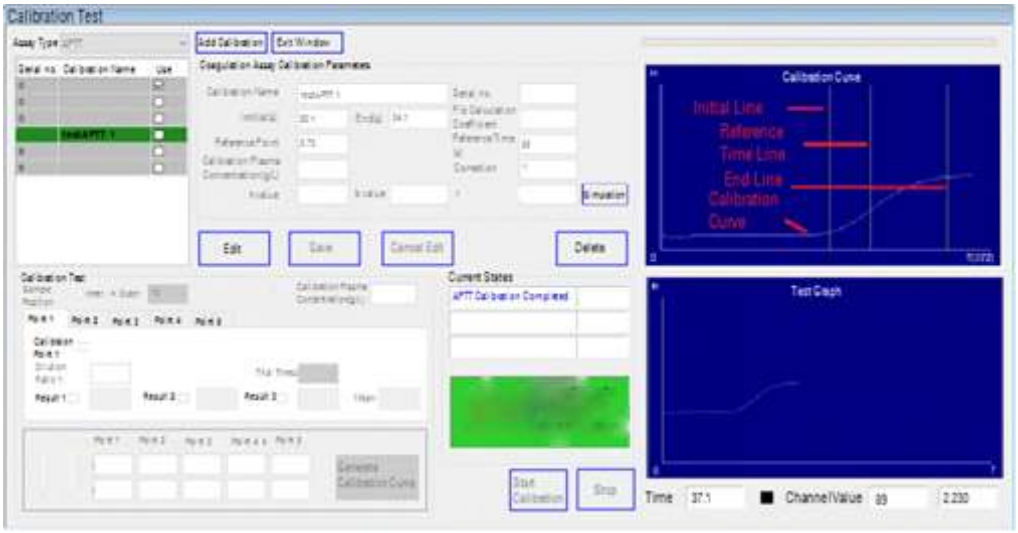

Figure-50

To Observe Calibration

- Select assay type in the assay type box. Calibrations of this assay type are shown in the list to the left.
- Select one calibration to show calibration parameters and calibration curve (in graph monitoring box).

Edit Calibration

- Click [**Edit**]. Click [**Save**] to save editing. Click [**Cancel Editing**] to cancel editing.
- Click [**Delete**] to delete the selected calibration.

Note: Only undimmed textboxes are editable.

Test Calibration

- After choosing a reagent producer, kindly read the instruction book carefully to understand the calibration method. Use normal blood plasma for calibration.
- For assay types that need blood plasma diluting, users can use the automatic dilution function of this device or manually dilute before calibration test.

Placement of Reagent and Sample

1) Place sample and reagent for calibration into the reagent disk. Wait for 10 minutes before the test.
2) If dilution is needed for calibration, place a diluted sample into the diluted sample position of the reagent disk. Place the samples from lower dilution ratio to higher. Diluted sample position 1 is for samples with the lowest dilution ratio.
3) Click **[Add Calibration]** and enter calibration type and other information in the calibration parameters boxes. See details in the notes below.
4) Click [**Start Calibration]** to automatically start the calibration test according to the test settings.

5) After completing the test, the system prompts a notice for users to input reference time for PT, APTT, and TT of coagulation assays (according to the reagent instruction book). The system automatically calculates reference points. For other assay types, system generates calibration parameters automatically.

Note:

- An undimmed textbox and pull-down list refer to content relevant to current calibration, which need to be filled or selected.
- Test graphs show up in the test graph monitoring box.
- During the test, click [**Stop**] any time to stop calibration.

9.7.11.1 PT Calibration

- Select PT and click [**Add Calibration**]. Enter calibration type, Fib coefficient, ISI value, correction coefficient, sequence number, and sample position. Click [**Start Calibration**]. After calibration, input reference time, and click [**Confirm Reference Time**].
- Reference time range is shown in the top notice box, as in the figure below where the range is 6.0~14.5.

Note:

- Reference time is usually the central value of reagent time range for specified assay types.

9.7.11.2 APTT Calibration

Select APTT and click [**Add Calibration**]. Enter calibration type, correction coefficient, sequence number, and sample position. Click [**Start Calibration**]. After calibration, input reference time, and click [**Confirm Reference Time**]. Reference time range is shown in the top notice box, as in the figure below where the range is 20.1~34.1.

Note :

Reference time is usually the central value of reagent time range for specified assay types.

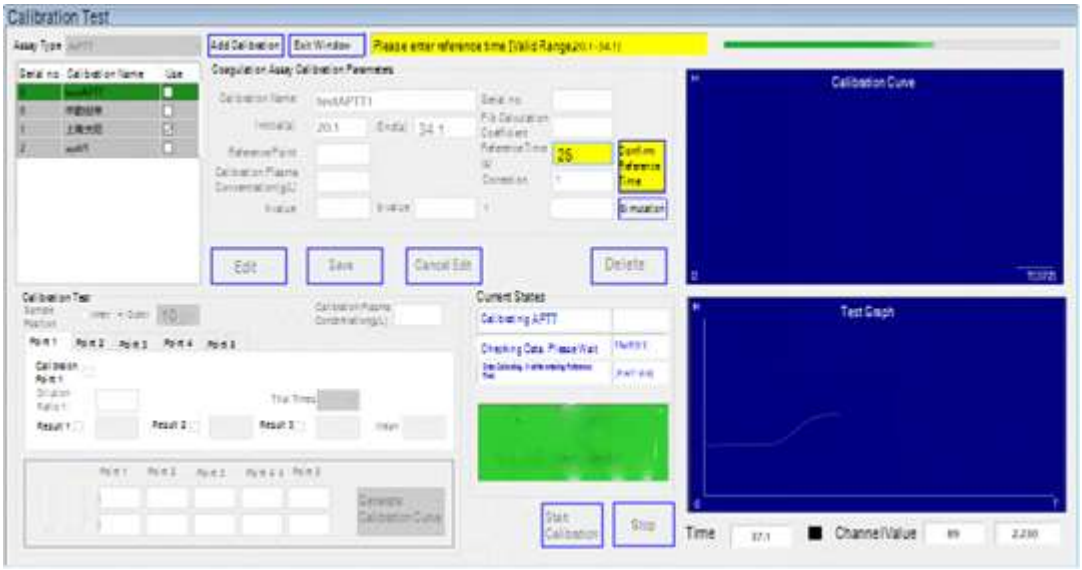

Figure-51

9.7.11.3 TT calibration

Select TT and click [**Add Calibration**]. Enter calibration type, correction coefficient, sequence number, and sample position. Click [**Start Calibration**]. After calibration, input reference time, and click [**Confirm Reference Time**]. Reference time range is shown in the top notice box, as in the figure below where the range is 14.2~22.3.

Note :

Reference time is usually the central value of reagent time range for specified assay types.

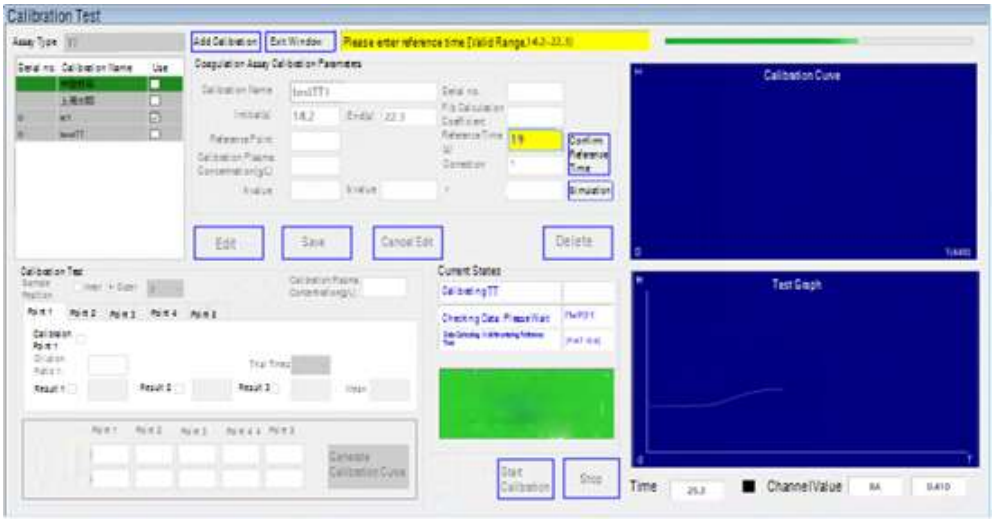

Figure-52

9.7.11.4 Fib Calibration

1) **【Reference Time】:【Reference Time】** can be obtained by PT test of standard sample (FIB quality control plasma). Enter the tested value in **【Reference Time】** textbox.
2) **【Reference Point】:** Enter calibration type, correction coefficient, sequence number, calibration plasma concentration, and FIB quality control plasma sample position. Click **【Test FIB Reference Point】**. System automatically obtains the reference point by testing FIB standard plasma sample.
3) **【Start Calibration】:** After confirming reference time and reference point, select at least 2 calibration points, and set dilution ratio and number of test times for each calibration point. Select sample position. Click **【Start Calibration】**. System prompts test setting window for each calibration point for user to edit corresponding test settings. After setting, click **【Save Test Mode】** and【Exit】. System starts test for current calibration and fills the result textbox for each calibration test automatically. After completing all calibration point, a notice prompts for user to select value for each calibration point. User can check the box near the result textbox for the system to automatically calculate corresponding mean value. Click **【OK】** in the notice block.

Then system prompts a notice for clicking【**Generate Calibration Curve**】. System generates calibration curve and calculates values of k and b. Save the data. Click【**OK**】in the notice block. At last, test setting window prompts for user to confirm whether settings reset to the initial settings. If confirmed, click【**Exit**】to complete calibration.

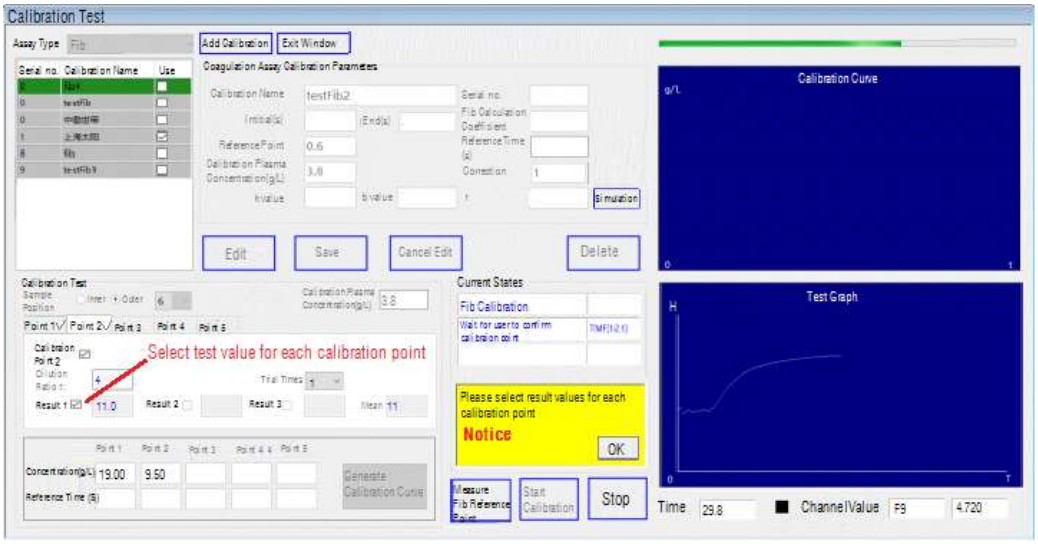

Figure-53

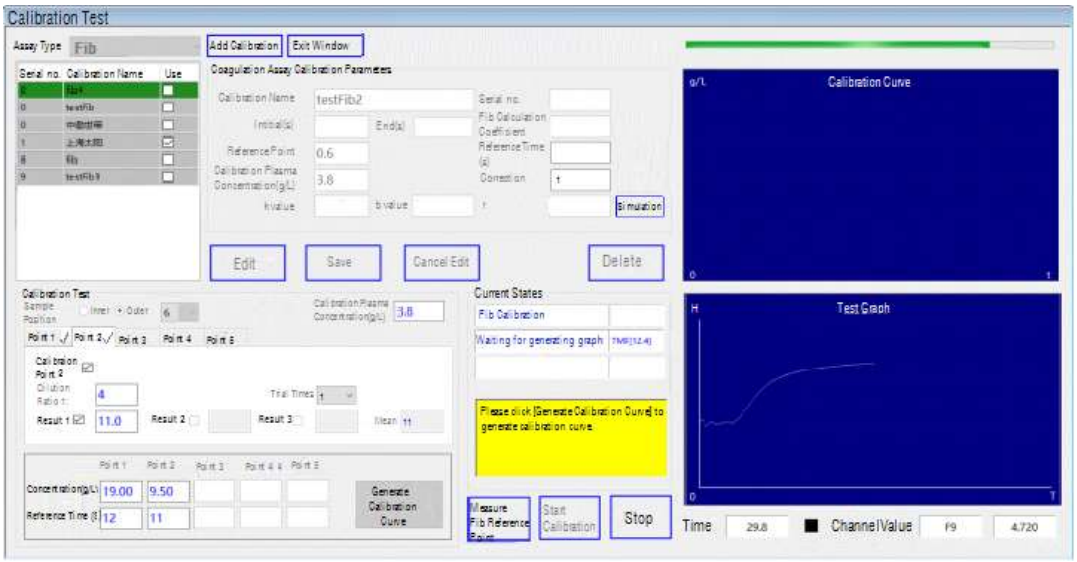

Figure-54

Figure-55

9.7.11.5 Dimer Calibration

1) Select D-Dimer and click **【Add Calibration】**.
2) Enter calibration type, correction coefficient, sequence number, and calibration plasma concentration. Select at least 2 calibration point and set dilution ratio and number of test times for each calibration point. Select sample position. Click **【Start Calibration】**. System prompts test setting window for each calibration point for user to edit corresponding test settings. After setting, click **【Save Test Mode】** and **【Exit】**. System starts test for current calibration and fills the result textbox for each calibration test automatically. After completing all calibration point, a notice prompts for user to select value for each calibration point. User can check the box near the result textbox for the system to automatically calculate corresponding mean value. Click **【OK】** in the notice block. Then system prompts a notice for clicking **【Generate Calibration Curve】**. System generates calibration curve and calculates values of k and b. Save the data. Click **【OK】** in the notice block. At last, test setting window prompts for user to confirm whether settings reset to the initial settings. If confirmed, click **【Exit】** to complete calibration.

   Note: Set tracking point low before calibration, usually lower than 60H.

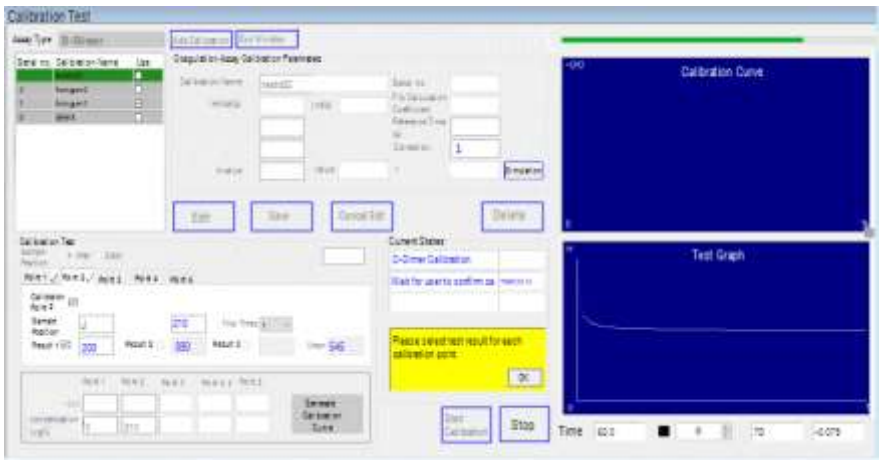

Figure-56

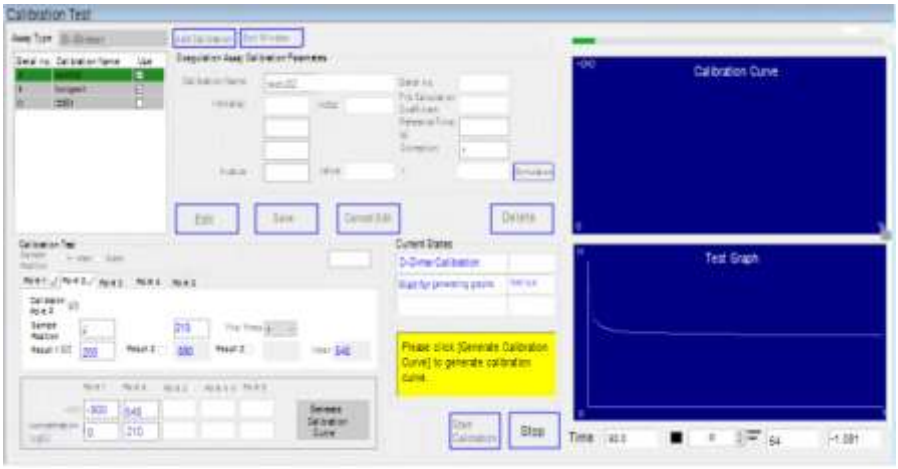

Figure-57

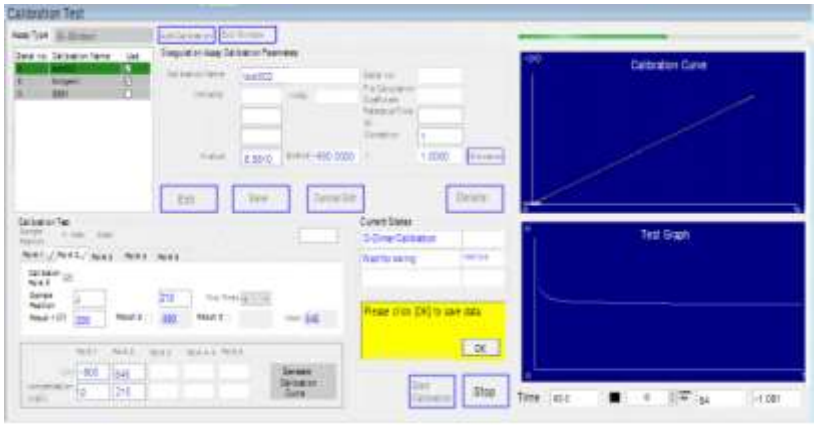

Figure-58

9.7.11.6 AT-III Calibration

- Select AT-III and click **【Add Calibration】**.
- Enter calibration type, correction coefficient, sequence number, and 100% standard activity concentration. Select at least 2 calibration point, and set dilution ratio, activity concentration, and number of test times for each calibration point. Select sample position. Click **【Start Calibration】**. System prompts test setting window for each calibration point for user to edit corresponding test settings. After setting, click **【Save Test Mode】** and **【Exit】**. System starts test for current calibration and fills the result textbox for each calibration test automatically. After completing all calibration point, a notice prompts for user to select value for each calibration point. User can check the box near the result textbox for the system to automatically calculate corresponding mean value. Click **【OK】** in the notice block. Then system prompts a notice for clicking **【Generate Calibration Curve】**. System generates calibration curve and calculates values of k and b. Save the data. Click **【OK】** in the notice block. At last, test setting window prompts for user to confirm whether settings reset to the initial settings. If confirmed, click **【Exit】** to complete calibration.

Note: Set tracking point high before calibration, usually higher than 90H.

Figure-59

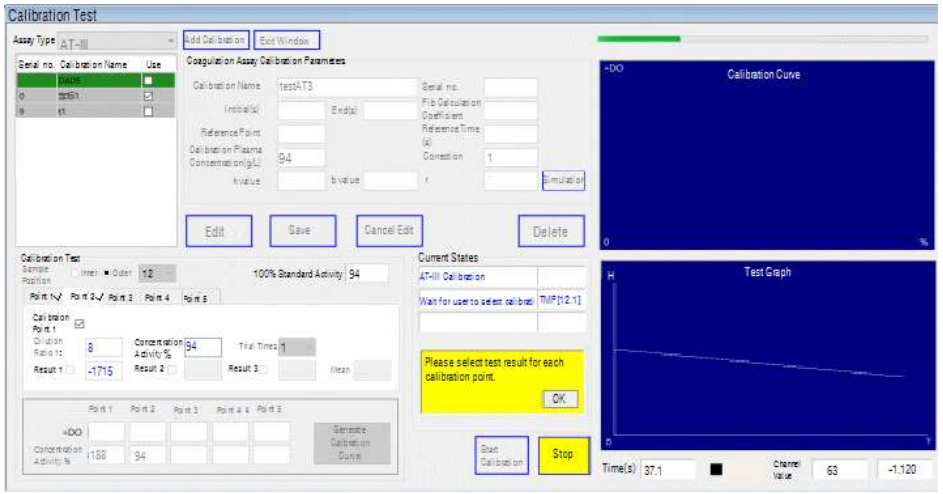

Figure-60

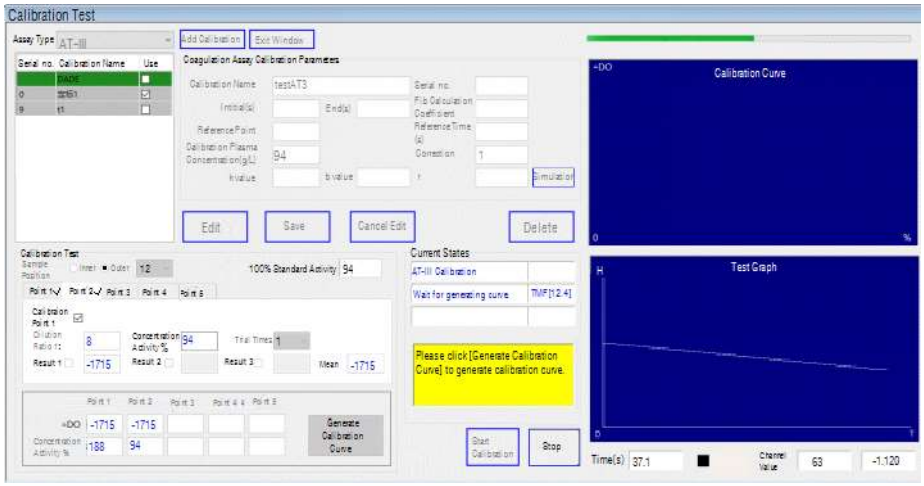

Figure-61

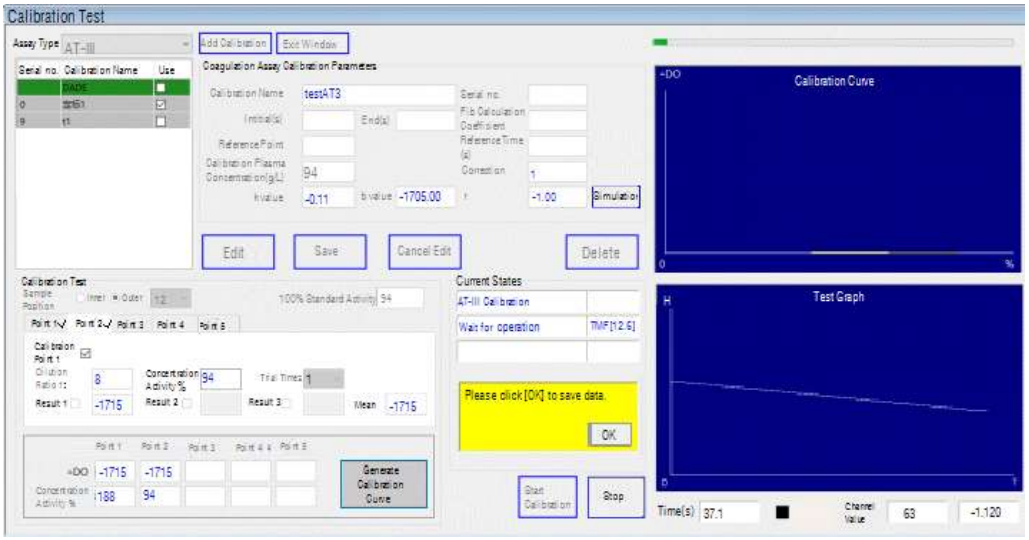

Figure-62

9.8 Data management

9.8.4 Patient Data

1) Search Patient Data

Users can search patient information and assay results in patient data, including normal patient data and emergency patient data, for reading, editing, deleting, and printing.

Results are given in the list of assay data. Currently selected patient data from the list is shown in the general information box. Additionally, selected data can be saved as Excel file by clicking【**Save to Excel**】.

Search Normal Patient Data：

Click【**Normal Patient Data**】under【**Data Management**】to enter normal patient data window.

Search for Emergency Patient Data：

Click【**Emergency Patient Data**】under【**Data Management**】to enter emergency patient data window.

Normal patient data window is shown as follows:

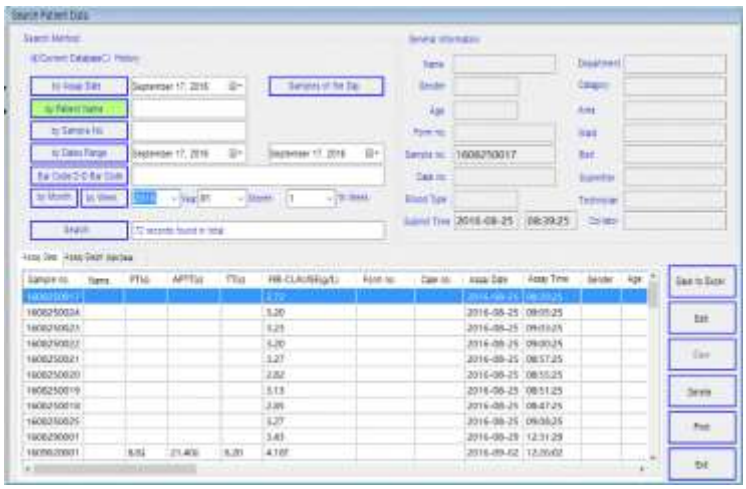

Figure-63 Emergency patient data window is shown as follows.

Figure-64

(1) Select present database or history.
(2) Select filter type and enter the key words. Filter types are listed as follows:
【by Assay Date】: Select assay date to show all data of selected date.
【Samples of the Day】: To list all tested samples of the present day.
【by Patient Name】: Enter the patient name to show the patient data.
【by Sample Number】: Enter sample number to show the sample data.
【by Dates Range】: Select two dates to show all data in the dates range.
【by Bar Code/QR Code】: To search by bar code/ QR code.
【by Month】: To search by entered month and year.
【by Week】: To search by entered week, month, and year.
(3) Click **【Search】** to search all filtered records showing under the list.
Select one record to show the patient's information in the general information block.
Click **【Assay Graphs】** option and select one assay type to see the assay graph of the selected one.

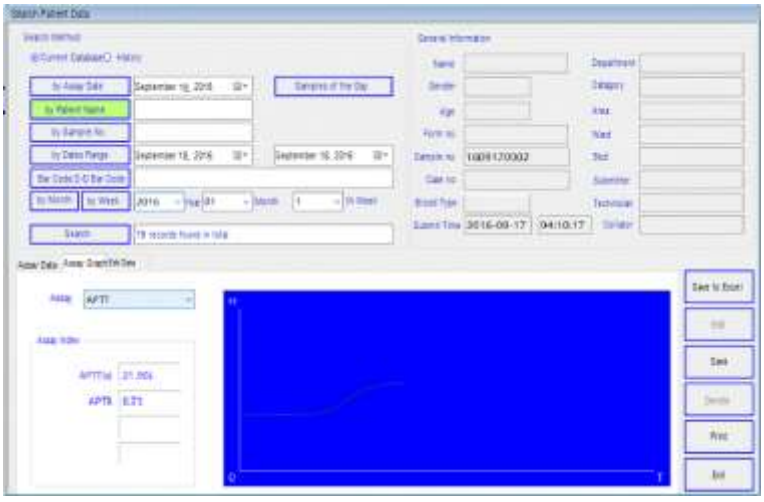

Figure-65

2) Editing Patient Data

- **Delete Data：** Select one record and click【**Delete**】to delete the record.
- **Editing Data：** Select one record and click【**Edit**】. Switch the option to data editing panel to edit the data. When finishing editing, click【**Save**】to save data editing.
- In the data editing panel, blue tagged textbox is not available for editing in general information block. In the assay results block, blue tagged text-box content is automatically calculated by the system.

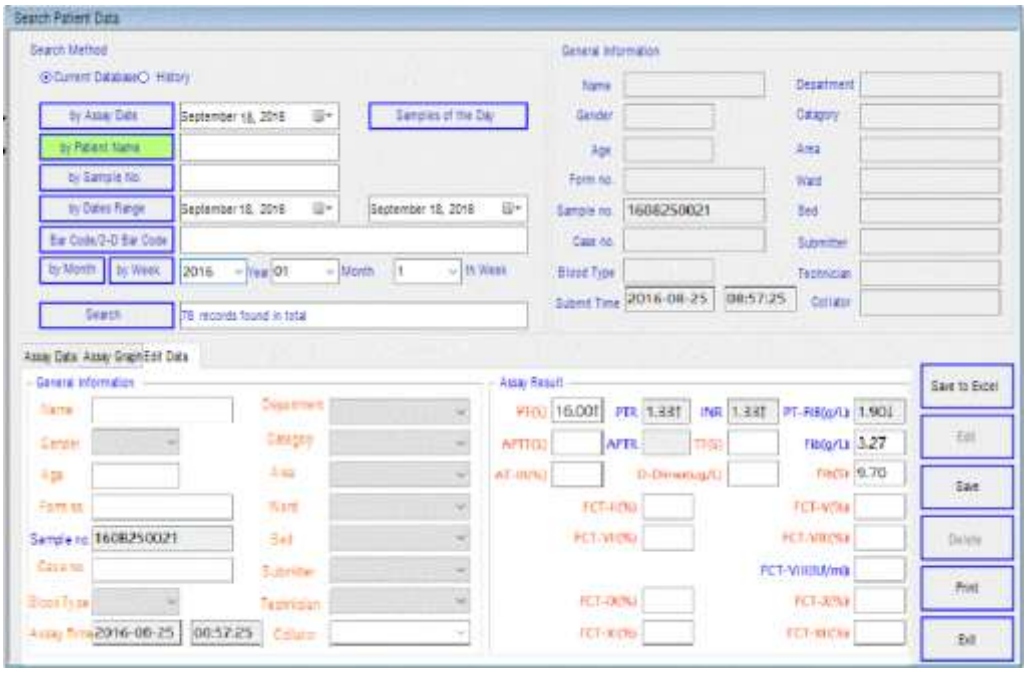

Figure-66

Print : Click【**Print**】 to preview the printed report. Click【**Print All**】or 【Print Current Page】to print report when printer connection is normally functioning.

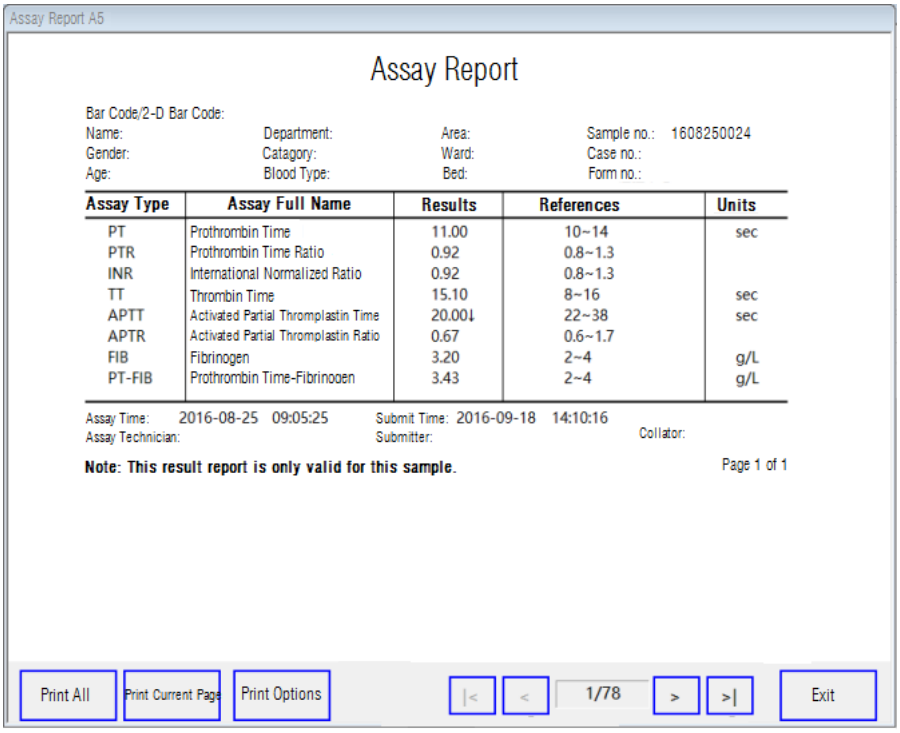

Figure-67

【**Print All**】: To print all reports.

【**Print Current Page**】: Use the navigation button to select one report to print.

【**Print Options**】: Print options window prompts for selecting specified items to print. Check items for printing, and click [**OK**] to print checked items, which are also shown in the reports.

9.8.5 Quality Control Data

Quality control data is saved data of quality control test. User is allowed to do quality control data analysis for data in a specified period or multiple records in continuing test.

Click 【**Quality Control Data**】under【Data Management】menu to enter quality control window.

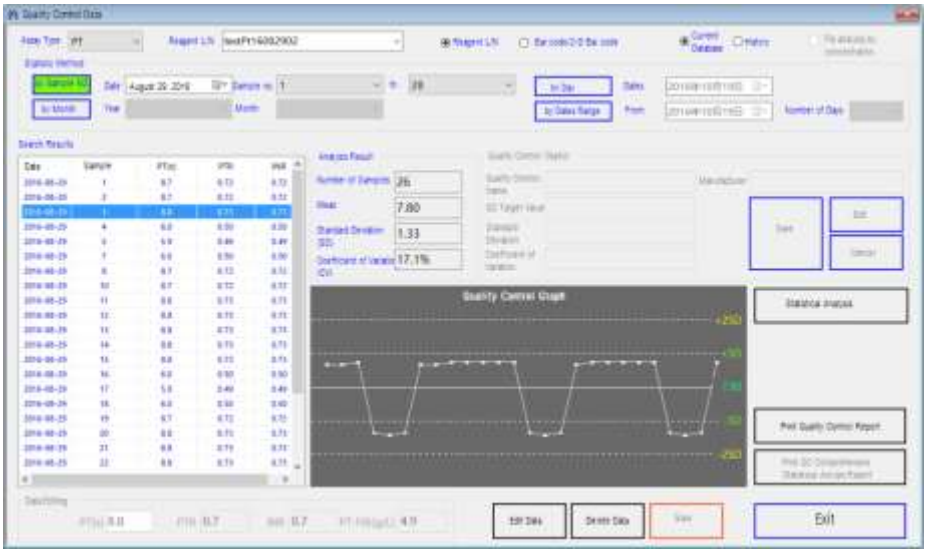

Figure-68

1) Statistical Analysis

Select assay type, reagent lot number or bar code, and database for analysis. If the assay type is FIB, 【FIB Analysis by Concentration】 option is available. Check to use Fib concentration for data in the analysis list. Uncheck to use Fib tested time value for the data analysis.

【Reagent L/N】: To filter analysis data by reagent lot number.

【Bar Code/QR Code】: To filter analysis data by bar code/QR code.

【Current Database】: To select currently presented database.

【History】**:** To select data backup from history records.

Select Analysis Method

【Statistics by Sample Number】 To analyze data in selected sample number range of selected date.

【Statistics by Day】 To analyze all quality control data of selected day.

【Statistics by Month】 To do statistical analysis for data means of all days in the selected month.

【Statistics by Dates Range】 To do statistical analysis for data means of selected dates range from a specified day in a selected month.

Click **【Statistical Analysis】** to do statistical analysis for selected data. Data is shown in the search results block. Results and quality control graphs are shown in the results text block.

When click **【Statistical Analysis】**, if analysis conditions are not satisfied, system prompts notice dialog box, as in the following figure.

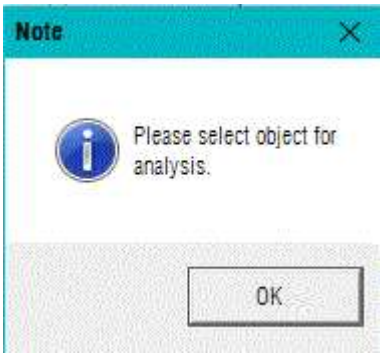

Figure-69

2) Data Editing

Data editing function is only available when user selects analysis by 【Statistics by Sample Number】or【Statistics by Day】.

3) To Edit Data

Select one of the data records in the result list and click【**Edit Data**】. Edit the data in the data editing block. Click【**Save**】to save the data. Click【**Cancel**】to cancel data editing.

Note：After editing, kindly click 【**Statistical Analysis**】to refresh data

4) To Delete Data：

Select one of the data records and click【Delete Data】to delete the data.

5) Report

【**Print Quality Control Report**】: Only available when doing analysis by sample number or by date. Click the button to enter report preview window and print the report.

【**Print Comprehensive Quality Control Report**】: ONLY available when doing analysis by month or by dates range. Click the button to enter report preview window and print comprehensive report.

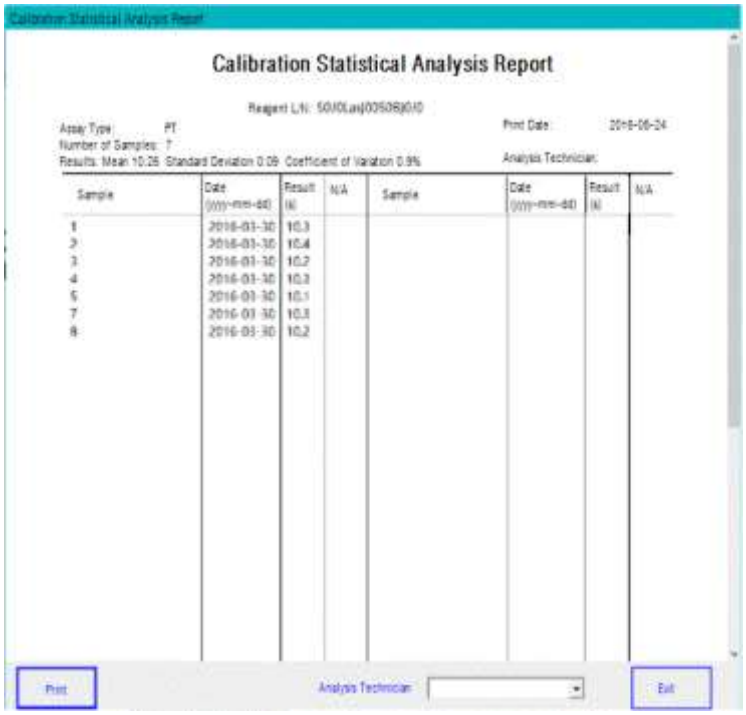

Figure-70

【**Print**】: To print the report using printer.
【**Exit**】: To return to quality control data window.
【**Select Analyzer**】Pull-down List : To select the physician who performs analysis.

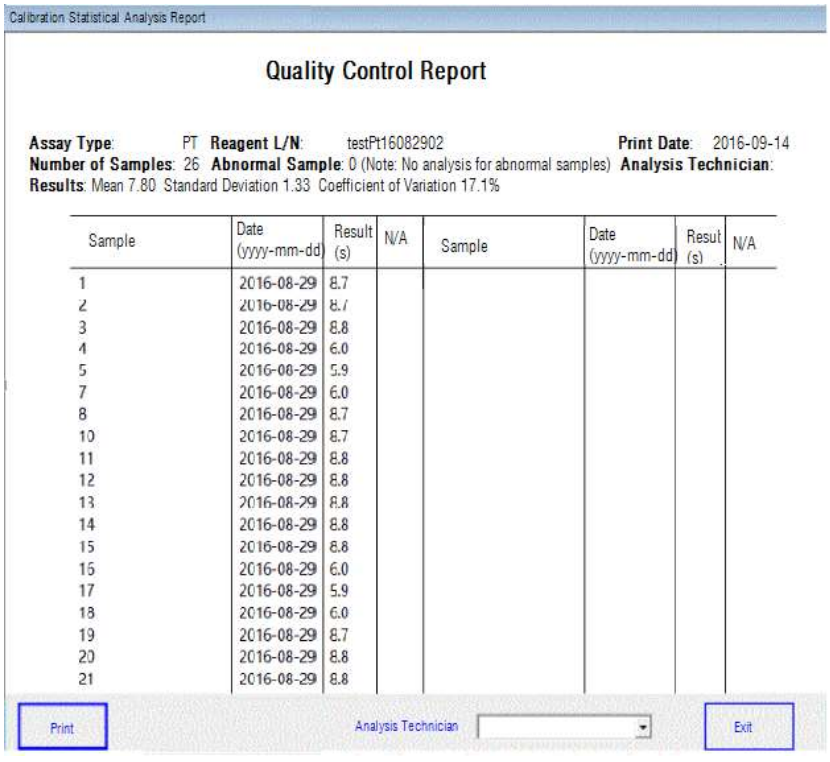

Figure-71

【**Print**】: To print the report using printer.
【**Exit**】: To return to quality control data window.
【**Company/Organization**】**Text-box** : To enter company/organization.
【**Comment**】**Text-box** : To comment on the analysis report.

6) Quality Control Object

Only available for analysis by month or by dates range.
【**Edit**】: To edit the data of quality control object.
【**Save**】: To save data editing.
【**Cancel**】**:** To return without saving.

9.8.6 Hospital Data

Hospital Data includes information of category, department, blood type, area, ward, bed number, clinical submitter, and clinical technician.
Click【**Hospital Data**】under【Data Management】 to enter hospital data window. Click options to enter data panel, as it shows in the figure below**.**

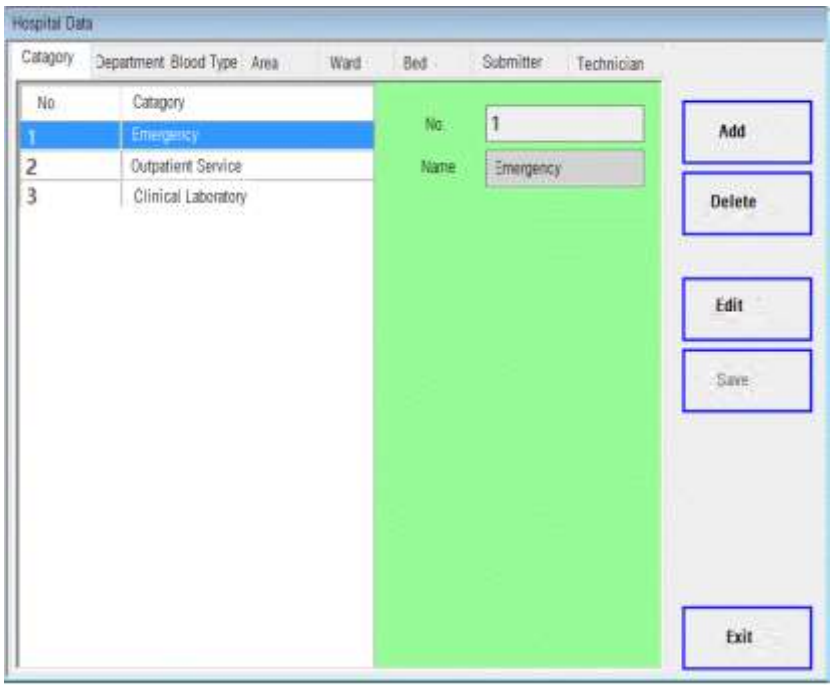

Figure-72

【**Add**】: To add new number and enter category.
【**Edit**】: To edit selected category.
【**Save**】: To save added category.
【**Delete**】: To delete selected category.
【**Exit**】: To exit the window.
Setting operations are similar for department, blood type, area, ward, bed number, submitter, and technician.

9.8.7 Data backup

Assay data is saved in the current database. With increasing data size, searching data process might be getting slower. Data saving capacity is also limited. User can select part of the data to save in the history database.

Click【**Data Backup**】under【**Data Management**】 to enter the data backup window. Data backup window is divided into data backup block and data deleting block.

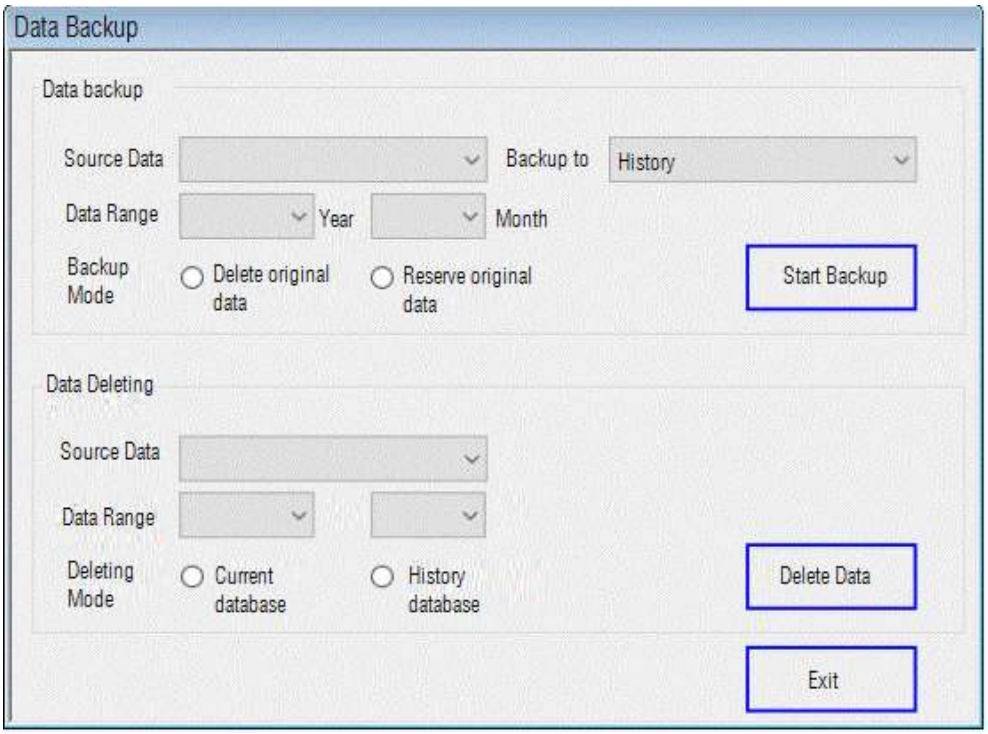

Figure-73

1) Data Backup Operations

- Select data for backup in the pull-down list of【Source Data】
- Select location for data backup in the pull-down list of【Backup To】
- Select 【Data Range】(All data, whole year, month & year) for data backup
- Select backup mode. 【Delete Original Data】to delete the original data in current database after backup ;【Reserve Original Data】to reserve the original data in the current database after backup.
- Click【**Start Backup**】to start data backup. Wait for a while until the notice "Backup Completed" shows up.

2) Data Deleting Operations

- Select data to delete in 【**Current Database**】or【**History Database**】
- Select data to delete in the pull-down list of【**Source Data**】
- Select【**Data Range**】(All data, whole year, month & year) to delete
- Click【**Delete Data**】to start to delete data. A notice "Deleting Completed" prompts after completing.

9.9 System alarm and Treatment

9.9.4 System Alarm

User can see and edit alarm settings and result in the alarm setting window.

- Click【**Alarm Setting**】under【System Maintenance】to enter alarm setting widow, as in the figure below.

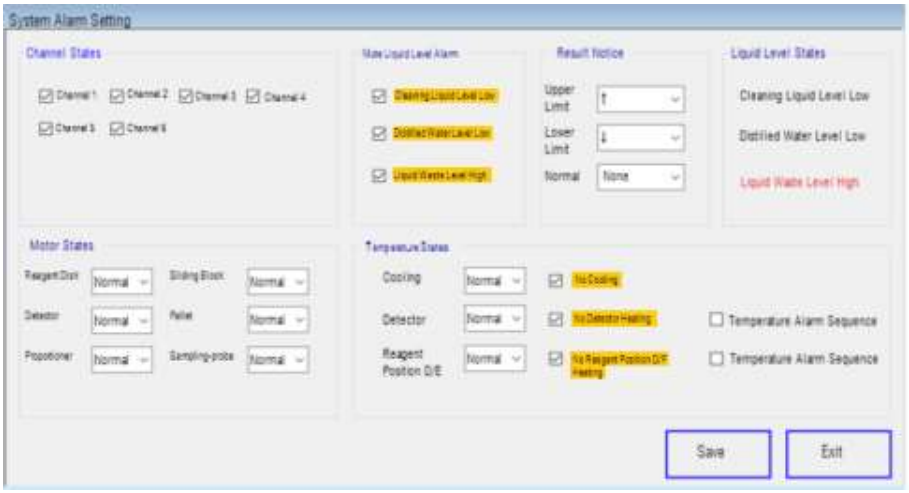

Figure-74

- Click【**System Alarm**】, and【Check System Alarm】, Only checking alarm and alarm results are allowed in checking system alarm window. Editing results is Not allowed.
- When there is a system alarm, RED alarm icon prompts in the toolbar. Click it to open【**Check System Alarm**】window.
- When the system prompts notice for caution, yellow notice icon prompts in the toolbar.
- Click it to open 【**Check System Alarm**】window.
- Text in red font means alarm. Background in yellow means notice for caution in this window.

1) Assay Result Notice

Set assay result notice for assay result. When generating patient result report, system automatically determines whether the assay result is in the reference range and adds result notice next to the assay result.

2) Liquid Level Indicating Alarm

There are 3 types of liquid level indicating alarm: Distilled water level alarm, cleaning liquid level alarm, and liquid waste level alarm.

Cleaning liquid level alarm pops up when cleaning liquid container is empty.

Distilled water level alarm pops up when distilled water container is empty.

During assay, if cleaning liquid level or distilled water level alarm pops up, user must

change the cleaning liquid or distilled water container; otherwise, assay processing stops.

Liquid waste level alarm pops up when liquid waste container is full. During assay, if this alarm pops up, user must empty the liquid waste container Immediately otherwise, assay processing stops.

3) Liquid Level State

It shows distilled water or cleaning liquid container low liquid level alarm, and liquid waste container high liquid level alarm.

When alarm, texts become rev d; black texts mean no alarm.

4) Temperature Alarm

System temperature nis monitored at the upper right corner of the main interface, as it shows in the figure below

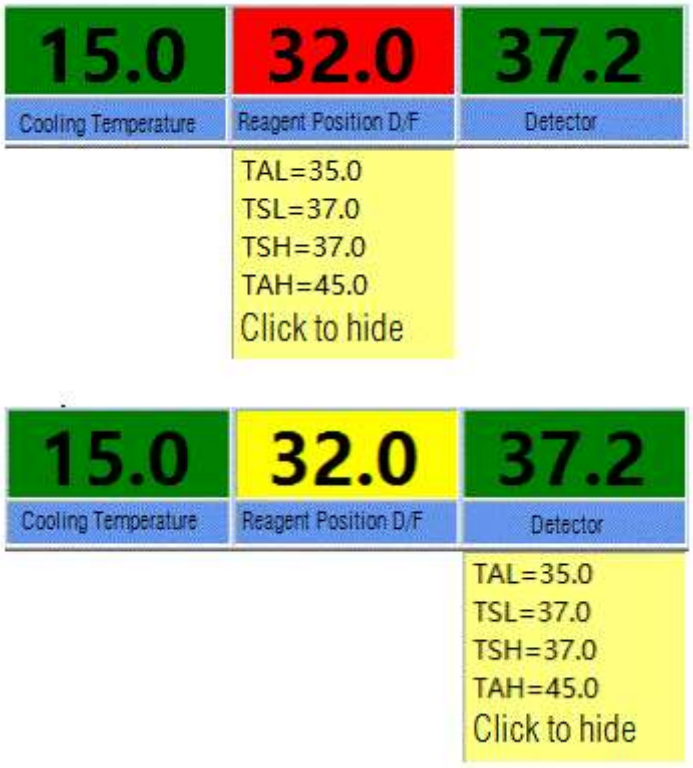

Figure-75

- As in the figures above, the system sets 3 temperature control spots: cooling temperature, reagent position D/F, and detector.
- If the background is green, the temperature is between the upper limit (TAH)and lower limit (TAL).
- If the background is yellow, the system is preheating. Heating temperature is lower than temperature control spot lower limit (TSL); while cooling temperature is higher than temperature control spot upper limit (TSH).
- If the background is red, the temperature is beyond the lower limit (TAL) and upper limit (TAH). Alarm pops up. If during the assay, the system will stop operations.
- Click temperature tag to show temperature settings.
- **TAL:** Temperature Alarm Lower Limit
- **TSL:** Temperature Control Spot Lower Limit. When the temperature is lower than this value, the heating switch turns on in heating system, or the cooling switch turns off in the cooling system.

- **TSH**：Temperature Control Spot Upper Limit. When temperature reaches this value, the system turns off heating switch for heating system or turns on the cooling switch for the cooling system.
- **TAH:** Temperature Alarm Upper Limit

To Check：

- 【**No Cooling**】：To turn off cooling
- 【**No Detector Heating**】：To turn off detector heating
- 【**No Reagent Position D/F Heating**】：To turn off reagent position D/F heating.
- 【**Temperature Alarm Sequence**】：Check this icon for system to stop operation when temperature alarm appears by determining temperature alarm as system error.
- **Warning**：When the system abnormally shuts down, temperature control system may not turn off. If this happens, kindly turn off the temperature control system, and restart the device before rebooting the temperature control system.

5) Motor Alarm

When the device is in motion, if there are any problems with the motor, the system will not operate normally. Notice prompts for operator.
If this happens, the system will stop operations.

9.9.5 Alarm Treatment

For alarms mentioned above, users are recommended to solve the problem by using the software first.

9.9.5.1 Temperature Alarm Treatment

When temperature alarm appears, if temperature is lower than 42℃, user can solve the problem by temperature correction. If temperature is higher than 42℃, user Must consult professional maintenance staffs.
Click **[System Maintenance]**, and **[System Test]**to open system maintenance window. Users can do temperature correction for detectors and reagent disk in the temperature correction area.
[Password]

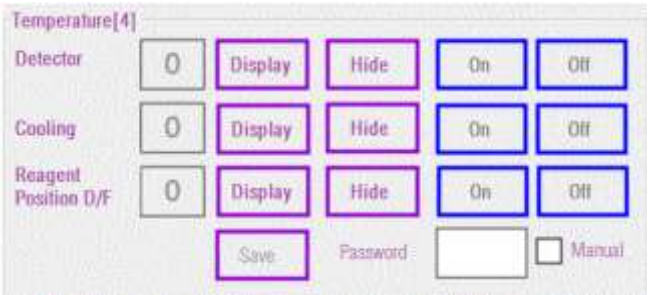

Figure-76

- Put the thermometer in the detector or holes of reagent disk. After about 20 minutes, read the value and check whether it matches the monitored value in the window.

- Adjust correction value in the temperature correction window. Increase the correction value to decrease the temperature value; Decrease the correction value to increase the temperature value. After adjusting, click '**confirm**' to save.
- Adjust the temperature about 37℃ as in thermometer reading. After adjusting, if the temperature cannot be set about 37℃, or always higher than 42℃, there must be problems in hardware. Kindly consult the maintenance staff if this happens.

9.9.5.2 Channel Alarm Treatment

If channel alarm appears, click【**Automatic Sensitivity Tracking Test**】under【System Maintenance】to open the window of automatic sensitivity tracking test.

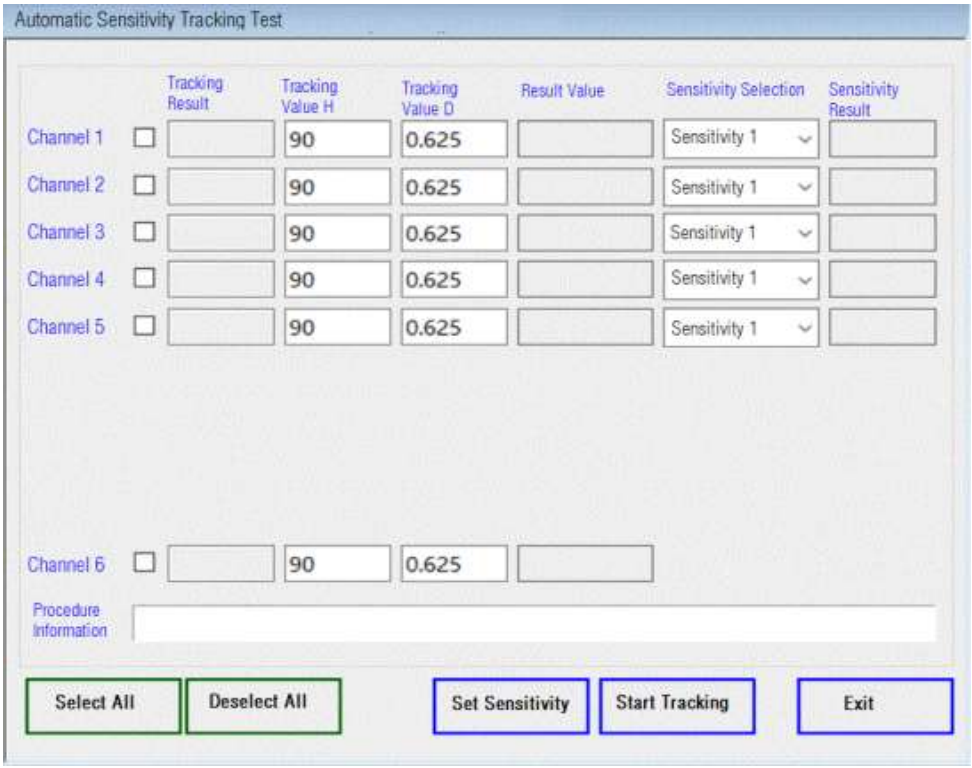

Figure-77

Select channel for test. Enter tracking point in 【Tracking Value H】between 20~E0.To select sensitivity, click【**Set Sensitivity**, and click【Start Tracking】. Tracking results will appear in the result box.
If the result says Ok, the channel is normal; if it says Fail, then there is error in channel tracking.
If tracking fails 3 times, user can set this channel to be in alarm state. The system will avoid using this channel when operating assays.

9.9.5.3 Alarm Setting

When an alarm appears, the user
needs to check the causation of the alarm and repair the device if needed.

When the device is back to normal, the user needs to do alarm settings in the pull-down bar of system maintenance, as it shows in the figure below:

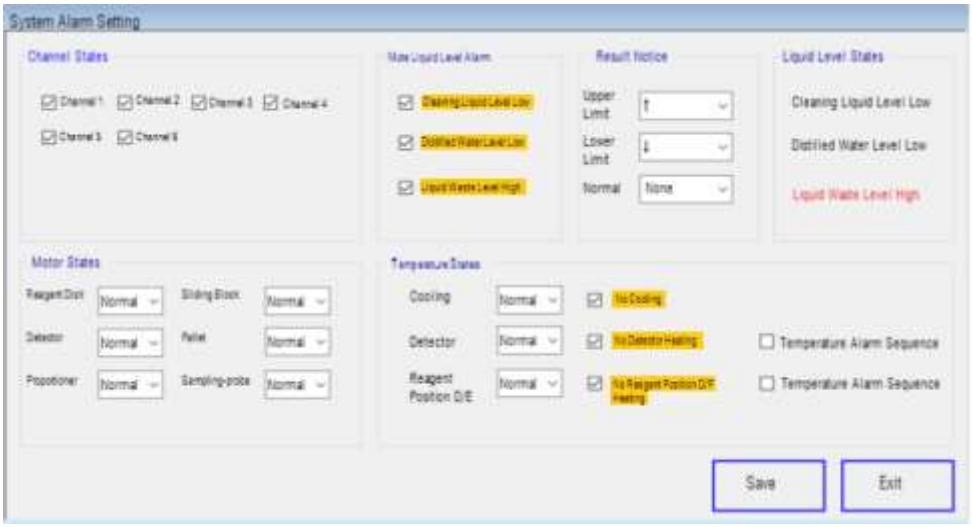

Figure-78

1) **Channel State Area**
   Checked channels are normal channels. Texts are in black. Channels are functioning.
   Unchecked channels have problems. Texts are in red. Channels are skipped by the system during assay.
2) **Temperature State Area**
   User can set temperature control state of reagent disk and detector. When temperature alarm appears, system automatically sets corresponding temperature control state to be in error state (Text turns red). Check to prevent heating and cooling. Background is in yellow.
3) **Motor State Area**
   User can set states of components in motion. "Normal" means the component is functioning (black font). "Abnormal" means the component has problem, which is not functioning (red font).
   Stop Liquid Level Alarm
   【Cleaning Liquid Low】: Check for system to ignore cleaning liquid level low alarm. The background is yellow.
   【Distilled Water Low】: Check for system to ignore distilled water level low alarm. The background is yellow.
   【Liquid Waste High】: Check for system to ignore liquid waste level high alarm. The background is yellow.

9.9.6 Emergency Treatment

When device is in motion, if abnormal situations happen, such as abnormal movements of sampling-probe, sliding block, pallet, reagent disk, or other problems, which require stopping the device operation immediately, push the emergency button to stop operation. Shut down the system and check the problems.

Check broken-down components and confirm there is no error. Then click 【**System Alarm**】under【System Maintenance】to restore the system. Click 【**System Debug**】to debug the system and then reboot the device.

Figure-79

9.10 Printer and report setting, Communication Setting

9.10.4 Report Setting

Click【**Setting**】then【Report Setting】to open report setting and printer selection window.

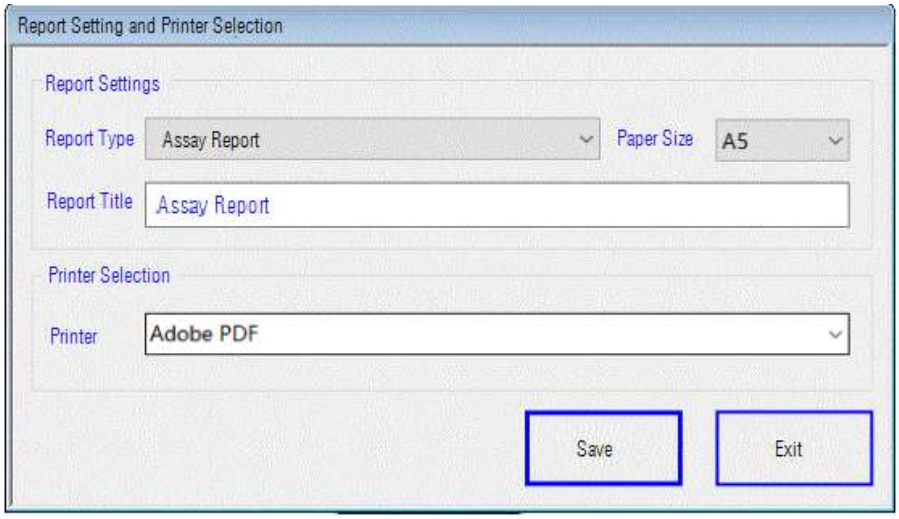

Figure-80

Report Type: To select report type in the pull-down list.
Paper Size: To select paper size. (A4 or A5). For the assay report, select A4 or A5. For others, only select A4.
Report Title: To enter report title.
Save: To save change.

9.10.1 Printer Setting

Select installed printer in the pull-down list of【Printer】. Then click【**Save**】.

9.10.2 Communication Setting

This device is installed with specified 232 serial port and acquisition card for data collection.
232 serial ports have two ports, COM2 and COM3 as usual.
Click【**Setting**】, then【Terminal Setting】 to open communication terminal setting dialog box.

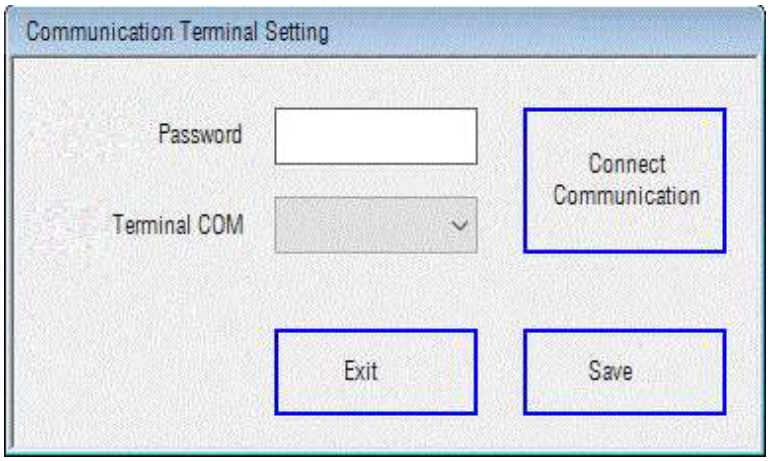

Figure-81

Enter【Password】and select one terminal in the pull-down list of【Terminal COM】. Click【**Save**】, then click【**Connect Communication**】. If the following dialog box appears.

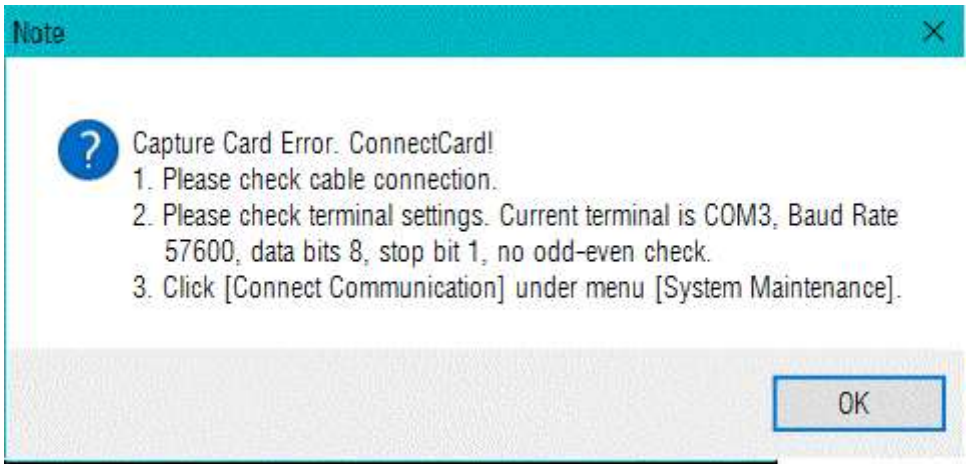

Figure- 82

Kindly connect 232 cables to 232 serial port of another computer and confirm the connection. Then click【Connect Communication】.

9.11 Manual Test Software Use Guide

- Manual test software is for emergency of this automatic blood coagulation analyzer.
- If automatic blood coagulation analyzer hardware has problems（e.g. Motor failure), software program for automatic mode will not be functioning normally. Use this software for emergency assays.
- Database for this software is the same file as the database for automatic mode software.

9.11.1 Software Use Conditions

- One ancillary electrical sampling pipette.
- Liquid waste container is not full.
- Temperature control of detectors is normal.
- Channels work normally. (At least one channel must work normally).

9.11.2 Preparation Before Use

- Connect electrical sampling pipettes to the pipette port.
- Test the sampling pipette. When users push the sampling button on the pipette until the button reaches the limit, liquid waste indicates light should turn off. When the user releases the button, the light should turn on, which means the pipette is connected successfully.

9.11.3 Software Use Guide

1) Click【**System**】menu, then【Manual Assay Mode】to enter manual mode interface.

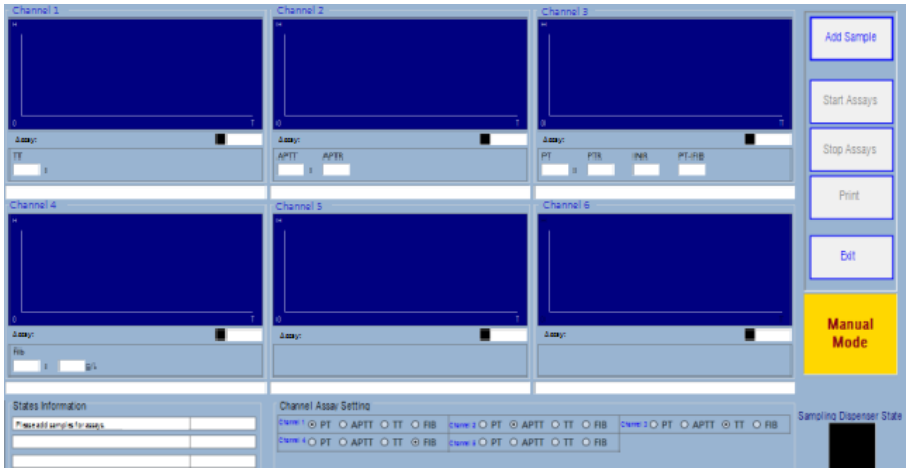

Figure-83

2) Before the test, run this software first to confirm that detector temperature meets requirements.
3) If needed, set parameters for manual assay mode.

Warning : Because sampling pipette indicating light shares the function of the liquid waste level indicating light, the liquid waste container Must be empty in manual assay mode.

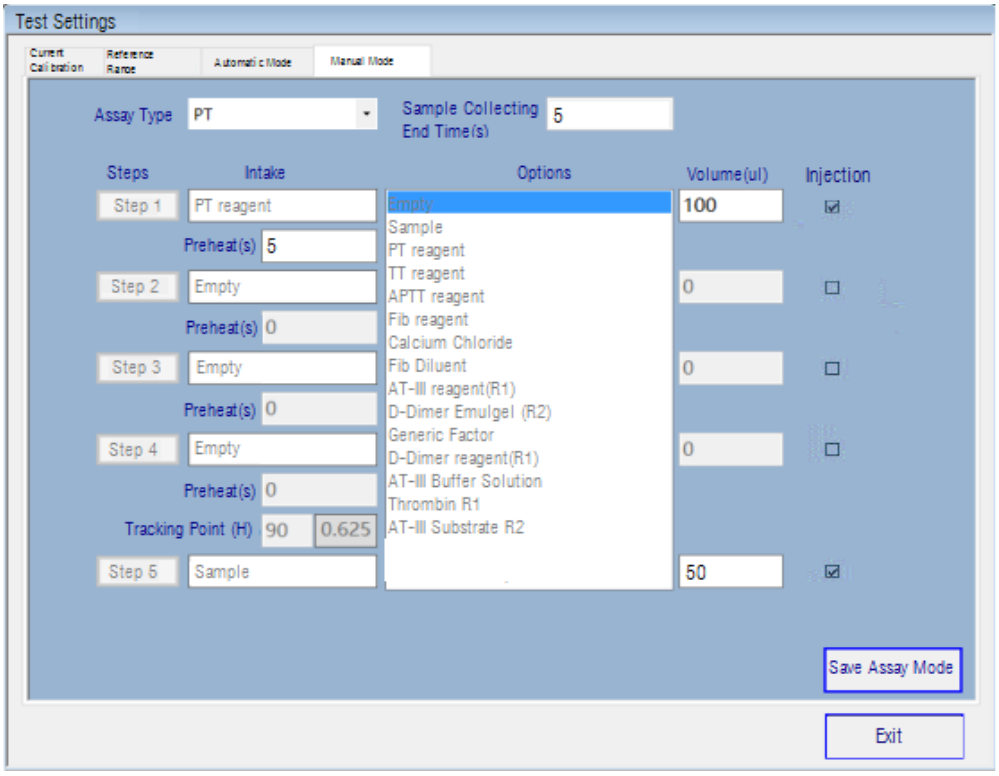

Figure-84

4) According to practical situations， set channels corresponding to assay types in channel setting area. One assay type for each channel. This software can only do assays of PT, APTT, TT, and Fib.

Figure-85

5) Before assaying, put empty cuvettes in the row of the pallet located above the detector. If the motor for detector breaks down, the detector cannot lift to the position. If this happens, remove the pallet, and put empty cuvettes in the detecting holes directly.
6) For assay, click【**Add Sample**】 to enter add patient assay window, fill the patient information, and confirm assay types. Then click 【**Add**】. Sample number is automatically generated after successfully adding sample. Click 【**Exit**】to return to manual assay interface.
7) To prevent mistakes, only add one sample at a time.

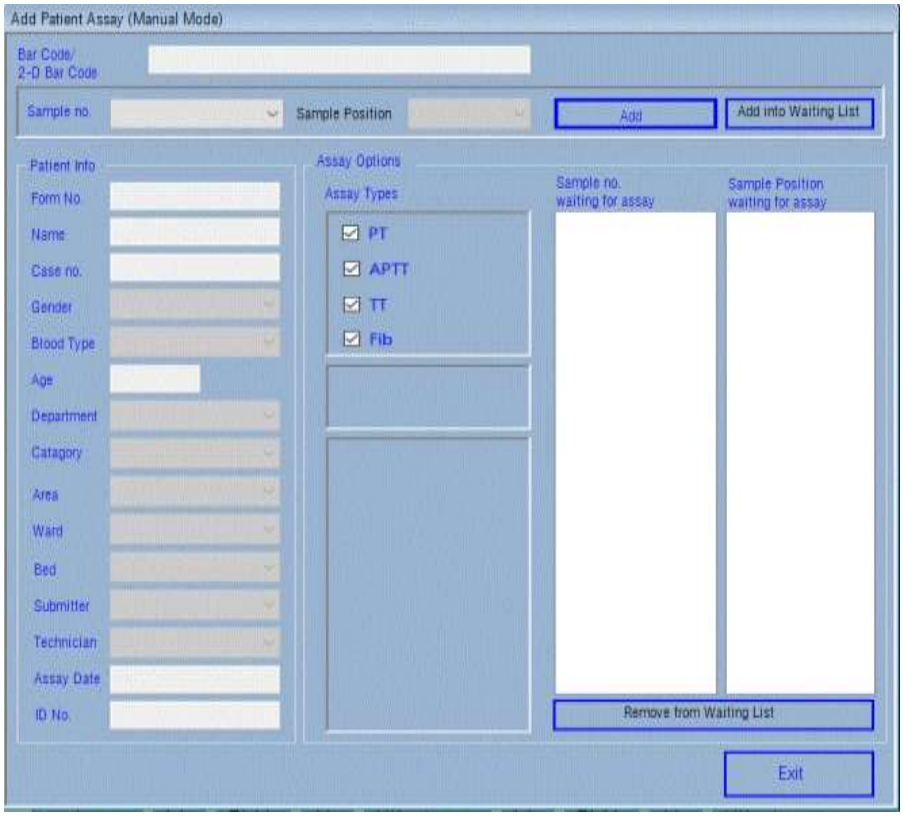

Figure-86

- In the main interface, click【**Start Assay**】to start. During assay, system prompts notice for adding sample and waits for user to complete adding sample. Every time when user completes adding sample, the system generates hint tone and continues processing.
- When completing, the system automatically generates completion notice.
- Print assay report if needed.

9.12 System Test

Motor parameters are correctly set before leaving the factory. Do not change motor parameters; otherwise, it may cause device problems.

Notes：

All distance parameters are measured with number of pulses.

If the input parameters are incorrect, the background of the corresponding textbox turns yellow.

Under the menu【**System Maintenance**】, click【**System Test**】, or type Ctrl + M to enter system test window.

Motor Selection: Select motors for setting parameters.

Password：Only after inputting correct password, parameters are allowed to change.

Save Motor Parameters：When finishing, click this button to save parameters.

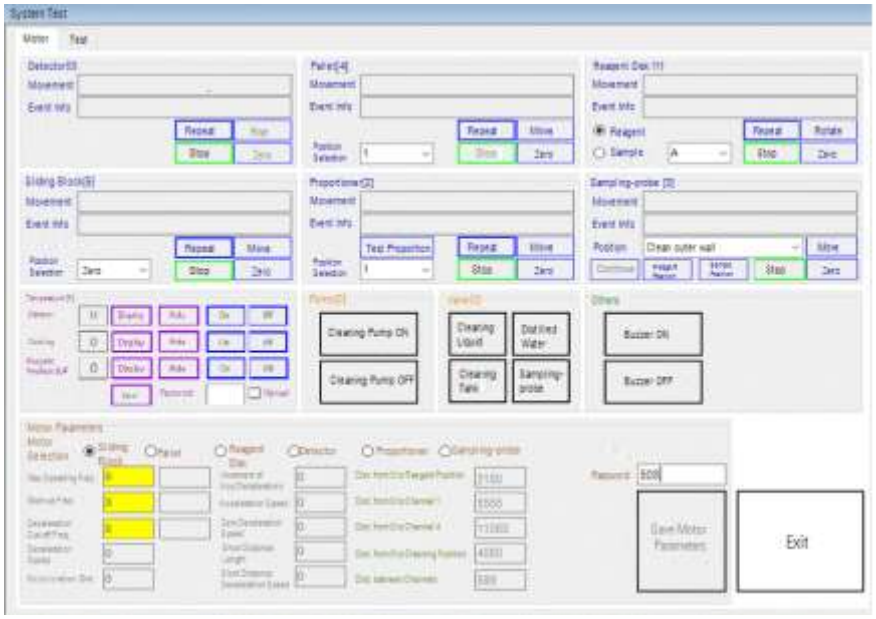

Figure-87

Important Note：

Before motor test, click 【Zero】first to zero the motor, and initial the motor for other motor test.

Movement Info：Indicating current motion state, as it is shown in the figure above.

Event Info：Indicating state of completed movements, as it shows in the figure above.

9.13 Detector

Zero：Zero the detector.

Rise: Rise the detector.

Repeat：Repeat detector movements from zero position to the test position until the user clicks【Stop】.

Stop：Stop repeating movements.

Figure-88

Maximum Operating Frequency：Confirm maximum operating frequency of motor.

Start-up Frequency：Start-up frequency to start the motor.

Deceleration Distance : Number of pulses when motor starts deceleration.
Increment of Acceleration/Deceleration : Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.
Acceleration Speed : Speed for motor acceleration. Increase this value to decrease acceleration.
Rising Distance： Number of pulses when rising to the test position.

9.14 Pallet

Position Selection : Select number of rows in the pallet for movement.
Zero： Zero the pallet.
Move : Pallet moves to the selected row position.
Repeat： Repeat the pallet movements from zero position to selected row position until user clicks Stop.
Stop： Stop repeating movements.

Figure-89

Maximum Operating Frequency : Confirm maximum operating frequency of motor.
Start-up Frequency： Start-up frequency to start the motor.
Deceleration Distance : Number of pulses when motor starts deceleration.
Increment of Acceleration/Deceleration : Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.
Acceleration Speed : Speed for motor acceleration. Increase this value to decrease acceleration.
Distance between Rows : Number of pulses between rows next to each other.

9.15 Reagent Disk

Position Selection： Select position in the reagent disk for rotating.
Reagent Position, Sample Position： Confirm the type of positions in the disk.
Zero： Zero the reagent disk.
Rotate： Rotate the reagent disk to selected position.
Repeat： Repeat reagent disk rotation from zero position to selected position until the user clicks 【**Stop**】.
Stop： Stop repeating rotation.

Figure-90

Maximum Operating Frequency : Confirm maximum operating frequency of motor.
Start-up Frequency : Start-up frequency to start the motor.
Deceleration Cut-off Frequency : Minimum frequency for motor deceleration.
Deceleration Speed : Speed for motor deceleration. Increase this value to decrease deceleration.
Deceleration Distance : Number of pulses when motor starts deceleration.
Increment of Acceleration/Deceleration : Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.
Acceleration Speed : Speed for motor acceleration. Increase this value to decrease acceleration.
Short Distance Length : When the number of pulses is lower than this value, motor does not accelerate.
Short Distance Deceleration Speed : Speed for motor deceleration within short distance. Increase this value to decrease deceleration.
Distance between Sample Position : Number of pulses between 2 sample positions next to each other.
Distance between Reagent Position : Number of pulses between 2 reagent positions next to each other.

9.16 Sliding Block

Position Selection : Select position for the sliding block to move.
Zero : Zero the sliding block.
Move : Sliding block moves to selected position.
Repeat : Repeat sliding block movements from zero position to the selected position until the user clicks【Stop】.
Stop : Stop repeating movements.

Figure-91

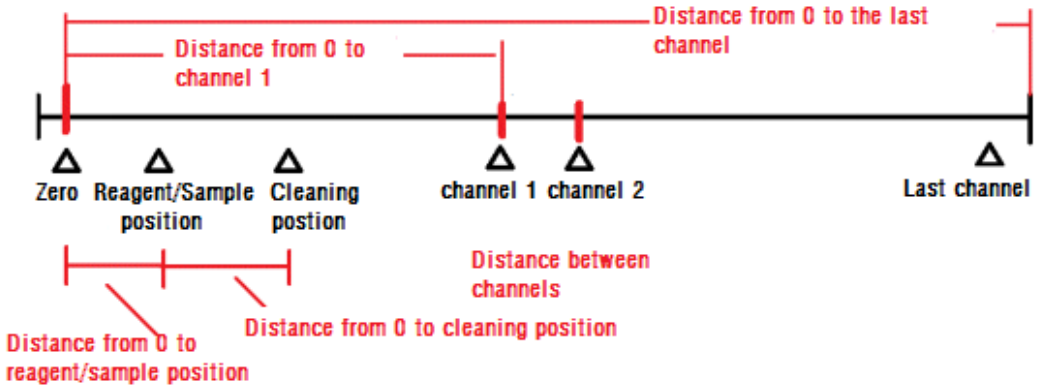

Figure-92

Maximum Operating Frequency : Confirm maximum operating frequency of motor.
Start-up Frequency : Start-up frequency to start the motor.
Deceleration Cut-off Frequency : Minimum frequency for motor deceleration.
Deceleration Speed : Speed for motor deceleration. Increase this value to decrease deceleration.
Deceleration Distance : Number of pulses when motor starts deceleration.
Increment of Acceleration/Deceleration : Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.
Acceleration Speed : Speed for motor acceleration. Increase this value to decrease acceleration.
Short Distance Length : When the number of pulses is lower than this value, motor does not accelerate.
Short Distance Deceleration Speed : Speed for motor deceleration within short distance. Increase this value to decrease deceleration.

9.17 Proportioner

Position Selection : Select position for proportioner to move.
Zero: Zero the proportioner.
Move : Proportioner moves to the selected position.
Repeat : Repeat proportioner movements from zero position to selected position until the user clicks【Stop】.
Stop : Stop repeating movements.
Test Volume : Click to prompt following dialog box.

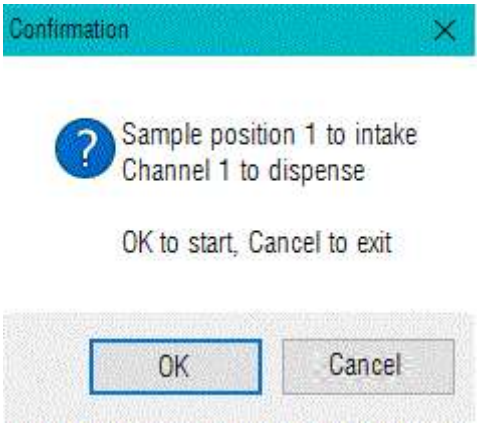

Figure-93

Click【**OK**】. Sampling-probe automatically takes in liquid of selected volume from sample position 1 and then dispenses the liquid into cuvettes in channel 1, for convenience of proportioner volume test.

Figure-94

Maximum Operating Frequency：Confirm maximum operating frequency of motor.

Start-up Frequency：Start-up frequency to start the motor.

Deceleration Distance：Number of pulses when motor starts deceleration.

Increment of Acceleration/Deceleration：Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.

Acceleration Speed：Speed for motor acceleration. Increase this value to decrease acceleration.

Unit Distance：Distance to move to next one unit position.

Sample Position：Sampling-probe moves to sample position automatically and repeat movements of taking in sample from the container in selected sample position, moving to zero position, and moving downward to dispense sample back to the reagent container for convenience of probe continuing moving downward after sample surface is indicated. This motion repeats until the user clicks【**Stop**】.

Stop：Stop repeating movements.

9.18 Sampling-probe

Position Selection : Select position for sampling-probe to move.
Zero : Zero the sampling-probe.
Move : Sampling-probe moves to the selected position.
Reagent Position : Sampling-probe moves to reagent position automatically and repeat movements of taking in reagent liquid from the container in selected reagent position, moving to zero position, and moving downward to dispense reagent back to the reagent container, until the user clicks【Stop】.
Sample Position : Sampling-probe moves to sample position automatically and repeat movements of taking in sample from the container in selected sample position, moving to zero position, and moving downward to dispense sample back to the reagent container for convenience of probe continuing moving downward after sample surface is indicated. This motion repeats until the user clicks【Stop】.
Stop : Stop repeating movements.

Figure-95

Maximum Operating Frequency : Confirm maximum operating frequency of motor.
Start-up Frequency : Start-up frequency to start the motor.
Deceleration Distance : Number of pulses when motor starts deceleration.
Increment of Acceleration/Deceleration : Increment of motor acceleration/ deceleration. Increase this value for quicker acceleration/ deceleration.
Acceleration Speed : Speed for motor acceleration. Increase this value to decrease acceleration.
Sample Intake : Number of pulses for probe to continue moving downward after indicating sample surface, when taking in samples.
Reagent Intake : Number of pulses for probe to continue moving downward after indicating reagent surface during reagent take-in.
Buffer Solution Intake : Number of pulses for probe to continue moving downward after indicating buffer solution surface during dilution.
Maximum Distance : Number of pulses from zero position to the maximum downward position.

9.19 Temperature

Display： Display temperature in toolbar.
Hide ：Hide temperature in toolbar.
Manual： Check to turn 【**ON**】or【**OFF**】 to manually control temperature reading.

10 Maintenance

10.6 Notice for Daily Use

- Keep surrounding clean.
- After use, close the cover to prevent dust.
- Keep reagent and sample position in reagent disk clean. No remaining liquid.
- Do not drop large pieces or liquid into detector holes for avoiding interference.
- After use, clean sampling-probe to prevent blockage.
- Stay away from direct sunlight and dangerous/heat-flash objects.
- Place the device on evenly levelled surface. No shaking and vibration.
- Be aware of erosion and moisture.
- Use stabilized voltage supply if possible.
- Do not touch heating components during operation.
- Do not block moving components with hand.
- Follow the steps to log out the system. Avoid shutting down by cutting power off.
- Turn off the device power after system logs out.
- When device has problems, stop using Immediately.

10.7 Parts Maintenance

Sampling-Probe: Add lubricant to guiding rod every week: put two drops of lubricant in the joint between supporting frame and Y-axis sliding track. Move the frame up and down manually.

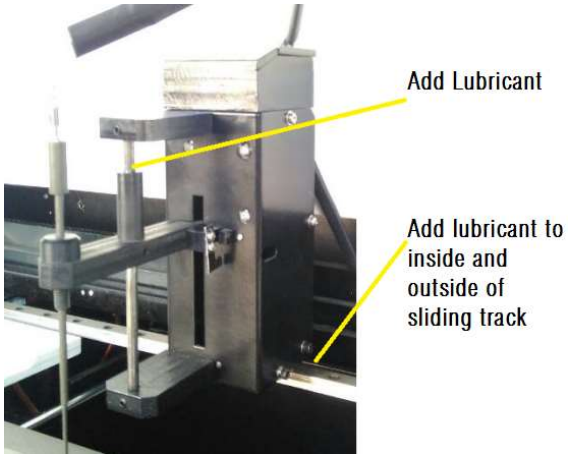

Figure-96

Reagent Disk： Clean every reagent and sample positions in the disk carefully. If accidentally drop liquid, clean it off Immediately.
Pallet： Keep the pallet surface clean. Clear used cuvettes as soon as possible. Add lubricant to Z-axis sliding track every week to decrease friction.

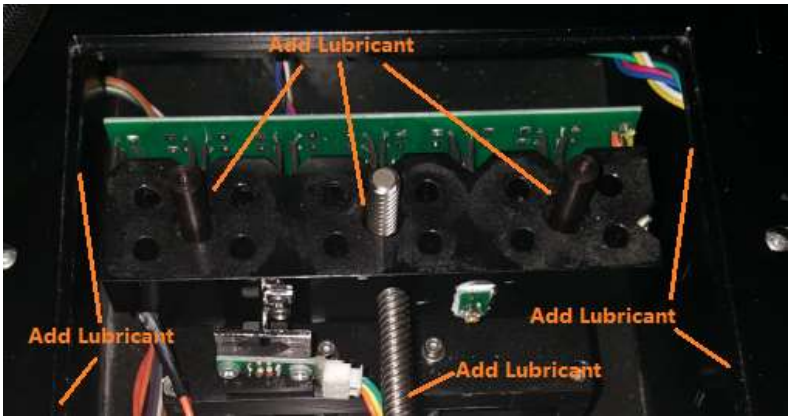

Figure-97

Sliding Block： To do maintenance of sliding block, add lubricant to X-axis sliding track every week for the slider to move smoothly.

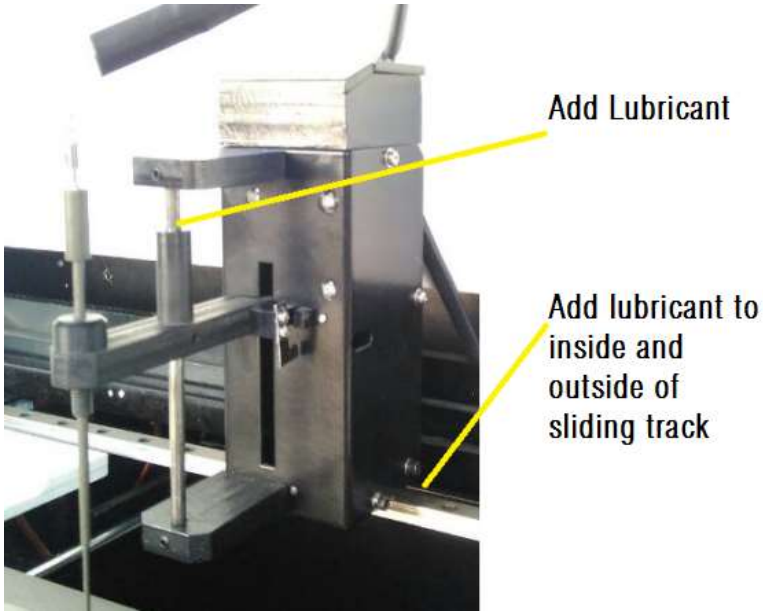

Figure-98

Detector： Add lubricant to the lead screw and guiding shaft every week.

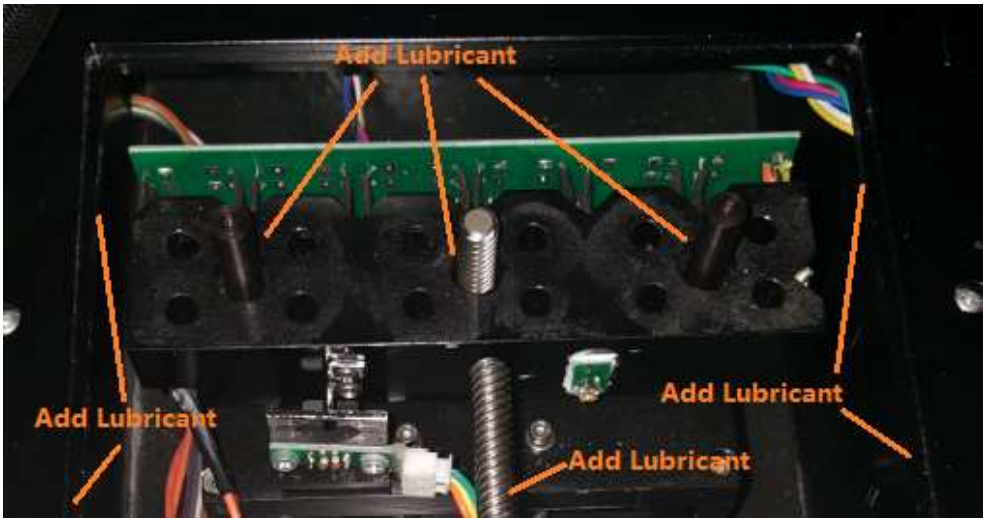

Figure-99

Pipeline: Check pipeline to prevent blockage and worn every week. If there is any damage, change the pipe as soon as possible.

10.8 Device Maintenance

10.8.4 Per day

- Empty the liquid waste container.
- Fill the cleaning liquid container if needed.
- Fill the distilled water container.
- Keep empty cuvettes matching the position setting in the system.
- Keep reagents in reagent disk matching the position setting in the system.
- Check whether there is paper in the printer.
- After one day of use, discard used cuvettes and remove samples and reagent from the reagent disk.

10.8.5 Per Week

- Rinse the pipeline with cleaning liquid.
- Check device components.
- Clean display, mouse, and keyboard.

10.8.6 Every half year

- Change pipes in the pipeline.
- Backup the data. If daily data size is large, user can do data backup in advance

11 Troubleshooting

1) **Device Does Not Power On**
   Issue: Cannot start the device when pressing the power button.
   Solution:
   Ensure the **power cable is securely connected**.
   Check the **fuse** for any damage or blown condition.
   Turn off the device completely, then **press the power button again** to restart.
2) **Monitor Display Issue**
   Issue: Monitor does not display in full screen.
   Solution:
   Verify the **screen resolution settings**.
   Set the resolution to **1024 × 900 pixels** for optimal display.
3) **Temperature cannot reach 37℃ long after turning on the device**
   Solution: Turn on Air-Conditioner for adjusting room temperature.
4) **Liquid waste does not flow into the liquid waste container**
   Solution: Check whether the pipeline is blocked.
5) **Sampling-probe cannot detect the reagent or sample**
   Solution: Check whether the container contains sample or reagent; Use sample or reagent container with larger inner diameter.
6) **Liquid flow from sampling-probe is skewed**
   Solution: Check whether the sampling-probe is blocked; Use given stylet from the package to clean the problem and clean the probe with cleaning liquid.
7) **No liquid flow in sampling-probe**
   Solution: Check whether the cleaning liquid container is empty; check whether the pipeline works normally.
8) **Temperature control system failure, Shutting down the system.**
   Solution: Turn the power off and restart. If the warning continues.
9) **Sampling-probe is abnormal**
   Solution: Check sampling-probe moving direction. Use a motor test program to check whether the sampling-probe is working normally.
10) **Sliding block is abnormal**
    Solution: Check sliding block moving direction. Use a motor test program to check whether the sliding block is working normally.
11) **Reagent disk is abnormal**
    Solution: Check the reagent disk rotating direction. Use motor test program to check whether the reagent disk is working normally.
12) **Proportioner is abnormal**
    Solution: Use a motor test program to check whether the proportioner is working normally.
13) **System has problems, not functioning**
    Solution: It is very likely to be temperature problem or motor problem. Check temperature control and motors. If both works, set states to be normal states in the alarm settings to restore operation.

14) **Channel n has a problem, not functioning for assays on this channel**
Solution: Open zero tracking window and start zero tracking of the channel 5 times repetitively. If tracking successes, set channel state to be normal state in the alarm settings to restore operation.
15) **Channels have problems. No channels available.**
Solution: Open zero tracking window and start zero tracking for all channels. For channels that are successfully tracked, set states to be normal in the alarm settings.
16) **The detector temperature problem cannot continue.**
Solution: Turn off the device and reboot.
17) **Reagent disks have problems, cannot continue.**
Solution: Turn off the device and reboot.
18) **Running out of cleaning liquid**
Solution: Fill the liquid container cleaning.
19) **Liquid waste container is full**
Solution: Empty the liquid waste container.
20) **No printer was found, Kindly check the printer connection.**
Solution: Check the connection of the printer and device; check whether the printer driver is installed properly.
21) **Overflow in the cleaning tank**
Turn off the device Immediately and cut the power off.