



# iPro-Lab

Clinical Chemistry Analyzer (Non-Sterile)



## Operator's Manual

IUENC-A04-220309

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This ENNOLIFE Clinical Chemistry Analyzer (Non-Sterile) is dedicated to use in each localized health care location, basic hospital institutions. It provides the first-line medical care operators with quick blood test information.


Contents of this manual cover operation, maintenance and troubleshooting for the ENNOLIFE Clinical Chemistry Analyzer(Non-Sterile). Please read this manual carefully before operating this device.



## WARNING


- Always be careful when handling blood samples or waste reagent rotors/discs.  
Incorrect or careless handling may cause a risk of getting sick or infected for the operator.
- The person using this device in clinical examination shall have the ability of handling hazardous wastes and the specific knowledge of this device. When operating this device for the first time, he or she shall be directed by an experienced person or by a person who has operated this device before.
- Do not touch any reagent rotors/discs or a container or surface that may have any sample residue. Always wear protective gloves to prevent from infections by pathogenic microbes when performing tests or maintenance.
- Separated used samples, tips and protective gloves from general waste and discard them according to local regulation.
- This analyzer is only for ***In Vitro Diagnostic*** reference, not for emergent treatment.
- This product has been tested with relevant environmental conditions before delivery. It is recommended that this analyzer should be used in proper operating temperature, humidity and non-condensation condition.

Please note caution marks below and follow the instructions described in this Operator’s Manual.



**To prevent injuries to yourself or others.**

**CAUTION**


















**Failure to follow the instructions may lead to incorrect results.**

**IMPORTANT**

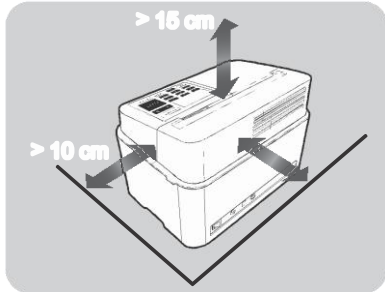
## Symbol Information

Symbols below marked in the manual and product labels.

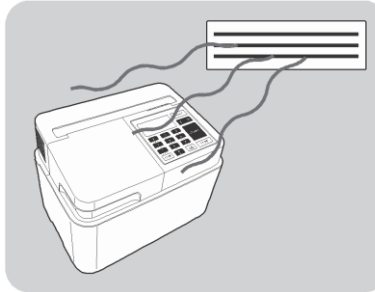
	Caution		Consult instructions for use
	Use by		Temperature limitation
	Manufacturer		Lot number
	In Vitro Diagnostic Medical device		Keep away from direct sunlight
	Keep dry		Do not drop in living refuses
	Date of manufacture		Serial number
	Denotes conformity to specified European directives		Biological Risks
	Authorised Representative in the EU		

# Safety Precautions

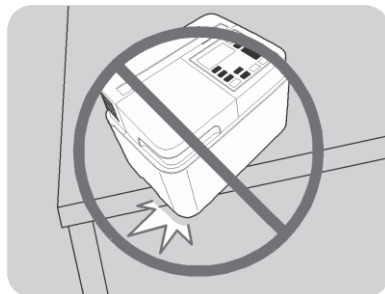
Always observe the following *Safety Precautions* before setting up or operating the device.



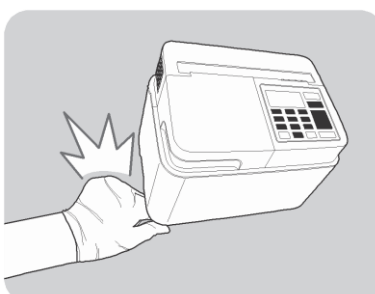
Be sure to leave an adequate space (at least 10 cm on each side and 15 cm on the upper part) between the device and the wall. Otherwise, it may cause overheating.



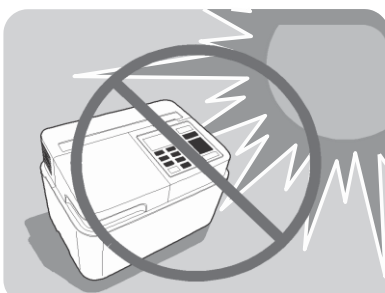
Place the device in a room with proper air circulation. Otherwise, the carbon dioxide concentration may affect the test and produce inaccurate results.



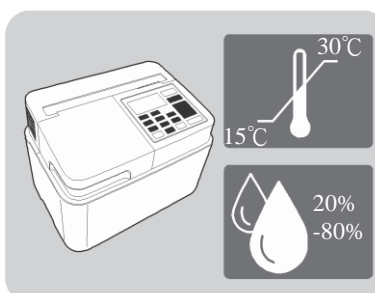
Place the device on a stable surface, free of vibration. Otherwise, it may damage the device and produce inaccurate results.



Be careful not to place your hand or fingers under the device. Otherwise, it may cause hand injury.



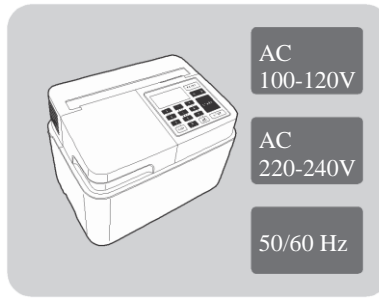
Do NOT expose the device to direct sunlight or windy places. Otherwise, it may produce inaccurate results or cause deformation or damage to the device.



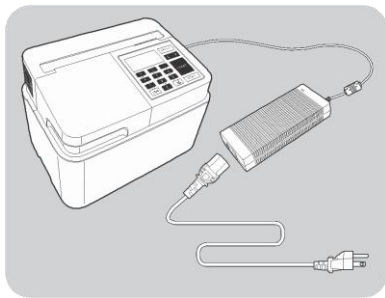
Place the device at a dry place at room temperature between 15~30°C (with 20~80% relative humidity). Otherwise, it may produce inaccurate results.



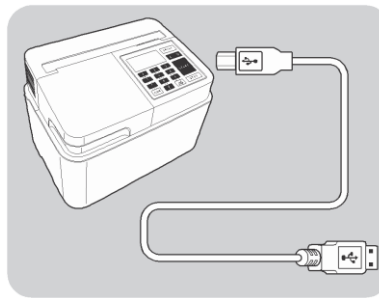
Do NOT expose your device to toxic chemicals or corrosive gases. Otherwise, it may cause injury or damage to the device.



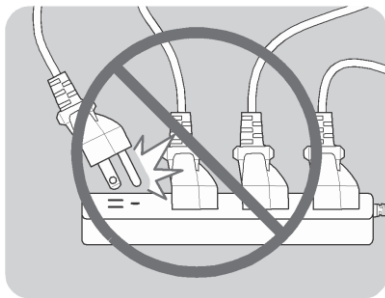
Before plugging the power supply into an electrical outlet, verify the power rating conforms with the specified voltage and frequency. Otherwise, it may cause electric shock or fire.



Only use the dedicated power supply that comes in the package. Otherwise, it may cause electric shock or fire.



When connecting to other device, be sure to use only the supplied cables that come in the package. Otherwise, it may cause electric shock or fire.



Do not use an extension cord outlet. Be sure to directly plug the power supply in an electrical outlet on the wall to avoid the likelihood of overloading.



Do NOT disassemble or repair the device yourself. Doing so will void its warranty and it may cause device malfunction.

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# Chapter 1 : Installation Introduction

## 1.1 Intended Use

ENNOLIFE Clinical Chemistry Analyzer(Non-Sterile), a new generation clinical analyzer developed by ProtectLife International Biomedical Inc. can measure multiple biochemistry or immunology parameters in a point-of-care-testing (POCT) environment. By using different reagent rotor/disc, professional users are capable of testing different parameters. For example, the Comprehensive Plus Panel is for measurement up to 16 physiological markers simultaneously in 15 minutes with as low as 0.14 mL (140  $\mu$ L) heparinized whole blood. Analyzer is nearly maintenance free and easy to operate which enables trained person to obtain results in a real-time, convenient, and reliable manner. Applicable samples include lithium heparinized whole blood or plasma, serum, and urine. A different reagent rotor/disc may apply for different sample type. Please refer to the package insert of the reagent rotor/disc. This device can also conduct analytical measurement of organophosphate pesticides (OPPs). The sample used is not collected from human body and shall be used with the corresponding dedicated reagent rotor/disc for pesticides. Please read the user's manual of the reagent rotor/disc before using this function.

### 1.1.1 Features

- Automatic centrifugation: The analyzer can automatically perform centrifugation when a sample of whole blood, serum or plasma, urine, and pesticide is injected into the sample injection port. The analyzer will automatically perform centrifugation once the whole blood or serum/plasma, urine, pesticide mode is selected.
- Automatic constant temperature dynamic testing, easy to operate. After the analyzer completes automatic centrifugation, the sample can automatically and evenly be mixed with reagent for testing
- Low sample volume is required: Only require at most 0.14 mL ( $\mu$ L) regardless of whole blood, serum, or plasma.
- Dry preservation and wet chemical testing: Easy to preserve and can achieve the laboratory level accuracy.

- Provide integration solution, convenient for integration and retrieval of the test results.
- A single platform that supports biochemical and immunoassay detection.
- Provides customized detection items with high scalability.
- Embedded barcode system, ensuring the test quality.

### **1.1.2 Measurement Principles**

This analyzer uses spectrophotometry method for detection. Reagent rotor/disc containing dry and liquid reagents is used to measure analyte concentrations by wet chemistry principles

### 1.1.3 Product Specifications

Item	Specifications
Reagent rotor/disc	ENNOLIFE dedicated reagent rotor/disc
Sample type	Tests of human physiological indices: : Lithium heparinized whole blood, ,Lithium heparinized plasma, serum and urine Tests of organophosphate pesticides (OPPs): Vegetables, tea leaves
Units	Common Units or SI Units
Sample size	Panel : 0.14 mL (140 $\mu$ L) Disc : 0.06 mL (60 $\mu$ L)
Result timing	Whole Blood : Approx. 15 minutes ; Plasma/Serum: Approx. 13 minutes OPPs : Approx. 15 minutes
Quality control	Able to determine by using the commercially available materials recommended by the manufacturer. For quality control, please read carefully the package insert for use of the reagent rotor/disc.
Storage Temperature and Relative Humidity	5°C ~ 40°C and 10~90%RH
Operating Temperature and Relative Humidity	15°C ~ 30°C and 20~80%RH (no condensation)
Interface	RS232,USB port 2.0
Power supply	110 – 240 volts AC, 50 – 60 Hz
Analytic Temp.	37.5°C
Net weight	7.5 kg
Dimensions	Length: 340 mm Width: 240 mm Height: 240 mm

# Operating Environment

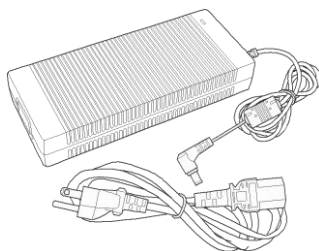
- Indoor use
- Altitude: below 2000 meters
- Temperature: 15~30°C
- Humidity: 20~80%(with no condensation)
- Power supply : 110-240 Volts AC, 50-60 Hz
- Transportations : -30-80°C ; 10-90% RH
- Acoustic alarm when an operation is complete or an error occurs

## 1.2 Package Contents

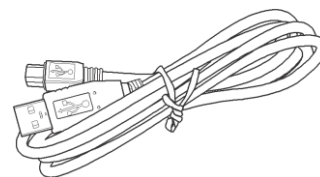
Carefully unpack your ENNOLIFE package. Ensure that the following items are included.



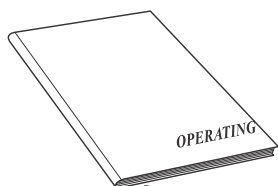
Analyzer



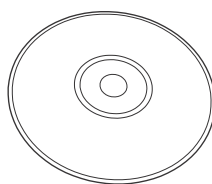
Power supply  
(Mode : DA-150A24)



USB cable (B-Type)



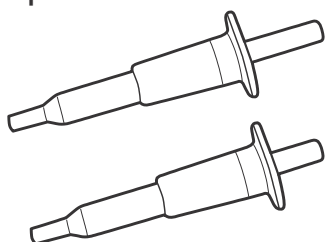
Operator's Manual



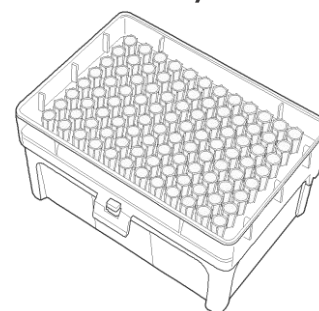
Software CD  
(\*Optional)



Warranty card



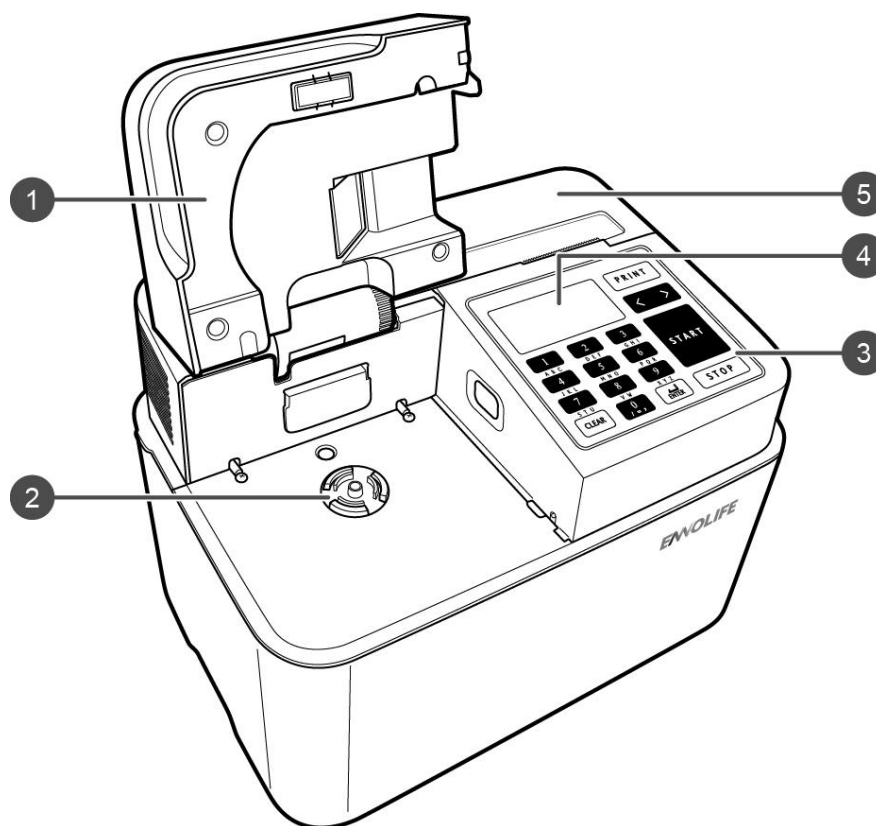
Pipette (60/140 µL)  
(Non-adjustable)



(Tip , 1box , 96pcs)

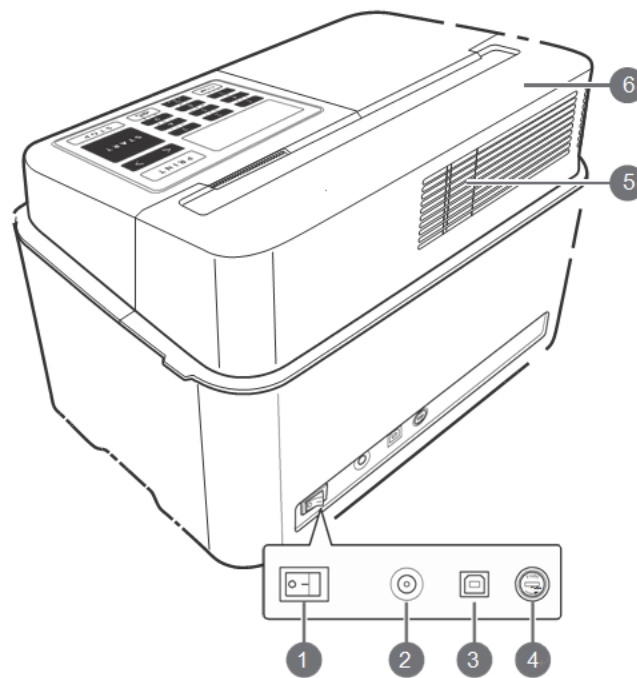
## 1.3 Product Overview

### 1.3.1 Front View



No.	Item	Description
1	Analyzer lid	Prevent the external light from entering the analyzer.
2	Spindle	Hold the reagent rotor/disc.
3	Control panel	For entering data or operate the device.
4	Screen	Display information including test values, functional parameters, device operating condition and other error messages.
5	Printer	Print out the test results.

## 1.3.2 Rear View

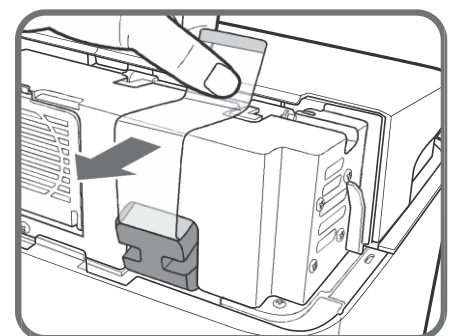


No.	Item	Description
1	Power switch	Press to turn the device on or off.
2	AC input	Connect the power cable.
3	USB port(COM)	Connect the external device (i.e. PC).
4	Fuse	Use to reset a tripped circuit breaker (due to overload or short circuit).
5	Cooling fan	Use to reduce the device operating temperature.
6	Maintenance cover	Remove this cover to access the printer cover or the fan filter compartment.

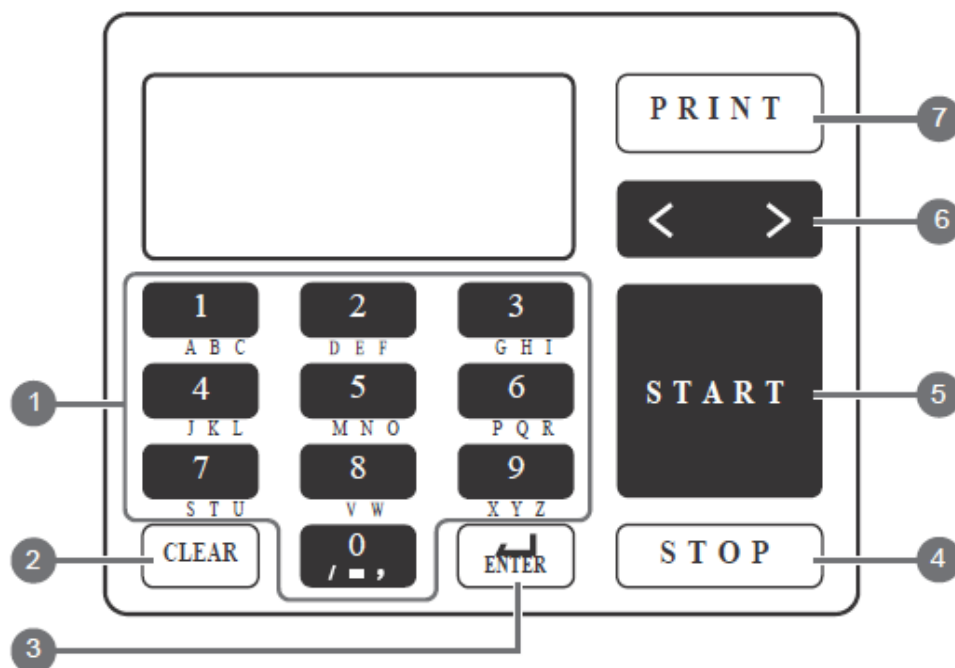



### Note:

- After unpacking the product, first open the maintenance cover and pull out the transparent sheet to remove the protective sponge for protection (as shown in the illustration).



### 1.3.3 Control Panel



No.	Item	Description
1	0~9	Press to enter numerical values and ID. Can input the English alphabets when you long press the number buttons.
2	<b>CLEAR</b>	Press to clear the input.
3	 ENTER	Press to confirm the entry.
4	<b>STOP</b>	Stop testing /return key
5	<b>START</b>	Press to start measurement.
6	< >	<ul style="list-style-type: none"> <li>Press to move the cursor left or right, one character at a time.</li> <li>Press to go to the previous/next page.</li> </ul>
7	<b>PRINT</b>	Press to print the test result.

## 1.4 Setting up the Analyzer



CAUTION

Before setting up the analyzer, read the following notes and always take proper safety precautions. If you have any question, please contact the local distributors.

### 1.4.1 Installation

This Operator's Manual is the most complete, essential reference for the ENNOLIFE Clinical Chemistry Analyzer(Non-Sterile). Please follow the Operator's Manual for detailed instructions and troubleshooting guidance. Place the Manual in a convenient place for easy access.

Please follow the instructions below to install the device.

#### Step 1: Unpack the analyzer and accessories

1. Place the reagent rotor/disc in the refrigerator (2~8°C, 36~46°F) immediately upon arrival.
2. Remove the analyzer from box and place it on a level surface.
3. Remove the plastic bag that holds the package and take out the analyzer.

#### Step 2: Install the analyzer

1. Place the analyzer near an electrical outlet (AC).
2. Connect one end of the power cable to the AC input of the device. (See 1.4.2).

Plug the other end of the power cable into an electrical outlet. Make sure all connections are secure.

#### IMPORTANT

- To prevent overloading, do not plug the analyzer into the same circuit as your centrifuge, refrigerator, or any other high current devices.
- It is recommended to plug the device into a surge protector that is

specifically designed for computer use.

- If the analyzer will be used in an area prone to electrical surges or power outages, it is recommended to use an uninterruptible power supply (UPS) for protection of this device.

### **Step 3. Connecting an external device (if necessary)**

When connecting with an external device, use USB port and USB cable (B type).

 **Note:**

- Make sure the analyzer lid is properly closed before turning ON the power. If any light source enters into the analyzer, an error will occur.

## 1.4.2 Notice of Installation

1. When removing the analyzer from the outer box, be careful of its weight and don't let it drop. Keep an operating space and clear the surface of the table in advance. When moving the analyzer, place it with care.
2. Keep the back of analyzer from the wall at least 10 cm to avoid overheating that may cause the analyzer unable to get an accurate test result or may cause fire. Also keep the fan outlet at the back of analyzer to be unblocked.
3. Reserved at least 15 cm space from the top of analyzer to open the Analyzer Lid without touching other objects.
4. The operating voltage for this device is 100-240V, 50/60Hz. Please use the designated power supply with correct voltage and current.
5. To avoid electric shock or fire, use an electric socket with grounding (three-hole type). If this type of socket is unavailable, contact your local distributor.
6. Insert the plug directly into the wall socket. The analyzer has overloading protection. Do not use an extension cord.
7. Do not disassemble or adjust the analyzer, it may cause damages.
8. Place the analyzer on the level and steady place and avoid vibration. Otherwise, it may cause incorrect test results.
9. Do not place the analyzer close to chemicals and corrosive gases to prevent from damage or failure. .
10. Avoid exposing the analyzer to direct sunlight or windy places and liquid spraying. Otherwise, it may cause incorrect test results and damage or failure to the analyzer.
11. Please using the ENNOLIFE designated cable to connect the computer or other device. Other cables may cause electric shock or fire.
12. If there has gas, petroleum or heating apparatus in the room where the analyzer is placed, ensure good ventilation or it may cause hazard to the human body and also affect the test result.
13. Do not let children or babies approach the plastic bag of the analyzer to avoid covering their head and causing suffocating.
14. Making sure power of analyzer is turned off before connecting the power.
15. Connect one side of the power cord to the AC input at the back of the analyzer and connect the other end of the cord to the electrical socket.
16. If an external computer is used, connect it by using the USB port and the USB cable (B type) at the back of the analyzer.

## 1.4.3 Initial Operation

### 1. Turn on the power

- Press the **Power** switch at the back of the analyzer to turn on the analyzer.



- After the screen displays warm-up and system version, the analyzer lid will lock up and the warm-up process will take about 20 minutes. Then, the screen will display the main page.

```
Warming      28/1/2019
              9:28
              1199sec
```

```
Warming      28/1/2019
Locking      9:28
              1199sec
```

- Once the device is warmed up, the Main Page appears on the screen.

```
Main Page    28/1/2019
              9:28
1:Measurement
2:History Results
3:Setting
```

## 2. Confirm the time and date

- Set the correct date and time.

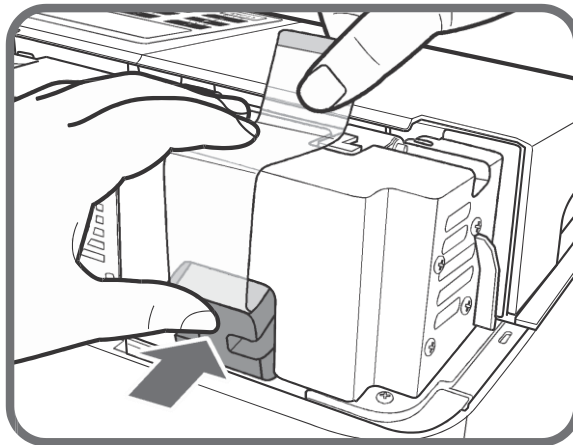
## 3. Turn off the power

- When the operation/setting is complete, turn off the power after the Main Page is displayed on the screen.

### 1.4.4 Transportation

Before transporting the analyzer, please follow instructions below:

1. Remove the maintenance cover and place the protective sponge into its slot as shown in the below illustration.



Then replace the maintenance cover.

2. Place the analyzer into a designated carrying case supplied by the manufacturer.
3. Use foam sheets or bubble wrap to prevent breakage during transit.

# Chapter 2 : Measurement

## 2.1 Outline of Measurement

### 2.1.1 Reagent Rotor/Disc

The ENNOLIFE dedicated reagent rotor/disc is only applicable to In Vitro Diagnostic and is only suitable for the ENNOLIFE Clinical Chemistry Analyzer(Non-Sterile).

One reagent rotor/ disc is for disposable use only. Do not repeat using it. A reused reagent rotor/disc will not be accepted by the analyzer. The used reagent rotor/disc shall be disposed per the medical waste disposal regulations stipulated by the local competent authority.

The ENNOLIFE Clinical Chemistry Analyzer(Non-Sterile) only uses with dedicated reagent rotor/disc. It is divided into two series of reagent rotor and reagent rotor/disc. Select a suitable disc per the need when testing.

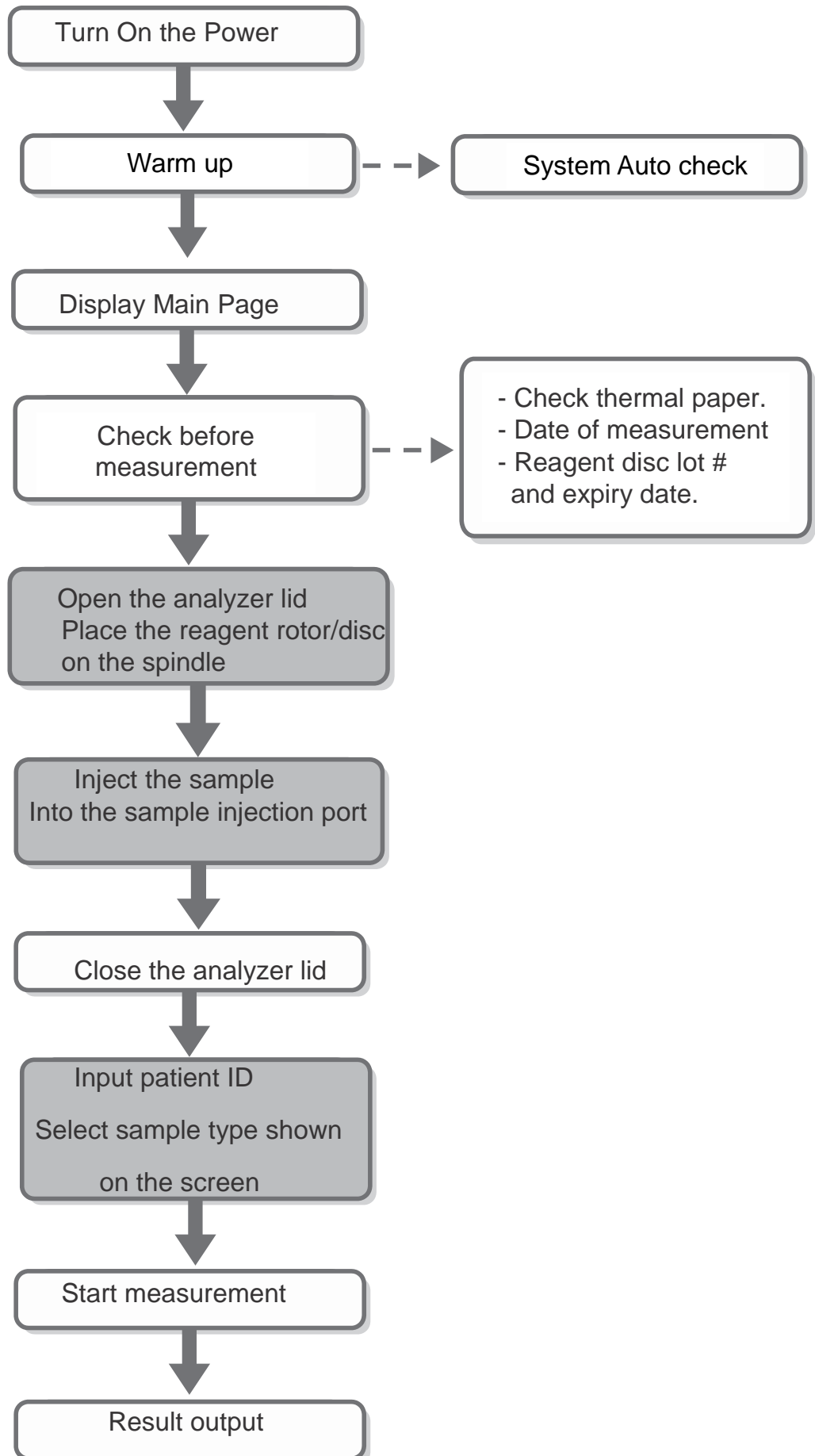
- **Reagent Disc**

The reagent Disc is presented as a fan-shaped plastic plate. It provides 1 to 4 test items. Select per the need when using it.

- **Reagent Rotor**

The reagent Disc is presented as a round-shaped plastic plate. It Provide 6 to 16 test items. Select per the need when using it.

## 2.1.2 Measurement Process



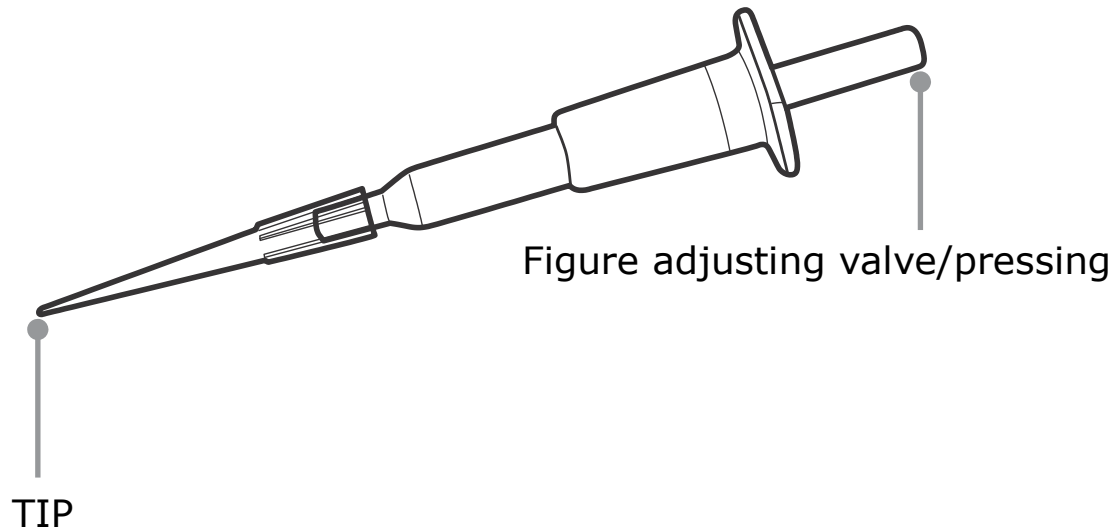
## 2.2 Cautions While Operation

- The analyzer is equipped with a temperature control. It is suggested to operate the analyzer under room temperature around 15~30°C with relative humidity at 20~80% without condensation.
- If the analyzer emits odor or smoke due to improper operation, turn OFF the power immediately and unplug the power cable. Otherwise, the analyzer may be damaged and cause fire.
- If the analyzer is malfunction, contact your local distributor for repair. Do not attempt to repair it by yourself. Doing so may cause damage to your device or personal injury.
- Do NOT place a container with samples on the top of analyzer. If the sample spills by accident, it may cause damage to the analyzer or fire.
- Do NOT move the analyzer during testing. It may cause malfunction, resulting incorrect test results.
- Before testing, ensure that the system warms up completely. While warming up, the system will perform self-check.
- After testing of each day, be sure to remove the used disc and turn off the analyzer.

### 2.2.1 Handling Sample with Pipette

#### 1. General laboratory prevention guidelines for operation:

- Wear gloves and a laboratory coat when handling blood samples. Change gloves when handle different samples.
- Do not place food or drinks in the laboratory or the laboratory refrigerator.
- After drawing or handling blood samples, be sure to place those sharp items such as, syringes, needles, blood sampling tubes, Pasteur pipettes in a hard and leaking-proof container. Also dispose them soonest possible per the waste disposal regulations to avoid medical injuries or sample splashing. Do not damage or bend needles.
- Wash hands frequently. In case of contacting blood, immediately wash hands or clean the skin surface with 75% disinfectant alcohol.
- For the required sample size, refer to the requirement of each reagent rotor/disc. Please use the pipette supplied with the analyzer or the equivalent product.



## 2. Pipette usage

- a. Choose the pipette depending on type of reagent rotor/disc, then insert the 200  $\mu\text{L}$  tip. Slightly press down the pressing head with the thumb. Then, place it in the sample before slowly releasing the pressing head. This step is to draw sample. Make sure now the sample has been smoothly drawn in the tip without bubbles. Then, leave the tip away from the sample liquid level. Each tip can be used once only.
- b. Move the pipette to the sample injection port of the reagent rotor/disc and insert the tip. Press down the pressing head with the thumb. Now, make sure the sample has been smoothly injected in the reagent rotor/disc. Then, take out the pipette. This step is to inject the sample.
- c. Discard the used tips. Place the used tips in a hard container labeled with "Biological Risks mark". After sterilization and cleaning per local relevant law and regulation, dispose them according to waste related regulations.

## 2.2.2 How to use the reagent rotor/disc and precautions

### IMPORTANT

- Always handle the reagent rotor/disc with care. Do not tap it on the table or laboratory bench.
- Do not use a reagent rotor/disc that has been dropped or fallen heavily.
- Carefully check every reagent rotor/disc for damage before use. **Never use a damaged reagent rotor/disc.**
- Select an appropriate reagent rotor/disc per the testing item. Please refer to the use method of the reagent rotor/disc and the label information on the aluminum foil bag of the reagent rotor/disc.
- Store each rotor/disc per the instruction labeled on the package to keep the reagents stable before its expiration date. Never use expired reagent rotor/disc which may cause incorrect test values, leading to misjudgment and causing serious consequences. If the reagent rotor/disc is expired, the analyzer after scanning the barcode will display an error message.
- **Reagent rotor/disc shall be stored in the cooling environment at 2~8°C (36-45°F) Do not freeze them. The rotor/disc can be used directly taking out from the refrigerator without warming.**
- Do not expose reagent rotors/discs in or out of their foil pouches and direct sunlight or to temperatures above 32°C (90°F).
- Do not use reagent rotors/discs whose Aluminum foil package is damaged.. A damaged pouch can allow entrance of moisture and affect the test accuracy.
- Open the pouch by using notches on both top sides of the Aluminum foil package.



### Note:

- You must use the reagent rotor/disc **within 20 minutes after** opening its pouch. If it is placed too long, it may affect the activity of the reagent and cause an inaccurate test result.
- Once the pouch is opened, do not place the reagent rotor/disc back in the refrigerator for later use.

- Keep the reagent rotors/discs clean. Handle them only by their edges to avoid smudges on the optical surfaces. Use a lint-free tissue to remove any spilled blood from the disc surfaces.
- Keep the reagent rotors/discs leveled to avoid spillage of the sample or the control.
- If the test values fall outside the acceptable range, please contact the doctor for further assistance. If necessary, you can use the new sample and redo the test, or dilute the sample and redo the test.
- Do not pick up the reagent rotor/disc after it is engaged onto the spindle.



**CAUTION**

**Follow good laboratory working practices.  
Handle all used reagent rotor/discs properly.**

**艾普萊 全套檢查升級試劑盤**  
**iPro-Lab Comprehensive Plus Panel**

樣本 140 µL  
Vol. 140 µL

For *In Vitro* Diagnostic Use Only 僅供體外診斷使用

16 Items/16項

For ALB, ALP, ALT, AMY, AST, BUN, CRE, GLU, IP, TBIL, TP, CA, GGT, GLOB, ALB/GLOB, BUN/CRE

**REF** 001-3G9A



\* Use rotor within 20 minutes after opening the pouch.  
試劑開封後，請於20分鐘內使用。

\* Use only Lithium Heparin for anticoagulant when collecting blood sample for this rotor. 請使用肝素鋰抗凝劑。

Components: Reagent rotor.....1 pcs  
Desiccant.....1 pcs

**LOT**  
Check Seal 見封口處

Use by

2°C 8°C



**CE IVD**



醫療器材商/製造廠名稱：嘉碩生醫電子股份有限公司  
醫療器材商/製造廠地址：桃園市平鎮區工業二路3號2樓

**EC REP**

**tstbio**

**艾普萊 高密度脂蛋白膽固醇試劑(未滅菌)**  
**iPro-Lab HDL Cholesterol Kit (Non-sterile)**

樣本 60 µL  
Vol. 60 µL

For *In Vitro* Diagnostic Use Only 僅供體外診斷使用

For HDL-C

**EC REP**

MedNet EC-REP GmbH  
Borkstrasse 10, 48163 Münster, Germany

**REF** 001-218A



\* Use disc within 20 minutes after opening the pouch.

\* Use only Lithium Heparin for anticoagulant when collecting blood sample for this disc.  
試劑開封後，請於20分鐘內使用。請使用肝素鋰抗凝劑。

Components:  
Reagent disc.....1pcs  
Desiccant.....1pcs

**LOT**  
Check Seal 見封口處

Use by

2°C 8°C



**CE IVD**



醫療器材商/製造廠名稱：嘉碩生醫電子股份有限公司  
醫療器材商/製造廠地址：桃園市平鎮區工業二路3號2樓

**tstbio**

**Reagent rotor/disc label schematics**  
**(Picture for reference only.)**

## 2.3 Preparation for testing

### 2.3.1 Preparation

Prepare the following necessary items before starting each test and calibration.

Item	Normal Measurement	Calibration for control
Protective gloves	O	O
Pipette/Tip	O	O
Reagent rotor/disc	O	O
Control	X	O

### 2.3.2 Startup

From powering up to displaying the main page, the operating steps of the screen are as follows:

1. Press the **Power** switch at the back of the analyzer.
2. The system initialization starts.
  - The name and system version of the analyzer are displayed on the screen and the warm-up process starts.
  - When a "Warming" message appears on the screen, the system begins to initialize self-check of each function.
  - It takes about 20 minutes for completing warm-up. The screen will display the "Main Page".

**Main Page**      28/1/2019  
    9:28

1:Measurement  
 2:History Results  
 3:Setting

**IMPORTANT** 

- Lithium Heparin is the only anticoagulant to be used. Using other anticoagulants may affect the test result. In general condition, the cap of the blood collection tube of lithium heparin is green.
- A different reagent rotor/disc may require different sample size. The reagent rotor needs 0.14 mL (140 µL) while the reagent disc needs 0.06 mL (60 µL).
- A whole blood sample shall be tested within 60 minutes after collected or separated into serum or plasma and stored it in the refrigerator at 2-8°C.
- To avoid hemolysis, do not draw blood too quickly or shake the whole blood violently.
- If the blood sample will not be tested immediately, serum or plasma can be kept in test tubes with caps and stored in the refrigerator at 2-8°C no more than 48 hours.

### 2.3.3 Rotor/ Disc Preparation

Take out the reagent rotor/disc from the refrigerator at 2-8°C. Inspect the unopened foil pouch for tears and punctures. Damaged pouch can allow moisture to reach the disc and may affect the test accuracy.

- Check the items are as required and also check the expiry date.
- Open the pouch by using notches on both top sides of the Aluminum foil package.
- Once the pouch is opened, do not place the rotor/disc back into the refrigerator for later use.

 **Note:**

- You must use the reagent rotor/disc within 20 minutes after the pouch is opened. If it is placed too long, the activity of reagent rotors/discs may be affected, causing an inaccurate test result.

## 2.4 Running the Test

### 2.4.1 Reagent rotor

When the **Main Page** appears on the screen, the analyzer is ready to start measuring your sample.

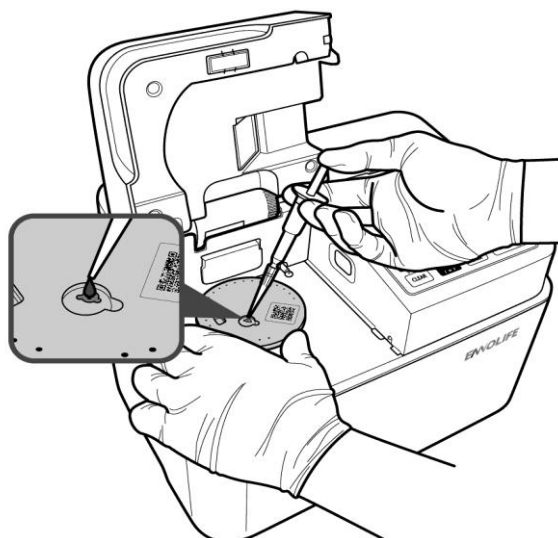
1. Open the analyzer lid and press the disc to engage onto the spindle. Now make sure the reagent rotor has been engaged and placed flatly. Press the center point of the reagent rotor with force to facilitate releasing of the diluting solution.



**CAUTION**

**Only ENNOLIFE dedicated reagent rotor can be used on the analyzer.**

2. Inject the 0.14 mL (140  $\mu$ L) sample into the sample injection port on the reagent rotor.



3. Go to the testing mode :

On the main page select and enter 1: Measurement.

```
Main Page    28/1/2019
              9:28
1:Measurement
2:History Results
3:Setting
```

4. Enter the patient ID number :

```
Patient ID:
(■          )
```

Then press the **ENTER** key to continue.

5. Select the sample type: 1. Whole blood 2. Serum/plasma 3.Urine 4. Pesticides 5. Control . If it is control, select 5.

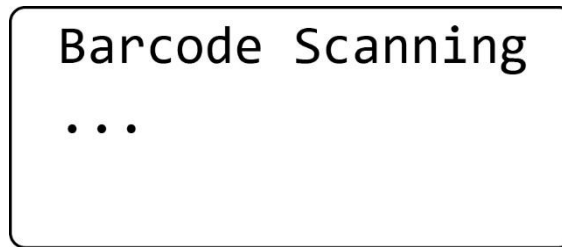
```
1. Whole Blood
2. Serum/ Plasma
3. Urine
4. Pesticide
5. Ctrol
```

6. Press the **START** key to confirm the selection :

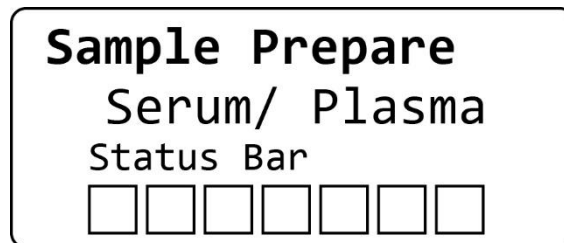
The analyzer will automatically start to process relevant steps and sample preparation.

```
ID : 1234
      Serum/Plasma
      Push START
```

7. The system will automatically scan the reagent barcode to identify the reagent, testing condition, lot number, manufacturing date and other related information.

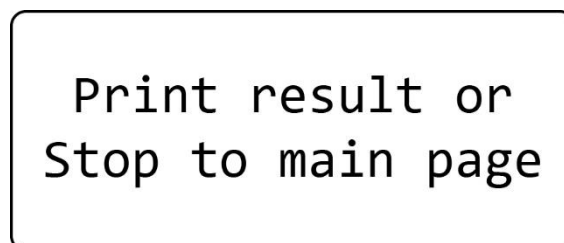


8. The system will automatically go through the procedure that has been set and start processing the sample. The screen will display the correct mode name and the status.



9. View the test result :

After the measurement is complete, the test result will be appeared on the test papers.



Press the PRINT key to print the test result or press the STOP key to go back to the main page.

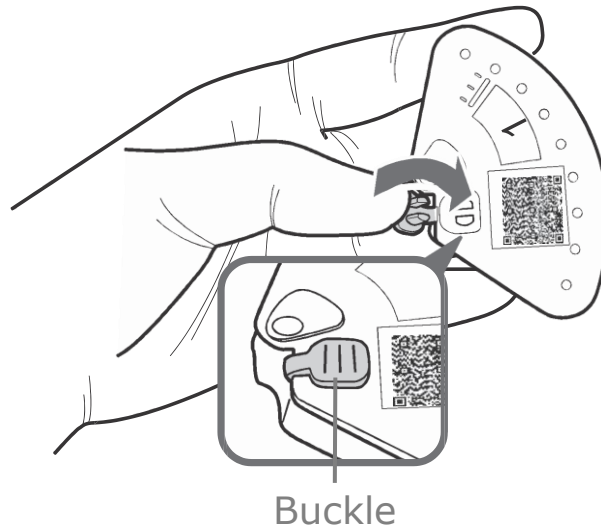
 **Note:**

- It takes 13~15 minutes to finish the measurement and display test result depending on the different sample type.

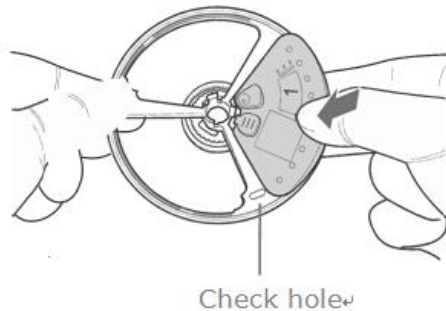
## 2.4.2 Reagent disc

Please follow steps below to perform the biochemical test:

1. Fold upward the buckle on the reagent disc and press it down with force to engage it into the corresponding hole.

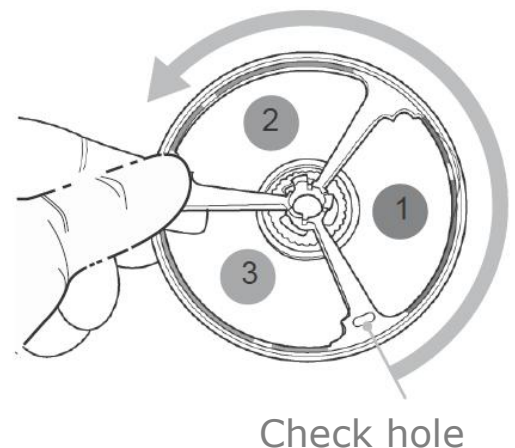


2. Locate the check hole and hold the adaptor disc firmly. Then embed the reagent disc into its corresponding position. Make sure the reagent disc has been pressed flattly. Embed another two discs by following the same step.

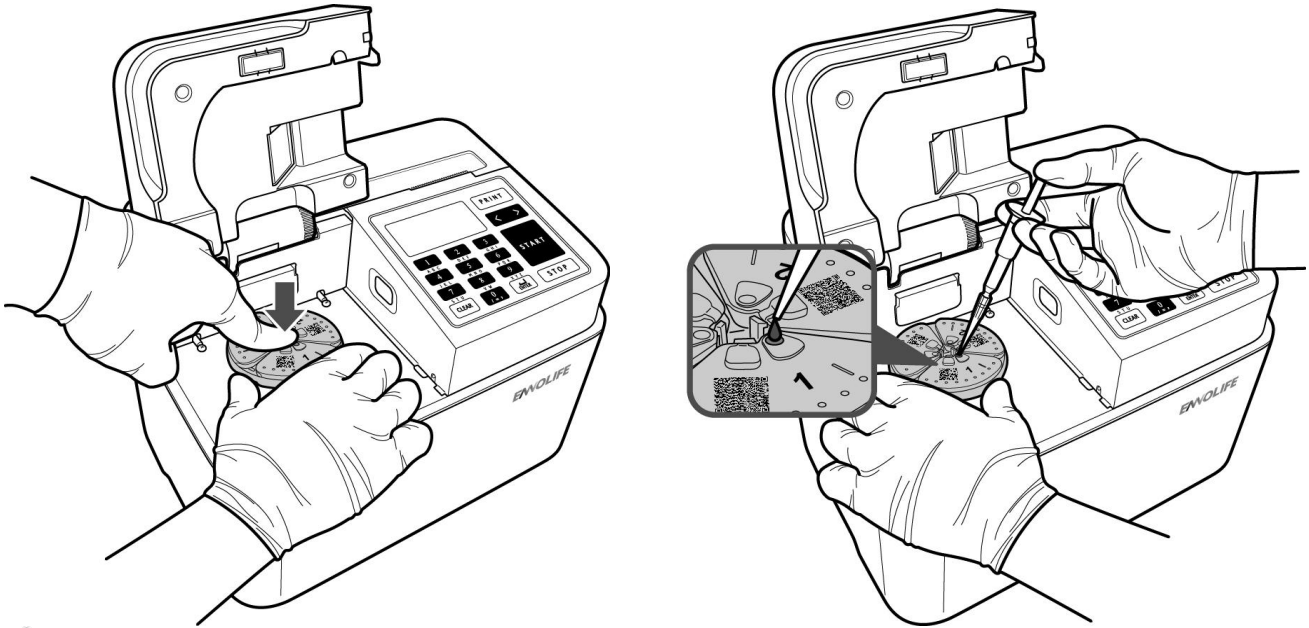


### Note:

- According to the check hole of the disc, fit the reagent discs in sequence with the counter-clockwise direction. (As shown in the right figure)
- Use a Dummy disc to place in the position where testing is not required.

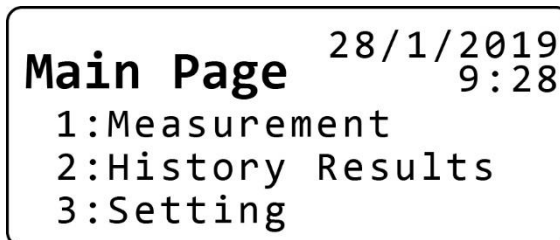


- Place the reagent disc in the analyzer and press flatly at the center point. Take out the 0.06 mL (60 µL) sample and inject it into the sample port on the reagent disc and close the analyzer lid.

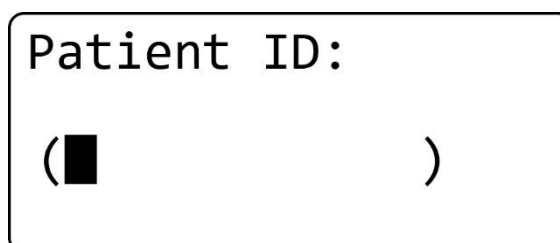


- Go in the testing mode:

On the main page select and enter **1: Measurement**



- Enter the patient ID :



Press the ENTER key to continue.

6. Select the sample type: 1. Whole blood 2. Serum/plasma 3. Urine 4. Pesticides 5. Control . If it is control, select 5.

1. Whole Blood  
2. Serum/ Plasma  
3. Urine  
4. Pesticide  
5. Ctrol

7. Press the START key to confirm selections :

The analyzer will automatically start to process relevant steps and sample preparation.

ID : 1234  
Serum/Plasma  
Push **START**

8. The system will automatically scan the reagent barcode to identify the reagent, testing condition, lot number, manufacturing date and other related information.

Barcode Scanning

...

9. The system will automatically go through the procedure that has been set and start processing the sample. The screen will display the correct mode name and the processing rate.

**Sample Prepare**  
Serum/ Plasma  
Status Bar  
□□□□□□□

★ Detecting ★

10. View the test result :

After the measurement is complete, the test result will be appeared on the test papers.

Print result or  
Stop to main page

Press the PRINT key to print the test result or press the STOP key to go back to the main page.

 **Note:**

- It takes 13~15 minutes to finish the measurement and display test result depending on the different sample type.

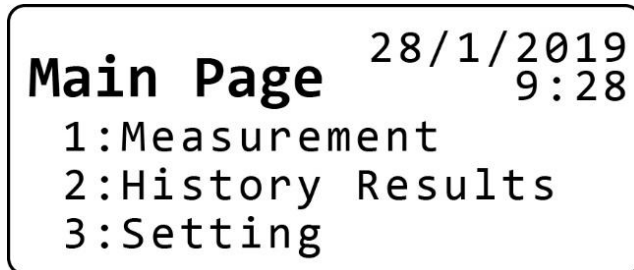
### 2.4.3 Enter Standby mode (Sleeping)

If analyzer is left idle for 30 minutes, the system will automatically enter the sleeping status. Now the backlight will be turned off. The screen will display "Sleep Mode ! Push START". Press the **START** key and the screen will appear the Main Page.

## 2.5 Recall History Results

To view the history results, do the following:

1. Select **2** to enter the **History Results** page.



2. Select the patient ID number.



Press the **ENTER** key to confirm the selection. The test record of the selected patient will be displayed on the screen.

3. Press the PRINT key to print results.

## 2.6 Configuring the Settings

In the Setting menu, you can change the measurement unit, adjust the date and time, perform light intensity check, and other functions.

1. Enter Setting mode.

Select **3** to enter the **Setting** page.

```

Main Page      28/1/2019
                9:28
1:Measurement
2:History Results
3:Setting
  
```

2. Select the item that you want to configure:

```

Setting
1:Unit          5:Int. fce
2:Time          6:Maintn.
3:Rf. Rng      7:2D Ctr.
4:Corr.         8:Motor_v
  
```

- Select **1** to enter the **Unit** page.
- Select **2** to enter the **Time** page.
- Select **6** to enter the **Maintn.** page.
- Select **7** to enter the **2D Ctr.** page.



### Note:

- Item 3, 4, 5 and 8 are reserved functions, which are only used by the maintenance and repair engineer.

## 2.6.1 Selecting Measuring Unit

On the **Setting** page, select 1 to enter the **Unit** page, where you can select the desired measurement unit.

```
Unit:
1:Common Unit
2:SI Unit
```

## 2.6.2 Adjusting the Date and Time

On the **Setting** page, select 2 to enter the **Time Setting** page. You can use the control panel to adjust the date and time settings.

```
Time Setting:
                24hr
20YY/MM/DD/hh/mm
(15/03/ / / )
ENT CLR STOP
```

## 2.6.3 Checking the Light Intensity

1. On the **Setting** page, select 6 to enter the **Maintn.** page. Select **1: Light Int. Check** to confirm the light intensity.

```
Setting-Maintain
1:Light Int. Check
2:Counts
3:Speed Check
4:Clear All record
```

2. The system takes about 15 seconds to perform the checking task.

```
Auto run after 15
sec
```

3. Once the checking task is complete, the result is displayed on the screen.

```
Spectrometer  count
340: 49278    11.7V
405: 37269
450: 44926
510: 43116
560: 48914
600: 47581
```

## 2.6.4 Deleting All Records

1. On the **Setting** page select 6 to enter the **Maintn.** page. Select **4: Clear All Record** to delete all records.
2. Select **7: Yes** to confirm the files deletion.

```
Do you want to delete
all records

7:  Yes
9:  No
```

## 2.6.5 Configuring Beep/Auto Print Function

On the Setting page select 7 to enter the **2D Ctr.** page, you can enable/disable the beep sound or automatically print function using the 2D barcode.

1. Prepare the barcode.

**Note:**

- Each function has its corresponding barcode. To obtain the correct barcode, please contact your local distributor.
2. In the **Setting-2D Control** page, place the barcode in front of the barcode reader and press the **START** key to scan the barcode. The instrument will automatically execute.

**Setting-2D Control**

Push **START** to  
Beep  
Auto Print ...

## 2.7 Quality Control

1. If the performance of the analyzer and reagent rotor/disc needs to be verified, use the control for quality control. The process is same with that of the general samples. Check if the control has expired and do not use the expired control which may affect the test result.
2. For quality control, the ENNOLIFE clinical chemistry analyzer (Non-Sterile) can use the commercially available QC materials recommended by the manufacturer. Prepare and use the control according to the product's direction for use of each brand of the control. For the variance of the QC result, the laboratory shall evaluate based on its own facilities.
3. Open the analyzer lid and put the reagent rotor/disc inside. Inject the volume of the control required by the target reagent rotor/disc. After selecting "1: testing" on the main page, select "5: Control". Then press the START key. The analyzer will run the test automatically.
4. After testing, the test results will be displayed automatically for comparing with the test values provided by the original manufacturer. If the test values fall within the qualified acceptable range, this means both the analyzer and disc are qualified for use. If the values fall outside the acceptable range, please confirm if the control fluid has been used correctly and the test was correctly performed. If nonconformity occurs in the second test, please contact your local dealer to fix the problem.

## Chapter 3 Maintenance

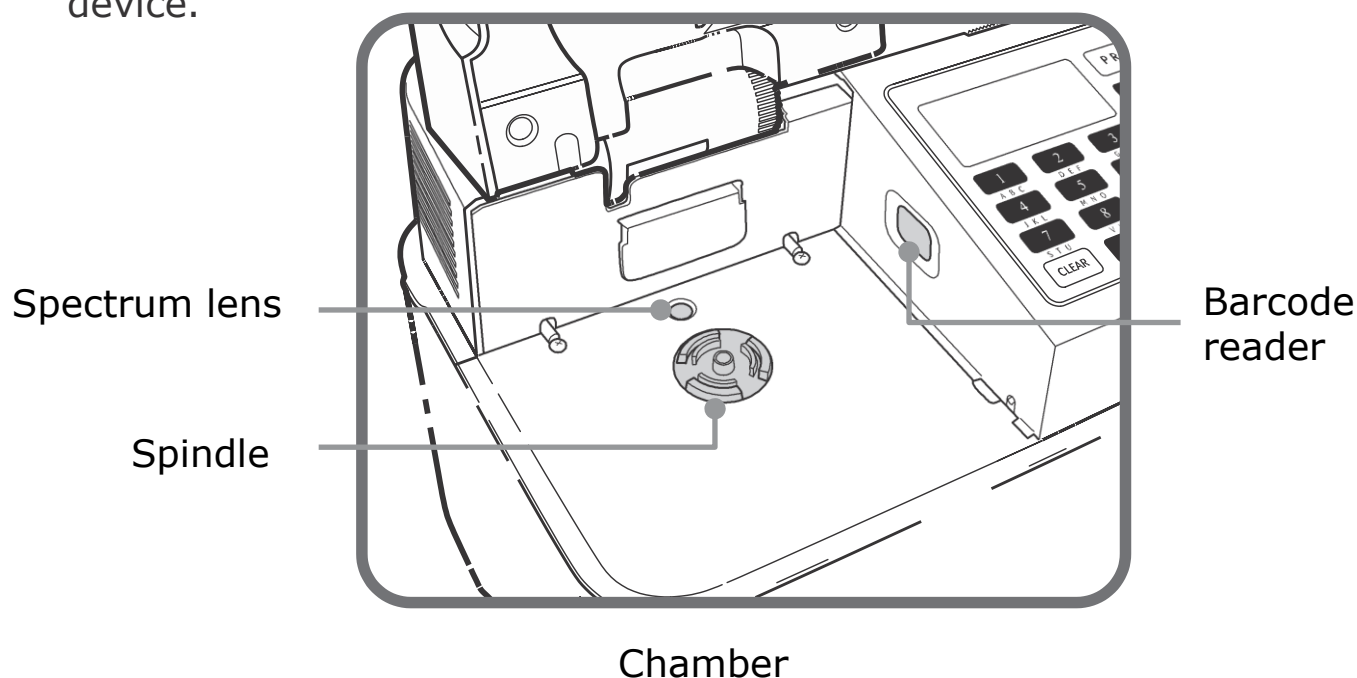
### 3.1 Basic Maintenance

The following table shows the parts that require routine or periodic maintenance.

Cleaning Area	Cleaning Frequency
Chamber	Daily
Spindle	Daily
Spectrum lens, Barcode reader	Weekly
Printer Paper	When paper runs out (When a red line appears)

 **Note:**

- Make sure the device is properly turned off before you start cleaning the device.



**CAUTION**

**Wear protective gloves to prevent exposure to pathogenic microbes when cleaning the chamber.**

## 3.2 Routine Maintenance

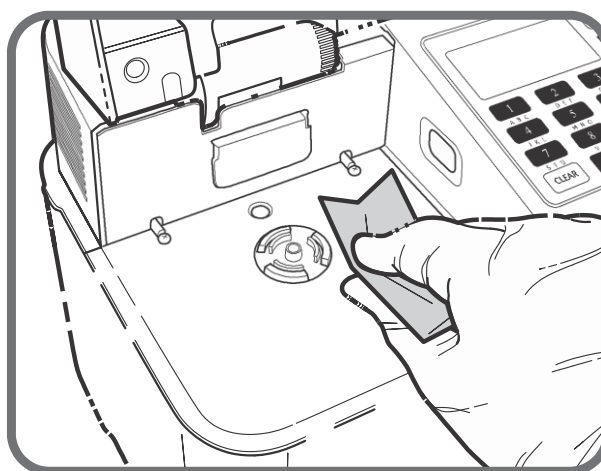
With numerous tests, the surrounding of the chamber may retain sample residues. Clean the outside surface of the analyzer once a week. Clean the inner surface of the chamber per the following steps. If you accidentally spill a sample, reagent, or other material on the analyzer, it is highly recommended to clean the surface immediately.

### 3.2.1 Cleaning the surface of Chamber and, Analyzer lid

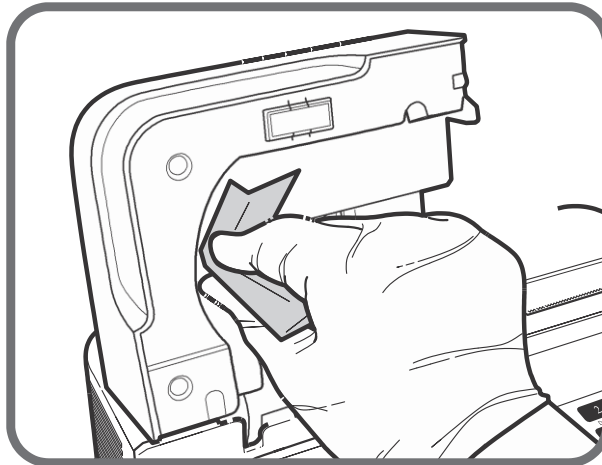
#### IMPORTANT

- **Wear protective gloves to prevent exposure to pathogenic microbes.**

1. Open the analyzer lid.
2. Use cotton swabs or towels cloth dipped in distilled water to clean the bottom and side wall of the chamber.
3. Use a soft cloth dipped in 75% ethanol solution to clean the side wall and plate of the chamber and the inner surface of analyzer lid (including the mirror).



4. Use a dry tissue or cotton to wipe the side wall and plate of the chamber and the inner surface of analyzer lid (including the mirror).



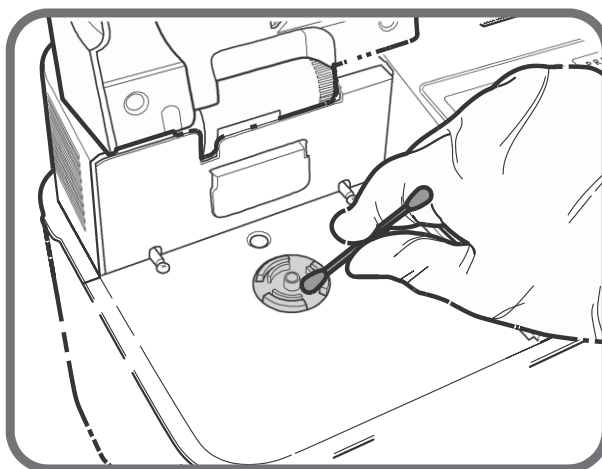
5. Close the analyzer lid. ◦

### 3.2.2 Cleaning the Spindle

#### IMPORTANT

- **Wear protective gloves to prevent exposure to pathogenic microbes.**

1. Open the analyzer lid ◦
2. Use cotton swabs dipped in 75% ethanol solution to clean the spindle.



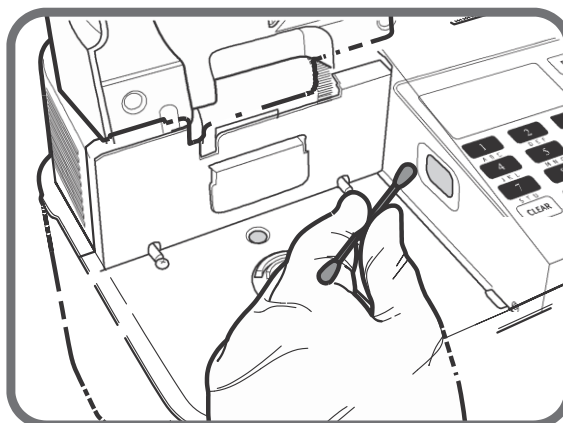
3. Close the analyzer lid.

### 3.2.3 Cleaning the Spectrum lens and Barcode Reader

**IMPORTANT** 

- **Wear protective gloves to prevent exposure to pathogenic microbes.**

1. Open the analyzer lid.
2. Use cotton swabs dipped in 75% ethanol solution to clean spectrum lens and barcode reader.

 **Note:**

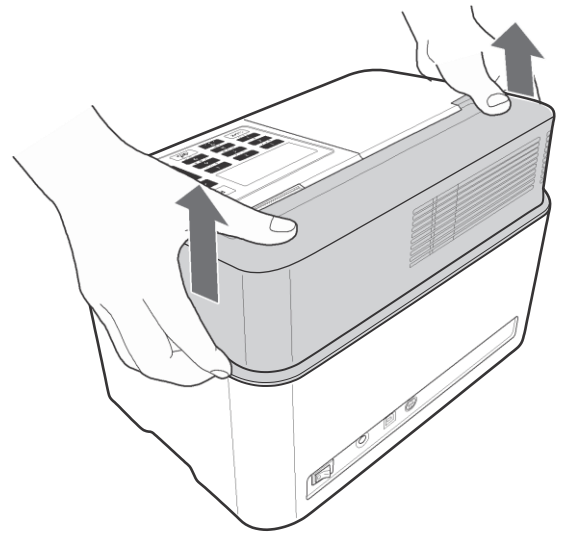
- Clean the grooves carefully and do not use too much force or the mirror surface may be scratched.

3. Close the analyzer lid.

## 3.3 Periodic Maintenance

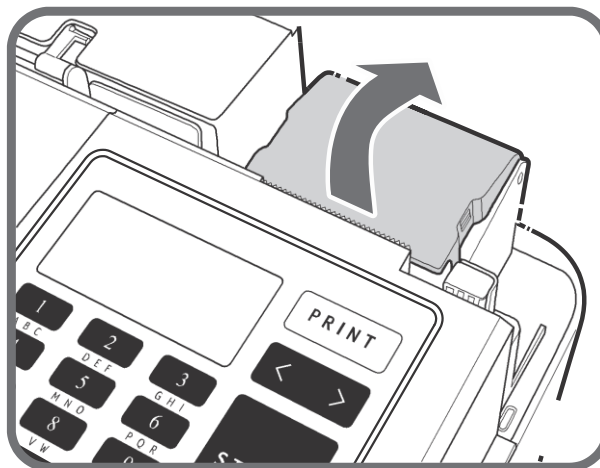
### 3.3.1 Replacing the Thermal Printer Paper

When the printer paper runs out, a red line appears on both sides of the printer paper. If the line appears, replace the printer paper with a new roll.

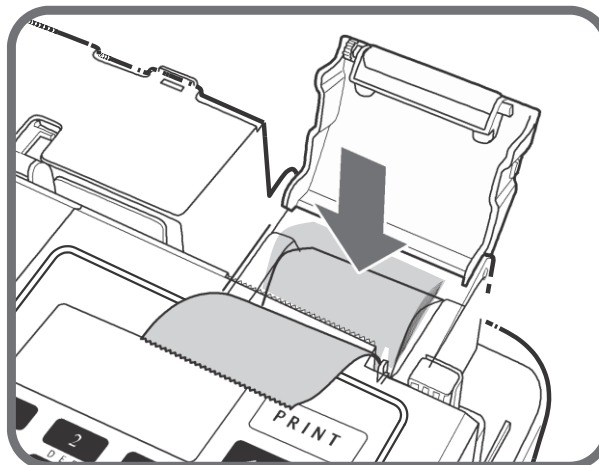


**To replace the printer paper, perform the following:**

1. Use both hands to remove the maintenance cover by pulling it upward.
2. Open the printer cover to access the paper roll slot (as shown in the figure).



3. Remove the empty paper roll and replace it with a new one. Note the paper roll direction (as shown in the figure).



4. After re-placing the printer cover, replace the maintenance cover.

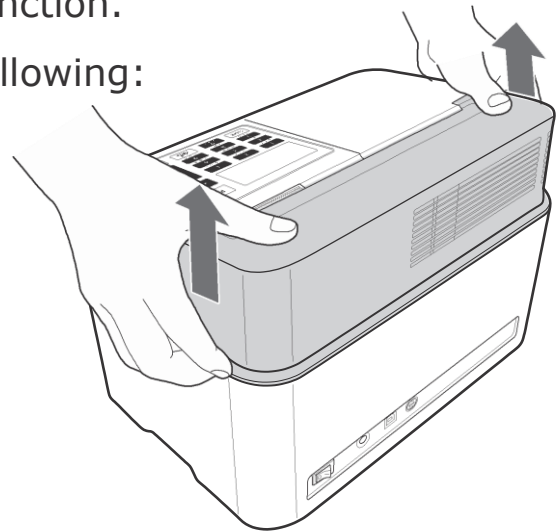
### 3.3.2 Cleaning/Replacing the Filter

#### **Note:**

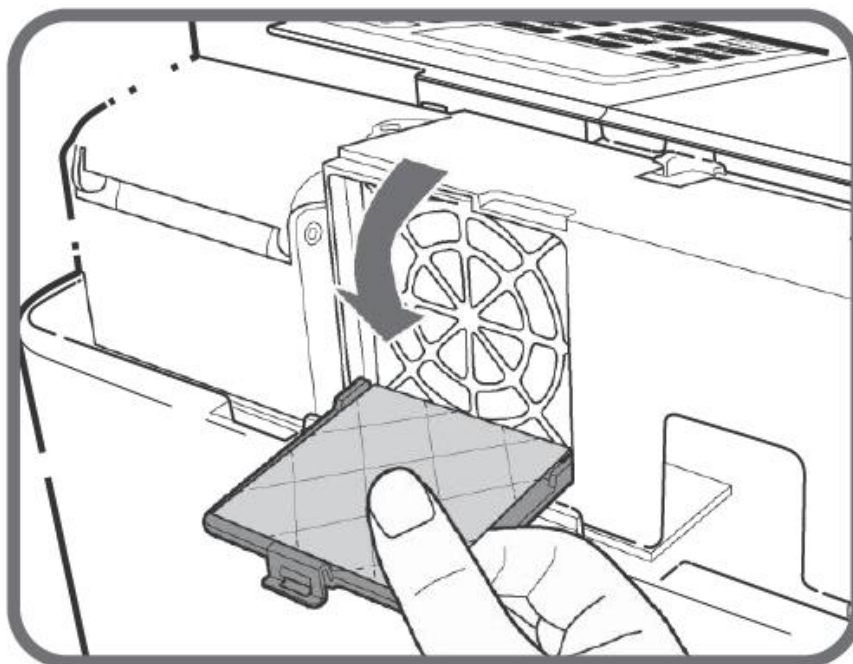
1. Dust and hair can cause device malfunction.

To clean/replace the filter, perform the following:

1. Use both hands to remove the maintenance cover by pulling it upward.



2. Open the filter compartment cover.



3. Remove the filter.

4. Clean the filter with a soft brush to remove the dust or hair.

Replace with a new filter if necessary

5. After re-placing the filter compartment cover, re-place the maintenance cover.

## Chapter 4 : Appendix

### 4.1 Troubleshooting

If you encounter any problem when operating this device, try the following solutions.

#### 4.1.1 Error Messages

When an error occurs, an alarm sounds and an error message appears on the screen.

Error Code	Screen display	Conditions and causes	Remedy
E01	Cover open	<ul style="list-style-type: none"> <li>The analyzer lid is opened during measurement or warm-up.</li> <li>The analyzer lid is opened.</li> </ul>	<ul style="list-style-type: none"> <li>Close the analyzer lid properly.</li> <li>Remove obstacle.</li> </ul>
E02	Power Down	<ul style="list-style-type: none"> <li>Power failure during testing.</li> <li>The device is switched off during testing.</li> <li>The cable is unplugged during testing.</li> </ul>	<ul style="list-style-type: none"> <li>Repeat the test</li> </ul>
E03	No disc	<ul style="list-style-type: none"> <li>The disc is not properly installed on the spindle.</li> <li>No disc.</li> </ul>	<ul style="list-style-type: none"> <li>Place the reagent rotor/disc correctly on the spindle.</li> </ul>
E04	Temp. Error	<ul style="list-style-type: none"> <li>The operating temperature fails to reach the defined control temperature.</li> <li>The ambient temperature is not in the system operation range.</li> </ul>	<ul style="list-style-type: none"> <li>Temperature too high: make sure the fan is working properly.</li> <li>Temperature too low: open the analyzer lid and make sure the chamber plate is heating.</li> </ul>

Error Code	Screen display	Conditions and causes	Remedy
			<ul style="list-style-type: none"> <li>Contact your local distributor, if the problem occurs often.</li> </ul>
E06	Wrong Disc	<ul style="list-style-type: none"> <li>The reagent rotor/disc is expired.</li> <li>Reagent rotor/disc has been reused.</li> <li>Reagent rotor/disc is reused when an error message appears.</li> </ul>	<ul style="list-style-type: none"> <li>Use a new disc which is not expired.</li> </ul>
E07	Sample Low	<ul style="list-style-type: none"> <li>No sample or insufficient sample volume.</li> <li>Use not anti-coagulated sample, causing it to coagulate.</li> <li>Stay too long after whole blood collected and cause sample coagulated.</li> <li>Gel in heparin tube block the microfluidic channel.</li> </ul>	<ul style="list-style-type: none"> <li>Use a new reagent rotor/disc and correctly inject the sample with a sufficient volume.</li> <li>Make sure there are no bubbles in the tip when collecting the sample. Make sure no sample residues in the tip after sample is injected.</li> <li>When collecting the sample with the pipette, not to draw it too quickly (easy to cause insufficient volume or bubbles), not to inject too quickly (easy to leave residues)</li> </ul>

<b>Error Code</b>	<b>Screen display</b>	<b>Conditions and causes</b>	<b>Remedy</b>
E08	Abnormal Data	<ul style="list-style-type: none"><li>• Calibration failure.</li></ul>	<ul style="list-style-type: none"><li>• Use new disc and redo the test.</li></ul>
E09	Diluent Low	<ul style="list-style-type: none"><li>• Insufficient diluents volume.</li><li>• Disc put on the analyzer for too long time without performing the test, it may cause diluent evaporation.</li><li>• The disc has been frozen causing diluents to spill.</li><li>• After the disc is placed on, no test is done and re-place it in the refrigerator or repeat the test.</li></ul>	<ul style="list-style-type: none"><li>• Use new disc and redo the test.</li><li>• Do not pick up the reagent rotor/disc after it is engaged onto the spindle.</li><li>• Make sure the reagent rotor/disc has been engaged onto the spindle and placed flatly.</li></ul>

Error Code	Screen display	Conditions and causes	Remedy
E10	Sample delivery Error	<ul style="list-style-type: none"> <li>• Fail to deliver the sample.</li> <li>• Use not anti-coagulated samples, causing it to coagulate and not able to flow smoothly through the micro-channel on the disc.</li> <li>• The sample has been stayed for too long and it starts to coagulate before anti-coagulant is used, causing it unable to flow smoothly through the micro-channel on the disc.</li> <li>• The rotational speed of the analyzer is abnormal, causing the sample unable to flow smoothly through the micro-channel.</li> </ul>	<ul style="list-style-type: none"> <li>• Use a new reagent rotor/disc to redo the test.</li> <li>• It is suggested to centrifuge the sample first and use the supernatant to eliminate the risk of blocking the channel.</li> </ul>
	Wrong Date/time	<ul style="list-style-type: none"> <li>• The Date/time setting is wrong.</li> </ul>	<ul style="list-style-type: none"> <li>• Adjust the correct date/time setting.</li> </ul>
E12	BCR Error	<ul style="list-style-type: none"> <li>• The barcode reader setting is incorrect.</li> <li>• Barcode reader connection error.</li> </ul>	<ul style="list-style-type: none"> <li>• Make sure the barcode reader setting is OK.</li> <li>• Connect barcode reader properly.</li> </ul>

Error Code	Screen display	Conditions and causes	Remedy
E13	Lipemia	<ul style="list-style-type: none"> <li>Lipemia sample</li> <li>CHEM QC: Warning message stands for an abnormal sample.</li> </ul>	<ul style="list-style-type: none"> <li>Check sample condition and redo the test depending on the sample condition.</li> </ul>
E14	Hemolysis	<ul style="list-style-type: none"> <li>Hemolysis of blood samples</li> <li>CHEM QC: Warning message stands for an abnormal sample.</li> </ul>	<p>* Rotor testing. If the + or ++ appears, the analyzer can calibrate automatically in most cases. The test values can be used for reference. However, it is suggested to redo the test if +++ appears.</p>
E15	Icterus	<ul style="list-style-type: none"> <li>Jundice sample</li> <li>CHEM QC: Warning message stands for an abnormal sample.</li> </ul>	
E16	Sample wrong	<ul style="list-style-type: none"> <li>Severe hemolysis/ lipemia samples.</li> <li>Hematocrit (HCT) level is greater than 60% (i.e. the percentage of red blood cells is too high), causing the blood cell to enter the reaction wells.</li> <li>Whole blood samples, but mistakenly use as a plasma/serum sample. With incomplete centrifugation process, this results the blood cell entering the reaction wells.</li> </ul>	<ul style="list-style-type: none"> <li>After being centrifuged externally, check sample condition if it is suitable for redo the test.</li> </ul>

## 4.1.2 Trouble Messages

Error Code	Error message	Conditions and causes	Remedy
T01	Optical Gain	<ul style="list-style-type: none"> <li>Fail to obtain the correct Optical Gain value.</li> </ul>	<ul style="list-style-type: none"> <li>Turn the device on again.</li> <li>If the problem persists, contact your local distributor</li> </ul>
T02	Calculation	<ul style="list-style-type: none"> <li>System calculation malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Turn the device on again.</li> <li>If the problem persists, contact your local distributor.</li> </ul>
T03	Light intensity Low	<ul style="list-style-type: none"> <li>The light output decayed or extinguished.</li> </ul>	<ul style="list-style-type: none"> <li>Make sure no used reagent rotor/disc in the chamber.</li> <li>Turn the device on again.</li> <li>Check the light intensity by following the procedure of 2.6.3.</li> <li>If the problem persists, contact your local distributor.</li> </ul>
T04	Device Error	<ul style="list-style-type: none"> <li>Electrical component malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Turn the device on again.</li> <li>If the problem persists, contact your local distributor.</li> </ul>

Error Code	Error message	Conditions and causes	Remedy
T05	Motor Error/ Light intensity Low	<ul style="list-style-type: none"> <li>• Transmission issue.</li> <li>• The motor shaft is stuck.</li> <li>• The optical sensor malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the device on again.</li> <li>• Make sure the motor can perform centrifugation normally and run at low speed.</li> <li>• Make sure there are no obstructions in the optical path.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>
T06	Memory : Product	<ul style="list-style-type: none"> <li>• Malfunction of writing data into memory or reading data from memory.</li> <li>• The power supply is cut off when the memory is read or the data is deleted. (writing/deleting).</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the device on again.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>
T07	Memory : Mechanism	<ul style="list-style-type: none"> <li>• Problem with the Optical System data stored in the memory.</li> <li>• The power supply is cut off when the memory is read or the data is deleted. (writing/deleting).</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the device on again.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>
T08	Memory : Optical	<ul style="list-style-type: none"> <li>• Problem with the Optical System data stored in the memory.</li> <li>• The power supply is cut off when the memory is read or the data is deleted. (writing/deleting).</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the device on again.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>

Error Code	Error message	Conditions and causes	Remedy
T09	Memory : Parameters	<ul style="list-style-type: none"> <li>• Problem with the parameters information stored in the memory.</li> <li>• The power supply is cut off when the memory is read or the data is deleted. (writing/deleting).</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the device on again.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>
T10	Intensity Wrong	<ul style="list-style-type: none"> <li>• Light intensity is not within the required range.</li> </ul>	<ul style="list-style-type: none"> <li>• Check the light intensity by following the procedure of 2.6.3</li> <li>• Turn the device on again.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>
T11	Analysis Time Out	<ul style="list-style-type: none"> <li>• Sample processing overtime.</li> <li>• Transmission failure.</li> <li>• Optical system failure.</li> </ul>	<ul style="list-style-type: none"> <li>• Press the <b>STOP</b> key to return to the Main Page and redo the test.</li> <li>• Make sure the motor can perform centrifugation normally and run at low speed.</li> <li>• Make sure no obstruction in the operating path.</li> <li>• If the problem persists, contact your local distributor.</li> </ul>

### 4.1.3 Warning Messages

When the following event occurs, a warning message will appear on the screen or will be printed out on the result report.

Message appears on the screen/printed paper	Conditions and causes	Remedy
Remain chamber no disc while warm-up process. Close cover, push START to continue.	<ul style="list-style-type: none"> <li>When a reagent rotor/disc has been placed on the chamber during the warm-up process, the system cannot execute the optical inspection automatically.</li> </ul>	<ul style="list-style-type: none"> <li>Remove the disc and close the analyzer lid properly. Then press the <b>START</b> key to continue.</li> </ul>
30 days countdown for lamp, contact your agent for replacement.	<ul style="list-style-type: none"> <li>The light output gradually decreases and the lamp needs to be replaced in about 1 month.</li> </ul>	<ul style="list-style-type: none"> <li>Contact your local distributor.</li> </ul>
Barcode Scanning Error	<ul style="list-style-type: none"> <li>Reagent rotor/disc is not placed properly.</li> <li>The barcode is damaged or the barcode is not attached to the reagent rotor/disc.</li> <li>Check the mirror in the upper lid or the barcode scanner lens for cleanliness. If it is dirty, it will cause inaccurate reading.</li> </ul>	<p>Note: Do not remove the reagent rotor/disc, try to clean the mirror or barcode scanner lens then redo the test.</p> <ul style="list-style-type: none"> <li>Open the lid and check if the disc is correct with a barcode.</li> <li>Slightly wipe the barcode on the disc and the barcode scanner with a clean cloth or paper.</li> <li>Redo the test.</li> </ul>

Message appears on the screen/printed paper	Conditions and causes	Remedy
Wrong Disc part/ Lot number	<ul style="list-style-type: none"> <li>The disc is not compatible with the version of your system.</li> </ul>	<ul style="list-style-type: none"> <li>Contact your local distributor and provide the system version # (that appears on the bottom of the display during start-up, e.g. 2.4.45BB_ CH) and the lot number of the reagent rotor/disc.</li> </ul>
Wrong Disc in a line	<ul style="list-style-type: none"> <li>Disc sequencing error.</li> </ul>	<ul style="list-style-type: none"> <li>Make sure the disc is placed on a proper position.</li> <li>Refer to "2.4.2 for reagent rotor/disc operation.</li> </ul>
Please use Serum/Plasma	<ul style="list-style-type: none"> <li>When use the whole blood sample, but mis-selecting serum/plasma on sample type selection page.</li> </ul>	<ul style="list-style-type: none"> <li>Wrong choice of a sample type may cause a seriously affected test result.</li> <li>Make sure the sample type and redo the test.</li> </ul>
Reagent rotor/disc cannot be used 2X dilu	<ul style="list-style-type: none"> <li>Sample with 2X dilution function</li> </ul>	<ul style="list-style-type: none"> <li>Redo the test, and use a correct sample.</li> </ul>

## 4.2 After Sales Service

### Warranty

A warranty card is included in this package. The warranty is necessary when the analyzer requires repair service.

After filling out all of the necessary items and confirming the contents, please keep the warranty card properly.

### Repairs

When the analyzer does not properly function	Contact your local distributor.
Repair within warranty period	Repairs and replacements can be made under warranty conditions. User needs to bear the expense of changing out
Warranty has expired	User needs to bear the entire expense of repairing or replacement.

<b>Your Local Distributor:</b>	
<b>Contact Information:</b>	



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