

EM7100P Series Auto Hematology

Analyzer Standard Operating Procedure (SOP) V1.0

1 Preparations before turning on the machine

Before turning on the main power of the analyzer, the operator must perform the following checks to ensure that the analyzer is ready:

- 1 Check whether the reagents are in sufficient quantity, whether they are cloudy or deteriorated, and whether the reagent pipelines are kinked.
- 2 Check whether the connection between the analyzer and the external equipment is correct;
- 3 Check if the power connection is correct;

2 Power on and user login

If you connect the printer, first turn on the printer switch. Then, turn on the power switch at the back of the analyzer. After the login interface appears, enter the username and password, and then access the main interface.

3 Background Check

The analyzer will automatically perform a background test upon startup, and once the startup is completed, it will automatically enter the "Sample" interface and display the background results. It will then determine whether the following requirements are met: $WBC \leq 0.20 \times 10^9 / L$; $RBC \leq 0.02 \times 10^{12} / L$; $HGB \leq 1 \text{ g/L}$; $PLT \leq 10 \times 10^9 / L$; $HCT \leq 0.5\%$. At least one background test will be conducted during the startup process. If the first test fails, another test will be performed. If both tests fail, it will report "background anomaly" and the troubleshooting section in the user manual will be followed for handling.

4 Daily QC control

Every day before sample analysis, the operator should conduct QC control analysis on the analyzer.

5 Select the working mode

- 1 Under the "Sample" interface, click the "Mode" button, and the "Mode" dialog box will pop up.
- 2 In the mode dialog box, you can select the modes of "Whole Blood CBC+DIFF", "Whole blood CBC", "pre-diluted CBC+DIFF", and "Pre-diluted CBC".
- 3 This analyzer can provide two sample information entry methods for the samples to be analyzed: sample number entry and full information entry;
- 4 After the Settings are completed, click the "OK" button, save the input content and return to the "Sample Analysis" interface.

6 Whole Blood Test

- 1 Mix the samples anticoagulated with EDTAK2 or EDTAK3 well and place them under the sampling needle, making sure the needle is inserted into the blood;
- 2 Press the sample aspiration key, and the sampling needle will automatically draw in the sample. When the buzzer sounds, remove the sample, and the analyzer will automatically perform sample analysis.

7 Pre-diluted Test

- 1 Click the "Diluent" button on the top left menu bar of the analyzer. Follow the on-screen prompts, take a clean centrifuge tube, open the lid, and then push the sampling needle vertically to the bottom of the centrifuge tube;
- 2 Press the sample aspiration key to allow the diluted solution automatically discharged by the analyzer to flow along the tube wall into the tube. Be careful to avoid liquid splashing or the formation of bubbles. After hearing the buzzer, remove the centrifuge tube. The operator can also use a pipette to transfer 380 μ L of the diluted solution into a centrifuge tube;
- 3 After adding the diluent, click the "Cancel" button to exit the diluent addition operation, and the dialog box will automatically close;
- 4 Manually collect 20 μ L of blood samples and inject them into a centrifuge tube containing the diluent. After closing the cap, mix well;
- 5 After leaving the pre-diluted blood sample for 5 minutes, mix it again and place it under the sampling needle. Press the aspiration key, and the sampling needle will automatically draw in the sample. When the buzzer sounds, remove the sample, and the analyzer will automatically perform the sample analysis.

8 Sleep

When the time for the liquid pipeline-related operations to stop reaches the sleep time set by the operator in the Settings interface on the host end, the analyzer will automatically enter the sleep state. At this point, any operation unrelated to the liquid path can still be performed.

When the analyzer is in sleep mode, you can press the sample aspiration key to cancel the sleep mode.

9 Shut down

- 1 After completing the daily work, click the "Shut Down" button in the main menu. A prompt will pop up asking whether to turn off the analyzer. Click "Confirm".
- 2 A prompt pops up on the screen to draw the probe cleanser. Place the probe cleanser bottle at the bottom of the sampling needle as required by the prompt. After the buzzer sounds, the probe cleanser bottle can be removed. Subsequently, the analyzer will automatically complete the shutdown and maintenance operation;

- 3 After the shutdown maintenance is completed, the screen will display "Please turn off power". Then, turn off the power switch of the analyzer and the power of other external devices;
- 4 Empty the waste liquid in the waste liquid bucket and handle it properly.

10 Regular maintenance

Regular maintenance

Clean the exterior of the analyzer. Use a clean cleaning cloth dipped in neutral detergent or distilled water to clean the outer surface of the instrument.

Note: Do not use corrosive acids, alkaline or highly volatile organic solvents such as acetone to wipe the surface of the instrument. Only neutral detergent can be used. It is prohibited to clean the interior of the analyzer.

Daily maintenance

Daily maintenance and upkeep are divided into two situations: operation and shutdown.

1 Operation

Daily maintenance of the analyzer during operation: Reach the set daily scheduled maintenance time.

Enter the Settings→Maintenance Settings interface, where you can set the daily scheduled maintenance time and the interval reminder time. When the scheduled time arrives, the analyzer will remind the user to perform probe cleaning and maintenance. If the user clicks "Cancel" to temporarily cancel, the analyzer will remind the user again to perform probe cleaning and maintenance after an interval of reminder time.

2 Shutdown

When the instrument performs the shutdown operation, it will automatically shut down the probe for cleaning and maintenance every day. The instrument will remind you to cut off the power after the shutdown process is completed. Please turn off the power of the instrument only after the instrument reminds you to cut off the power.

Weekly maintenance

- 1 Prepare the probe cleanser;
- 2 Enter service→Maintenance→Overall soak. Draw the probe cleanser according to the on-screen prompts and complete all subsequent operations. ◦

Note: The blood cell analyzer is a precision instrument. It is recommended to perform maintenance once a day. If the sample volume is large, the frequency of maintenance should be appropriately increased.

Monthly maintenance

- 1 Prepare ethanol (with a concentration of 95%) and cotton swabs;
- 2 Use a cotton swab dipped in alcohol to wipe the outer wall of the sampling needle. Gently wipe the outer wall of the sampling needle clean. Do not bend it forcefully;

- 3 Wipe the bottom of the swab with a cotton swab dipped in alcohol;
- 4 Click the Service→Maintenance →Cleaning →Sampling Needle button to perform two sampling needle cleanings.

Precautions: When performing the above cleaning operations, please take protective measures (such as wearing gloves and protective glasses) to avoid direct contact with the internal components of the instrument.

Maintenance of analyzer when they are not in use for a long time or during transportation

If the instrument is not used for more than two consecutive weeks or needs to be packed and transported, the following methods and steps should be followed:

- 1 Click the Service→Maintenance → Fluidics → Pack-up, and follow the on-screen prompts to complete all operations;
- 2 Cover the remaining reagents with the bottle cap and tighten it. Store and keep the reagents in accordance with the instructions for use. Users should establish and maintain effective reagent storage measures to prevent the deterioration, misuse and ingestion of reagents;
- 3 Use the pipe plugs removed during the first installation and install them onto the pipe interfaces on the rear panel of the instrument one by one according to their colors;
- 4 Clean the dilution bottle cap assembly, waste liquid bottle cap assembly and lyse agent liquid guide tube respectively with distilled water, dry them in a cool place and then package them in plastic bags;
- 5 Clean the power cord with a clean cleaning cloth dipped in neutral detergent, place it in a cool place to dry, and then pack it in a plastic bag;
- 6 Put the instrument and the components packaged in plastic bags into the instrument's packaging box and seal it well.

11 Fault handling

In case of any malfunction, you can click on the fault information area at the lower right corner of the interface to obtain the fault assistance information

12 Power supply requirements

- 1 The analyzer must be used under good grounding conditions;
- 2 Use the fuse of the specified specification and the power cord provided by the original factory;
- 3 Before installing the analyzer, make sure the power supply meets the requirements of the analyzer.

13 Environmental requirements

- 1 Temperature, humidity and pressure requirements:
Normal operating temperature range: 10 °C to 30 °C;

Relative humidity range: 20% to 85%;

Atmospheric pressure range: 61.6 kPa to 106 kPa;

- 2 The environment should be as dust-free as possible, free from mechanical vibration, pollution, major noise sources and power interference;
- 3 It is recommended to assess the electromagnetic environment of the laboratory before operating the equipment;
- 4 Stay away from sources of strong electromagnetic field interference;
- 5 Do not approach brush-type motors, flickering fluorescent lamps and electrical contact devices that are frequently switched on and off;
- 6 Avoid direct sunlight or place in front of heat sources and wind sources;
- 7 Choose a well-ventilated location;
- 8 It has a good grounding environment;
- 9 Do not place the main unit on an inclined surface. Use it indoors.