XC-A30 Automated ESR Analyzer

Operation Manual

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Chapter 1. General

XC-A30 automated Erythrocyte Sedimentation Rate (ESR) analyzer is a fast and easy-to-use instrument controlled by micro-computer system.

The analyzer can measure 30 tubes simultaneously, monitoring the change of the erythrocyte sedimentation rate during the whole testing process. The measurement of each sample is independent. The result is in mm/1h. The sedimentation curve can be displayed at LCD screen with 3 minute interval and can be printed out by internal printer.

Scope of application: erythrocyte sedimentation rate analysis

Features:

- 1. Utilizing of Micro-processor technology, fully controlled by computer programs.
- 2. Large LCD screen with backlight, man-machine conversation interface, touch-screen input, very easy to use
- 3. Two measure modes selectable: 30 min (correspond to Westergren 1 hour result) or 60 min (correspond to Westergren 2 hour result)
- 4. The ESR results under temperature of 150C ~ 320C can be automatically compensated to 180C

- 5. The throughput is up to 60 samples per hour
- 6. Up to 9 digits for patient number
- 7. Results can be displayed on LCD screen and printed out by internal printer
- 8. Standard RS-232 interface, can be connected to external computer for remote communication and data process
- 9. Memory for 200 sample results

Chapter 2. System Structure

The analyzer consists of the main unit (including the socket for 30 tubes), analysis system, display, operating component, internal printer and ESR tubes.

1. Front panel (figure 2-1)



Figure 2-1

- 1) ESR tube socket: to hold the sample tubes
- 2) LCD: to display date, time, instrument temperature, operating modes, working status, ESR tube status, ESR result (mm/1h), sedimentation curve and function prompts.
- 3) Touch screen: touch the menu on the screen with finger to select

the corresponding operations

- 4) Recorder cover: open this cover to fit new printing paper
- 5) Printing paper: thermal paper roll, width 57mm

2. Rear panel (figure 2-2)

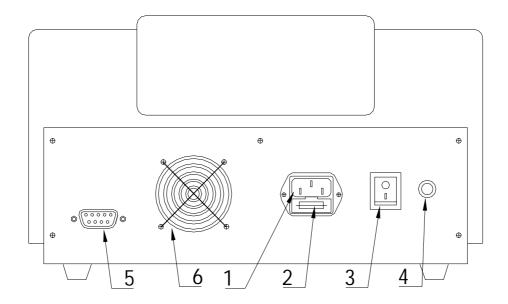


Figure 2-2

- 1) Power socket: input voltage AC220/110V \pm 10%, 50/60Hz \pm 1Hz
- 2) Fuse: 0.5A ($5 \times 20mm$)
- 3) Power switch
- 4) Grounding pole
- 5) RS-232 interface: serial communication with external computer
- 6) Fan

Chapter 3. Installation

1. Unpacking and inspecting

Carefully open the carton when you receive the analyzer, inspect the instrument to make sure it is not damaged, then check the accessories against the packing list. Notify the supplier immediately if you find anything damaged or missing. Carefully handle the glass ESR tubes.

2. Environment requirements:

To ensure the instrument under optimum working status, it must be installed according to the following requirements:

- 1) The environment should be clean and as free as possible from the dust
- 2) The instrument should be installed on a stable and solid platform that is free of mechanical vibration and away from vibration source
- 3) Do not place the instrument in direct sunlight.
- 4) Ambient temperature: 150C~320C, humidity: less than 85%.
- 5) Power supply must be stable, input voltage: AC220/110V \pm 10%, 50/60Hz \pm 1 Hz
- 6) The instrument should be away from the strong electrical interference

3. Installation

Pay attention to the following points when you install the instrument:

- 1) The power adapter of the instrument is a three-core socket, the grounding terminal must be well connected to ground to ensure safety and reliable operation.
- 2) The instrument must be placed horizontal to ensure that ESR tube vertical after it been inserted into the hole. Meanwhile the instrument should be placed stably, reliably and anti-vibrant. After then, turn on the power, the instrument will run self-test and system setting automatically. The system settings include date, time, operating mode, initial test number and temperature adjustment.

Recommendations:

- 1) Please read the user manual carefully before adjusting the system setting
- 2) Usually the operating mode is set to 30min.
- 3) The default setting of the temperature compensation for the measuring result is referred to 180C

Chapter 4. Operation

1. Reading principle

Monitor 30 tubes simultaneously by the measuring board that consists of infrared photocell. The vertical measuring interval is 0.16mm (i.e. the resolution of the instrument), and the measuring cycle is 3 minutes. When the tube inserted, the analyzer automatically starts the measurement. The time for the first reading is set as "0 min", and the blood level in the tube is been detected. The acceptable range for the blood height setting is 50mm ~ 64mm (starting from the bottom of the ESR tube), the recommended height is 55mm (the corresponding volume is 1.6ml, i.e. 0.32ml anticoagulant and 1.28ml whole blood). The operating mode is 30 min if measures the tube for 10 times, and 60 min if measures the tube for 20 times. For the details of measuring and calculating principles, please refer to "Chapter 5 - Measuring Principle"

2. Sample Preparation

It requires 1.28ml whole blood for each sample. The blood can be directly injected into the ESR tube which contains 0.32ml anticoagulant. This is to ensure proper volume of the blood in the ESR tube. There are two indicating lines on the ESR tube. Inject the blood into the tube until the level is between the two lines, then seal the tube tightly with a rubber cover, slowly reverse the tube for at least 5 times to mix the anticoagulant

and whole blood completely.

Note: Air bubbles should be excluded from the anti-coagulated blood.

3. Label

Every ESR tube has a label. The label should be attached on the tube flatly, otherwise the tube may be not able to insert into the hole or can not reach the bottom and cause wrong measuring result. The correct label position on the ESR tube is shown as figure 4-1. There are two indicating lines on the label. The distance between the two lines is 9mm, the position is shown as H in figure 4-1. The recommended position of the blood height (M) is 55mm (corresponding to 1.6ml, i.e. 0.32ml anticoagulant and 1.28ml whole blood). The blood level should reach between two indicator lines, thus the analyzer can detect the blood level correctly.

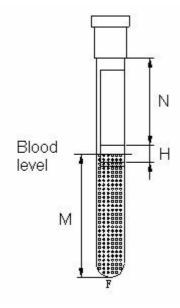


Figure 4-1

Note: the injected blood and coagulant should not exceed the

range of H. In figure 4-1, the maximum value of M is 64mm and the minimum is 50mm. This is the effective blood height.

4. Sample mixing

The sample must be fully mixed before measuring. The method is indicated in "Section 2: Sample preparation", or you can use the rotated mixer or special mixer.

5. Sample Insert

The sample should be inserted into the analyzer immediately after mixing. Therefore, it is suggested to mix the sample near the analyzer. The sample tube can be inserted into the analyzer at any time, either in working status or in standby status. After the sample been inserted, the corresponding position will show "tube" like position #15 (without patient ID input) or #19 (with patient ID input) in figure 4-2. The position without "tube" is free to use.

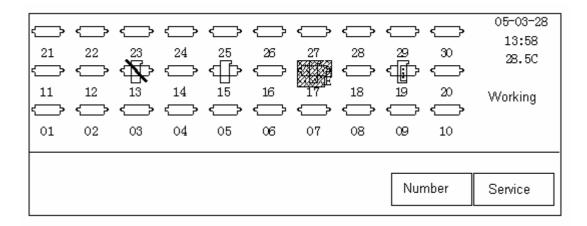


Figure 4-2

6. Sample Remove

Do NOT pull out ESR tube during testing.

If you pull out the tube during testing, the analyzer will give out "beep" sound and the test will be cancelled. Then after one measuring cycle, the status of the corresponding position will change from "with tube" to "without tube". When the test finished, symbol "E" will be displayed on the corresponding position (as position #17 in figure 4-2). Remove the sample tube, then the status of the position will change to "without tube". It indicates the position is free and new sample can be inserted for testing.

7. Interface

7.1 Turn on the power, the instrument runs self-test, and after a few seconds, the screen displays:

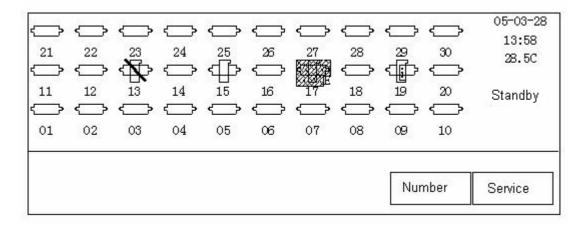
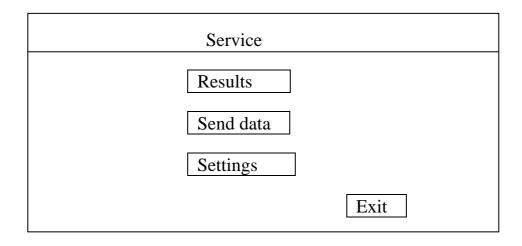


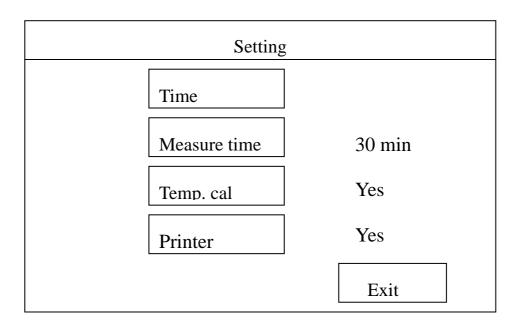
Figure 4-3

If the self-test failed, the screen will display "Measuring board failure", and the instrument will halt.

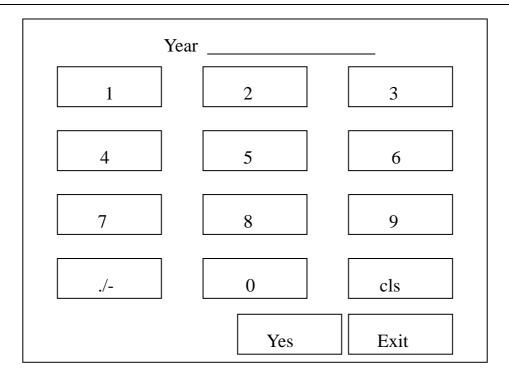
7.2 Press "Service", enters into service menu, the screen displays:



7.2.1 Press "settings", enters into system setting menu, the screen displays:

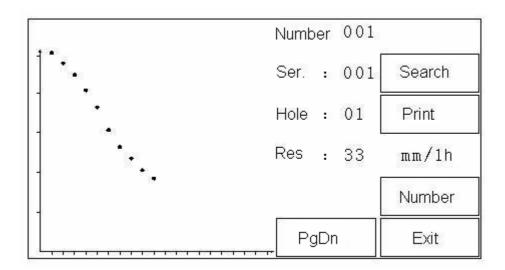


a) Press "Time", the screen displays:

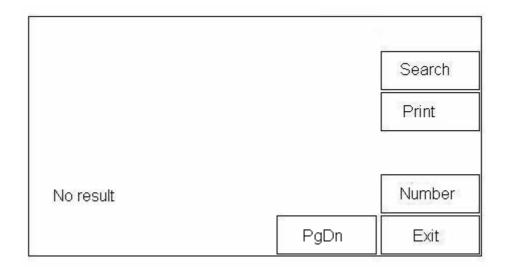


Input "year" and press "Yes" to save. Input "Month", "Date", "Hour" and "Minute" accordingly. Press "Exit" to return to the previous menu.

- b) Press "Measure time", the setting switches between "30 min" and "60 min".
- c) Press "Temp. cal", the setting switches between "Yes" or "No". (The temperature compensation mode can not be changed during testing)
 - d) Press "Printer", the setting switches between "Yes" or "No".
 - e) Press "Exit" to return to the previous menu.
 - 7.2.2 Press "Send data" to transfer the data.
- 7.2.3 Press "Results", the screen will display the result and ESR curve if there are results stored in the analyzer. Otherwise it will just display "No Result"

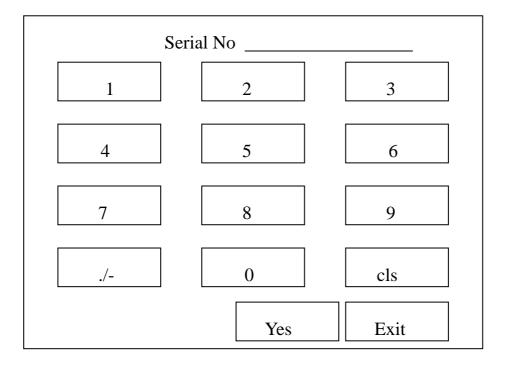


(Screen display with result)



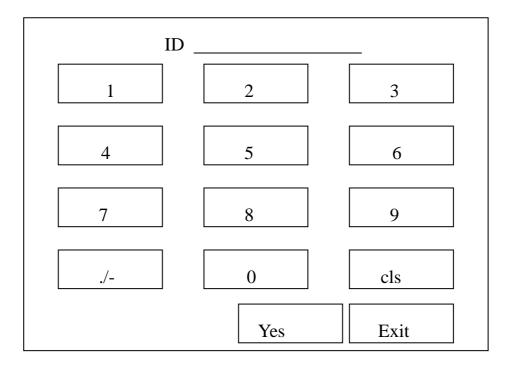
(Screen display without result)

a) The operator can search the results by serial number. Press "Search", the screen will display:



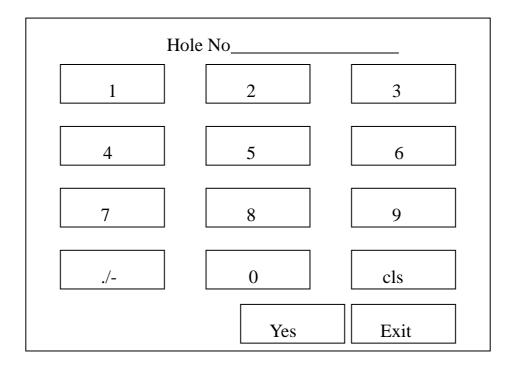
Input the serial number. Press "Yes" to accept, then the screen will display the result corresponding to the input serial number.

b) If the operator wants to change the sample number, press "Number", the screen will display:

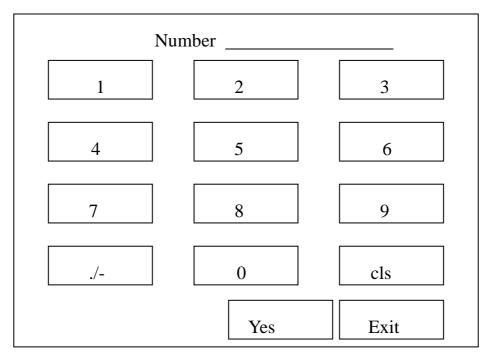


Input the correct sampler number. Press "Yes" to accept. The screen will display the result with new sample number.

- c) Press "PgDn" to review the result of the next sample.
- d) Press "Print" to print out the searched data.
- e) Press "Exit" to return to the previous menu.
- 7.3 The operator can input the patient numbers before test. Press "Number" in main menu, the screen will display:



Input the hole number. Press "Yes" to accept, then enter into patient number edit menu, the screen will display:



Input the patient number, press "Yes" to accept and return to the main menu.

8. Operation

- 8.1 Turn on the power, the instrument runs self-test automatically.
- 8.2 Press "Service", enter into service menu, then press "Setting", enter into setting menu.
 - A. Press "Time", enter into time setting menu, set the time properly.
- B. Press "Measure time", the screen will display "30 min" or "60 min".Usually "30 min" is suggested.
- C. Press "Temp. cal", the screen will display "Yes" or "No". Select "Yes" for temperature compensation.
- D. Press "Printer", the screen will display "Yes" or "No". Select "Yes" to print out the result automatically.
 - E. Press "exit" to return to main menu.

- 8.3 Press "Number" in the main menu, input the corresponding hole no. and sampler number for the samples to be tested.
- 8.4 After warming up for 15 minutes, insert the sample tubes into the holes accordingly and start the testing. The result will be printed out automatically once the test finish.
- 8.5 After all the tests finish, power off the instrument.

Chapter 5. Measuring Principle

1. Measuring Method

The principle of data reading is shown in Figure 5-1. The moving area of the infrared optical coupler (TX-RX) is C, L is the bottom position, H is the top position.

During the movement of the infrared optical coupler (TX-RX) from bottom (L) to top (H), if the infrared light can not reach the receiver, then it means the infrared light is obstructed by high density red blood cells. Once the infrared light can go through ESR tube and reach the receiver, the receiver will send signal to the computer to calculate the distance to the bottom.

L1: the height of the blood in the ESR tube at 0 min.

L2: the height of the blood in the ESR tube at 30 min.

L3: the height of the blood in the ESR tube at 60 min.

K: the height of the blood in the ESR tube when the optical coupler moves to the bottom. It is decided by the system itself and setting in the computer.

Each time adding 1.6ml anti-coagulated whole blood into ESR tube, the height of the blood will be slightly changed due to the difference of the ESR tube. To compensate this difference, the instrument will take into account of the initial height in a certain range and the sedimentation

percentage.

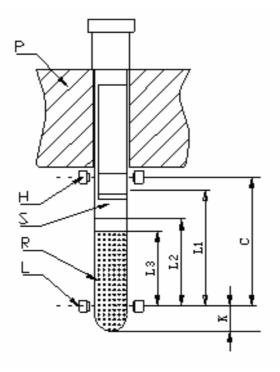


Figure 5-1

P: ESR tube socket.

H: The highest position of the optical coupler (TX-RX).

L: The lowest position of the optical coupler (TX-RX)

R: Red blood cells

S: Blood Serum

C: Measuring range

K: The distance from the bottom of ESR tube to position "L".

L1: Initial height (at 0 min)

L2: The height of red blood cell at 30 min.

L3: The height of red blood cell at 60 min.

2. Calculation

The calculation of 30 min Sedimentation percentage is as formula (1)

$$%S30' = 100(L1-L2)/(L1+K)$$
 (1)

The calculation of 60 min Sedimentation percentage is as formula (2)

$$%S60' = 100(L1-L3)/(L1+K)$$
 (2)

After summarizing abundant testing results from plenty of hospitals and labs, formula (3) is to convert sedimentation percentage at 30 min or 60 min to Westergren 1h or 2h result respectively.

$$Y = aX + b \tag{3}$$

Y: Westergren result

X: Sedimentation percentage

a, b: constant

Westergren 1h result is calculated from (a1, b1) and %S30', while Westergren 2h result is calculated from (a2,b2) and %S60'

3. Compensate to Westergren result at 180C

The calculated ESR result at different temperatures can be compensated to the standard Westergren ESR result at 180C by interpolation. If the temperature compensation is turned off during testing, it can be done manually against the manual compensation table.

The range of temperature compensation is $15 \circ C \sim 32 \circ C$. If the

temperature is lower than 15oC, the result will be considered as at 15oC and be compensated accordingly. If the temperature is higher than 32oC, the result will be considered as at 32oC and be compensated accordingly.

The recommended operation temperature is 15 oC ~ 30oC_o

Manual Compensation table

| 18oC | 15oC | 18 o C | 20oC | 25oC | 30oC |
|--------------|--------|---------------|--------|--------|--------|
| Compensation | Test | Test | Test | Test | Test |
| value | Result | Result | Result | Result | Result |
| 5 | 4 | 5 | 5 | 6 | 8 |
| 10 | 9 | 10 | 10 | 12 | 16 |
| 20 | 18 | 20 | 21 | 25 | 31 |
| 30 | 27 | 30 | 31 | 37 | 45 |
| 40 | 36 | 40 | 42 | 49 | 58 |
| 50 | 46 | 50 | 52 | 60 | 71 |
| 60 | 55 | 60 | 62 | 71 | 82 |
| 70 | 63 | 70 | 72 | 82 | 93 |
| 80 | 72 | 80 | 82 | 93 | 104 |
| 90 | 81 | 90 | 93 | 103 | 114 |
| 100 | 90 | 100 | 103 | 114 | 125 |

4. ESR curve.

ESR curve is retrieved from the sedimentation percentage results that obtained every 3 minutes. It has two types: 30 min or 60 min. 30min ESR curve is shown as figure 5-2, and 60min ESR curve is shown as figure 5-3.

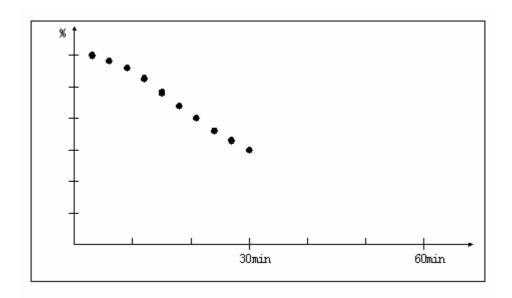


Figure 5-2 30min ESR curve

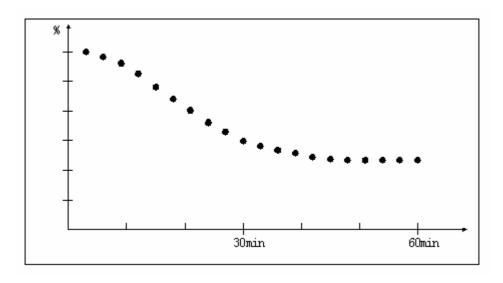


Figure 5-3 60min ESR curve

5. Print out result

When the internal recorder is turned on, once the test finished, the recorder will automatically print out the ESR result (mm/1h), ESR curve, date, time, number and patient ID.

The printing format is as below:

ESR curve (as shown in figure 5-2 or 5-3)

Date: 06-04-25 Date: April 25th, 2006

Serial No. 001 Serial No. 001

Pat-ID: No.001 Patient ID 001

POS: 01 ESR tube position: 01

TEMP: REF.TO18C Compensated result refer to 18°C

hour (Westergren)

Chapter 6. Specifications

Area of Application: Erythrocyte sedimentation rate analysis

Measuring time: 30 minutes or 60 minutes selectable

Throughput: up to 60 samples per hour

Reading channel: 30

Loading capability: Max 30 samples at a time

Loading pattern: random

Analysis result: in Westergren ESR value (mm/1h)

Temperature compensation: refer to 180C automatically.

Measuring principle: Infrared barrier

Reading resolution: 0.2mm

Reproducibility: <3% or ± 2 mm/1h

Result resolution: 1mm/1h

Blood level range: 50mm ~ 64mm

Display: LCD screen with backlight

Input: Touch screen

Interface: RS-232 serial port

Print: internal thermal recorder

Power supply: AC 220V/110V \pm 10% 50/60Hz \pm 1 Hz

Power: 50W

Dimension (LxWxH): 400 x 300 x 200 mm

Net Weight: 11.5kg

Operation conditions:

Temperature: 15oC ~ 32oC

Humidity: 85%

Chapter 7. Maintenance

- 1. There is no special maintenance required. Keep the operation environment dry and clean. Keep the ESR tube hole away from the dust. Otherwise, it will affect the performance of the optical coupler (TX-RX) and make it unstable. Handle the glass ESR tube very carefully to avoid broken. Avoid direct sunlight to the instrument.
- 2. Do not clean the instrument surface with wet cloth or corrosive liquid. Prevent the liquid from flowing into the ESR tube insert holes, otherwise it will the damage the instrument.

Chapter 8. Troubleshooting

1. No print out after the test finished

Cause: The recorder is turned off. Change its status to "Yes".

2. Insert the ESR tube, after one measuring cycle, it shows status like position #13 in figure 4-2

Cause: The blood level in ESR tube exceeds the measuring range, or nontransparent material is inside the hole.

3. The motor doesn't stop during testing and gives out abnormal noise.

Cause: The optical coupler on the measuring board is malfunction.

4. The screen shows tube inserted in a hole, but actually there is no tube.

Cause: The optical coupler on the measuring board is malfunction, or seriously contaminated by dust or oil.

- 5. No display on the screen after power on.
 - a) Check the power supply.
 - b) Check the fuse. If broken, replace with a new one.