ALS – SC 4

SEMI AUTOMATIC BLOOD COAGULATION ANALYZER

Operating Manual

ALARİS MEDİKAL ve ELEKTRONİK SİSTEMLER SAN.TİC.

www.alaris.com.tr

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PRODUCT AND LABEL INFORMATION

Name	SEMI AUTOMATIC BLOOD COAGULATION ANALYZER
Model	ALS – SC 4
Certificates	CE
Manufacturer	ALARİS MEDİKAL ve ELEKTRONİK SİSTEMLER SAN.TİC.
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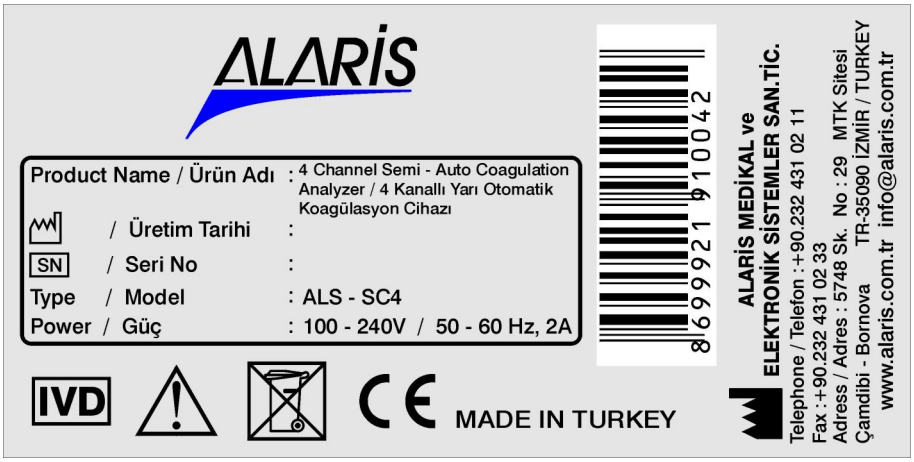


POWER REQUIREMENTS

The instrument's power requirements are explained as follows. If the local power supply is not stable or higher or lower, the instrument must never be used. The voltage of power supply must meet these requirements, ± % 10 deviation is tolerable. Otherwise instrument will be damaged.

- Power Supply Voltage : 110V ~ 220V
- Power Supply Frequency : 50Hz / 60Hz
- Power Supply Output Impedance : 0.5 Ω or below
- Grounding : For extra protection, the instrument must be connected to a grounding device or plug, after power supply is connected.

WARNING: The user should wait for at least 5 seconds before switching the unit on again after power off.

SAFETY REQUIREMENTS

Safety requirements for the operator is explain in this chapter. Please read carefully these instructions before setting up the instrument to ensure operator's safety. If these instructions violated, death or serious injury may occur.

Follow these safety instructions:

- System meets the Type BF general equipment, Class I, IEC Standards.
- No modifications are allowed on system. Contact your authorized service if necessary.
- All settings of the system is done before the distribution. Please don't try to add anthing.
- If any error occures during operation, please cut the power off immediately. Contact your dealer or technical service.
- Please use grounded wall outlet, never take off the ground line.
- When connecting external electronic or mechanic systems, confirm that they meets the EN60601-1 standards. Check any electrical leakage or other safety performance to avoid any potential injury.
- Setting up must be done by the authorized personal. Don't try to set up the instrument by yourself.
- System is not designed to work in flammable area. Such an area can cause explosion.
- Turn the system off, before cleaning. Do not use wet cloth or corrosive fluid to wipe the upper surface in case fluid flows into the system.

When expiration period of this instrument is over contact with your local dealer, call technical service to dispose of.

1. General Introduction

1.1 Features

- **"ALS – SC 4"** is easy operating with user friendly operator interface, clinical analyzer controlled by build-in microcomputer throughout the whole process.
- With graphic LCD, English menu promting, man-instrument conversation interface, extremely easy to operate.
- It constantly and simultaneously scans 4 tests.
- A 10 digit patient ID can be entered.
- Tested results can be displayed on LCD, as well as being printed out by a built-in printer.
- The analyzer has an RS-232 standard interface to connect with an automation center to process patient datas.
- 350 testing results can be stored.

1.2 Intended Purpose

"ALS – SC 4 " Semi Automatic Blood coagulation Analyzer is exclusively employed for analysis of the human blood coagulation time. It constantly and simultaneously scans 4 tests. It scans the coagulation interval of each sample independently and stores the result. The result can be showed on LCD, or printed out by the built-in printer, or sent to a host computer.

1.3 Environmental Requirements

- Make sure the surrounding is clean and free of dust.
- Put the instrument on a stable and flat tablet o avoid vibration.
- Keep away from direct sunlight and moisture, strong magnetic and electric field disturbances.
- Environmental temperature is at 15-32˚C and relative humidity is lower than 80%.

1.4 Working Conditions

- The voltage of power supply should be at 110V-240V 50Hz ±%2. If the local power supply is not constantly stable, the user is required to use an UPS (Uninterruptable Power Supply).
- Keep away from strong magnetic field (such as centrifuge) and electric field disturbances. No electric apparatus with strong current nearby is allowed.

1.5 Safety Requirements

The instrument must be operated with a protective ground connected via the appropriate power cord of three wires and power supply socket with earth lead. If the socket has no stable contact with the earth, please use a special earth wire to ensure security and stabilization of the measurement.

1.6 Impact to the Environment

The instrument has the following CE certificates.

EN 61326-2-6 : 2006 Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment İletilen/Işınan Parazit Yayınımı

EN 61326-2-6 : 2006 Conducted/Radiated RF Emission

EN 61326-2-6 : 2006 Radiated RF Immunity

EN 61326-2-6 : 2006 EFT Burst Immunity

EN 61326-2-6 : 2006 Surge Immunity

EN 61326-2-6 : 2006 Conducted RF Immunity

EN 61326-2-6 : 2006 Voltage Dips, Short Interruptions, and Voltage Variations

EN 61326-2-6 : 2006 ESD Immunity

IEC 61010-1 / EN 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements

IEC 61010-2-101 / EN 61010-2-101 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101 : Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment

2. Working Principle and Structure

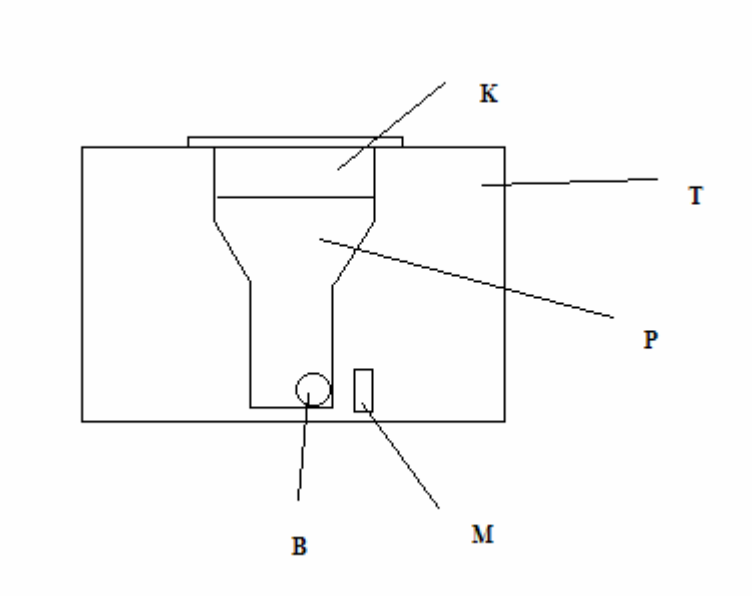
2.1 Working Principle

2.1.1 Measuring Principle

Coagulation is a complex process by which blood forms clots. It is an important part of hemostasis, the cessation of blood loss from a damaged vessel, wherein a damaged blood vessel wall is covered by a platelet and fibrin-containing clot to stop bleeding and begin repair of the damaged vessel. Disorders of coagulation can lead to an increased risk of bleeding (hemorrhage) or obstructive clotting (thrombosis). Measuring the coagulation interval and evaluating this measurement are valuable parameters on clinical studies.

The coagulation test starts when incubated cuvettes inserted in test holes and reagent for that test included to the cuvette. The test is mechanical. When the metal ball in the cuvette starts to turn with the cuvette, it means that the coagulation is completed. This time is determined by hall-effect sensors. The measuring principle is to determine the time interval between inserting the reagent and metal ball turning.

2.1.2 Measuring Method



K : Test cuvette
T : Test hole
P : Mixed plasma and reagent
M : Magnetic sensor
B : Metal ball

After reagent included to the plasma, T test hole starts to turn around with the K cuvette. In that time, B metal ball is in front of the M magnetic sensor, and never moves. When the coagulation occurs, B metal ball leaves the M magnetic sensor. Microcontroller calculates this time interval.

3. Installation

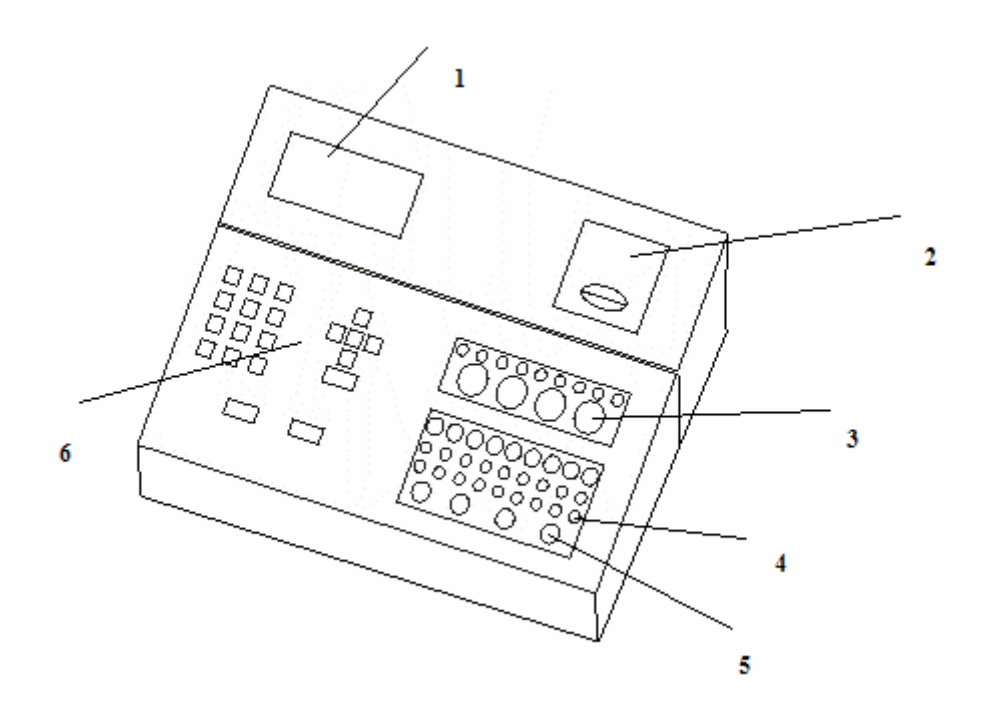
3.1 Environmental requirements

Please follow below instructions to ensure the optimal working conditions of the analyzer.

- Make sure the environment is clean and free of dust
- Install the analyzer on steady, fixed and vibration-free workbench. Vibration can effect the test results.
- The ideal environmental conditions are temperature between 10°C and 30°C, and relative humidity no higher than 80%.
- Make sure that there is no electromagnetic interference sources.
- Make sure that the instrument is well grounded.

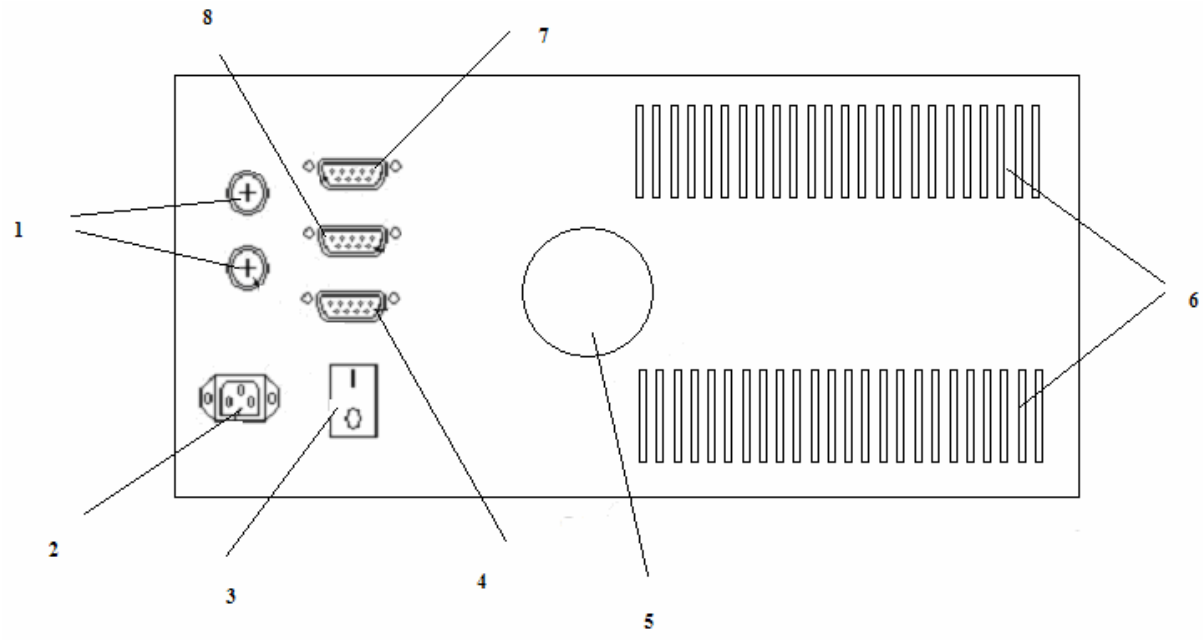
3.2 Introduction of the Analyzer

3.2.1 Front Panel



1 : Graphik LCD Screen
2 : Thermal printer
3 : Mixer holes
4 : Incubation holes
5 : Test holes
6 : Keyboard

3.2.2 Rear Panel



1 : Fuses, 2A/250V
2 : 220 V AC inlet
3 : Power Switch
4 : External Printer Connection
5 : Fan Hole
6 : Air Flow Panels
7 : Barcode Reader ConnectionBarkod okuyucu girişi, supports RS 232 output barcode readers
8 : RS232 connector for HOST Computer

4. Menus and Usage

After the analyzer powered on, the date, time and the temperature of the incubation plate are displayed on the screen. This information screen stands still, until the incubation plate reaches 37°C. Until that time, analyzer never lets the user to do anything on itself.

After reaching the 37°C, the normal working screen, which has 4 channels datas, appears on the screen. Channel number, the working test for that channel, and the required result units (second, proportion or INR) are displayed on that screen. When a test starts, the patient ID (if entered), passed test time and (when the test ends) the results will be shown on the screen.

4.1 Programming the Channel for the Test

Press MENU button. MAIN MENU appears on the screen. Select the PROGRAMS menu by using arrow buttons. Activate PROGRAMS menu by pressing ENTER. Choose the channel which you will program. Select the test (PT, APTT, FIB etc) by using arrow keys and press ENTER. The channel will use the selected test parameters from now on.

4.2 Defining the Test Parameters

Enter MENU-PROGRAMS-TEST PARAMETERS by using arrow buttons and ENTER button. Here;

Choose TEST to select the test which it's parameters will be changed.

Choose RESULT to select the unit of test result (second, %, INR)

Choose INC.TIME to enter the incubation time of test.

Choose MAX.TIME to enter the maximum test duration time.

Choose MNPT to enter mean PT of the laboratuary. If the test is PT. This value is used to calculate INR. Leave 0 if the test is not PT.

Choose ISI to Enter international Sensitivity Index which is assigned by the manufacturer for each lot of reagent. Leave this as 0 if the test is not PT.

Choose V1-S1…V5-S5 to enter the 5 results of a pre-known plasma, diluted 5 times. Every laboratory must perform this dilution process when the reagent changes.

4.3 Setup Menu

Enter MENU-SETUP by using arrow buttons and ENTER buton. Here;

Choose PRINTER ON to get a printout after every finished test.

Choose PRINTER OFF to not to get any printout.

Choose HOST F1 or F2 to send the results of finished tests to host computer.

Choose HOST OFF to not to send the results to the host computer.

Choose BARCODE READER ON to enable the usage of a barcode reader.

Choose LANGUAGE ENG to English menu.

Choose DATE to enter the current date.

Choose TIME to enter the current time.

Choose IGNORE FIRST 3 SECONDS YES to disable the reading of the test for the first 3 seconds. This could be useful, if user touches the metal ball while pipetting the reagent. Choosing YES will ignore such false readings.

4.4 Archieve Menu

Enter MENU-ARCHIEVE by using arrow buttons and ENTER button. The finished test datas will be displayed on the screen. Theh last finished test will be on the top. You

can use arrow buttons to navigate on this list. Also you can print or send to host the finished tests. To do that, you should use ENTER button to check the records. All the records between two check mark can be printed or can be sent to host computer.

4.5 Quality Control Menu

Enter MENU-QUALITY CONTROL by using arrow buttons and ENTER button. Here;

Choose SAVE LAST TEST L1 to save the last test as L1 value. L1 value is normal value of the calibration plasma. Analyzer checks the last test, defines the test (as PT, APTT etc.) and saves the result for that test's L1 value. Last 7 values of L1 are stored.

Choose SAVE LAST TEST L2 to save the last test as L2 value. L2 value is abnormal value of the calibration plasma. Analyzer checks the last test, defines the test (as PT, APTT etc.) and saves the result for that test's L2 value. Last 7 values of L2 are stored.

Choose TEST to select the test you will work on it.

Choose L1 MIN VALUE to enter the minimum value of the L1 of the test you selected by TEST option.

Choose L1 MID VALUE to enter the middle value of the L1 of the test you selected by TEST option.

Choose L1 MAX VALUE to enter the maximum value of the L1 of the test you selected by TEST option.

Choose L2 MIN VALUE to enter the minimum value of the L2 of the test you selected by TEST option.

Choose L2 MID VALUE to enter the middle value of the L2 of the test you selected by TEST option.

Choose L2 MAX VALUE to enter the maximum value of the L2 of the test you selected by TEST option.

Choose LOT NO to enter the lot number of the calibrator plasma.

Choose QC GRAPHS to see the QC graphics of the test you selected by TEST option. You can see SD, MEAN and %CV values of L1 and L2, and its graphs.

5. Maintenance

No special care and maintenance is required for **"ALS – SC 4"** . Keep the working environment dry and clean. Keep the cuvette holes clean and free of dust.

Do not use wet cloth or corrosive fluid to wipe the upper surface of the analyzer in case the fluid flows into the analyzer and damage the analyzer.

6. Troubleshooting

- Analyzer is not working ; Check if the power cord is unplugged. Check the wall outlet. Check the fuses at the back side of the analyzer.

- No printing after measurement; Printer is off. Turn printer on at the setup menu.

- No display; Pull out the power plug, check the fuses, change if necessary. Please contact the manufacturer.

7. Warnings

IVD Information : The Coagulation Analyzer is for IN VITRO DIAGNOSTIC use.

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- Installation, expansion, modification and repairement made by authorized personel of "Alaris Medikal ve Elektronik San.Tic.",
- The accordance of local or national requirements of electrical installations of the room and the damaged caused by the usage of the instrument accidentally or directly.

8. Dimensions and Weight

Dimensions	: Length 46cm * Width 35cm * Height 10cm
Weight	: 12 Kg

9. RS232 Interface

RS232 is the most widely used standard bus in asynchronous serial communication. The analyzer can send out data as an intelligent terminal through RS-232 interface.

9.1 Features

Electrical specification	: Meeting EIA RS-232C
Transmission mode	: Asynchoronous
Stop Bit	: 1
Data Bits	: 8
Parity	: None
Transfer speed	: 9600bps

9.2 Host Format

$$$ id date time test second proportion inr Chr(&H0d)Chr(&H0a)

Whole data is text and starts with "$$$", ends with CRLF. Space character included between every datas. Explanation of the format is as follows:

id	: Patient's barcode id
date	: The date that test performed (format is dd-mm-yyyy)
time	: The time that test performed (format is hh:mm)
test	: Name of the test
second	: Result of the test as seconds
proportion	: Result of the test as proportion
inr	: Result of the test as INR (only for PT test)

"0.0" for a test means the result is not required by the user.

10. RS232 Interface Connections

Cable connections are as follows: 2-3, 3-2, 5-5. The analyzer has 9 pin male connector on itself. (DB9-P).

11. Barcode Reader Parameters

The analyzer can support any RS232 output barcode reader. Before using, the barcode reader's parameters must be set as follows (by using its programming handbook given with the barcode reader):

INTERFACE SELECTION	: RS232
BAUD RATE	: 19200bps
PARITY	: NONE
DATA BITS	: 8
STOP BIT	: 1
MESSAGE TERMINATOR	: CR