



bt- sedi

AUTOMATIC

ERYTHROCYTE SEDIMENTATION RATE (ESR)

ANALYZER

OPERATING MANUAL

BİLİMSEL TIBBİ ÜRÜNLER PAZ.SAN.TİC.LTD.ŞTİ.

www.bilimseltip.com

www.btproducts.com.tr

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PRODUCT and LABEL INFORMATION

Product Name	AUTOMATIC ESR ANALYZER	
Model	bt – sedi 20/100	
Certificates	CE	
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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, \pm % 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 anything.
- If any error occurs 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

- “bt – sedi 20” is, fast-measuring, easy operating with user friendly operator interface, clinical analyzer controlled by a built-in microcomputer throughout the whole process.
- With keypad and LCD, English menu prompting, man-instrument conversation interface, extremely easy to operate.
- Automatically converts results measured between 15°C and 32°C to reference temperature of 18°C.
- It constantly and simultaneously scans 20 test tubes. The instrument can give the result of 30min in 15 minutes by a special approach.
- A 10 digit patient ID can be entered.
- Tested results can be displayed on LCD, as well as being printed out by an external printer.
- The analyzer has an RS-232 standard interface to connect with an automation center to process patient datas.
- 1000 testing results can be stored.

1.2 Intended Purpose

“bt – sedi 20” Automatic Sedimentation Rate Analyzer is exclusively employed for analysis of the Erythrocyde Sedimentation Rate (ESR) of blood sample. It constantly and simultaneously scans 20 test tubes for ESR analysis. It scans the sedimentation rate of each sample independently and stores the result. The result is showed in mm/h on LCD screen, or printed out by the built-in printer.

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 \pm 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 passed the LVD and EMC tests according to CE standards.

Declaration tests according to instrument's CE norms:

EN 61326-2-6 : 2006 : "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In-vitro diagnostic (IVD) medical equipment."

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

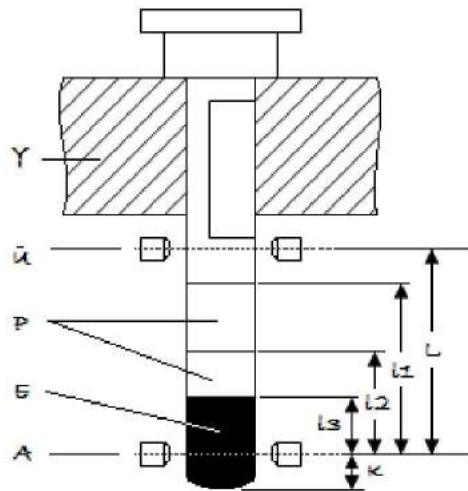
2. Working Principle and Structure

2.1 Working Principle

2.1.1 Measuring Principle

Erythrocyte Sedimentation rate (ESR) is commonly used in clinical examination. The blood sample is collected to a test tube containing anticoagulant and mixed well. For mixing process, it is advised to use special mixers. Then the tube is put vertically in any sample holder on the instrument. Under the influence of gravity, erythrocytes will sedimentate gradually and transparent plasma will be left at the top of the tube. The analyzer will detect the interface point of erythrocytes and transparent plasma by moving a pair of infrared transmitter and receiver up and down on the tube and obtain the ESR dynamic changing result within a certain period of time.

2.1.2 Measuring Method



- Y: Holder plate of test tubes
 Ü: The highest position of infrared transmitter - receiver
 P: Plasma
 E: Erythrocyte in blood
 A: The lowest position of infrared transmitter - receiver
 L: Measuring range
 K: The distance from the bottom of test tube to the lowest position of infrared transmitter - receiver
 I 1: Initial height (at zero time)
 I 2: Height of erythrocyte after 30 minutes
 I 3: Height of erythrocyte after 60 minutes

When infrared transmitter receiver move from Ü to A, if infrared ray cannot reached by receiver, it means infrared ray is barred by high density blood cells. If infrared ray penetrates through test tube and reaches receiver, the receiver will send signal to the microcomputer to count the distance that the ray reaches the terminal position.

2.2 Formulation

Calculating Formula of sedimentation percentage after 30 minutes:

$$\%30' = 100(I1 - I2) / (I1 + K)$$

Sedimentation percentage after 60 minutes:

$$\%60' = 100(I1 - I3) / (I1 + K)$$

After research and data analysis of a large quantity of hospitals, the sedimentation percentage after 30 minutes in the test tube can be converted to that of Westergren's method after 1 hour, and the sedimentation percentage after 60 minutes in the test tube can be converted to that of Westergren's method after 2 hour by following formula:

$$A = Bx + C$$

A: Sedimentation rate in Westergren's method

X: Sedimentation rate

B,C: Constants

Choosing B1, C1 and %S 30' value can get sedimentation rate of Westergren's method after 1 hour; choosing B2, C2 and %60' value can get sedimentation rate value of Westergren's method after 2 hour.

2.3 Converting Measured Results to Westergren's ESR at 18°C

Sedimentation rate from $A=Bx+C$ formula, can be converted to standart sedimentation rate of Westergren's method at 18°C by temperature correction that uses interpolation method and completed automatically by the analyzer. (It is optimal, can be disabled by the user).

Temperature correction range is between 15°C and 32°C, the correction is the same as that below 16°C. If the temperature is above 32°C, the correction is the same between 27°C and 32°C.

3. Installation

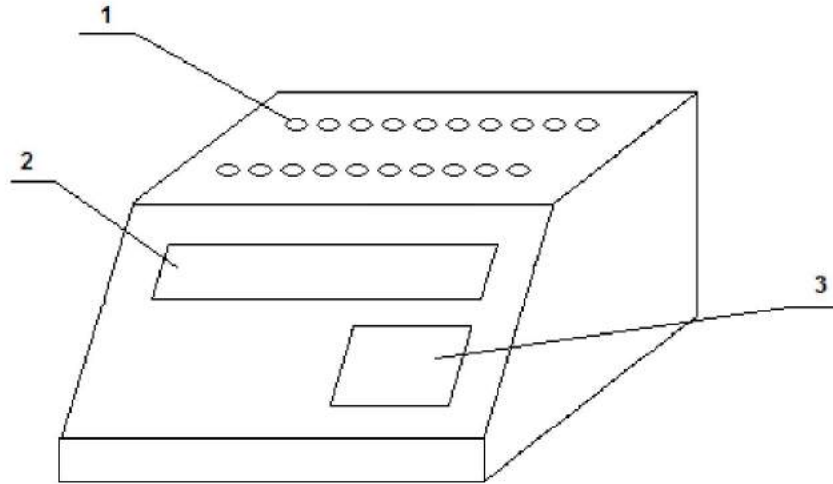
3.1 Environmental Requirements

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 installation place should be away from direct sunlight and moisture to ensure normal operation of infrared photoelectric detectors.
- 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.

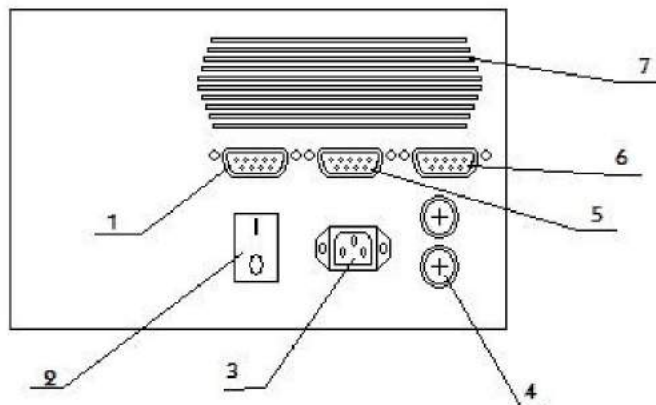
3.2 Introduction of the Analyzer

3.2.1 Front Panel



- 1: The holes for test tubes
- 2: LCD Screen
- 3: Keypad

3.2.2 Rear panel



- 1: Barcode reader input, supports RS232 output type barcode readers.
- 2: Power switch
- 3: 220 V ac input
- 4: Fuses, 2A/250V
- 5: RS232 interface output for the host
- 6: External printer output
- 7: Air flow panels

3.2.3 Menus and Usage

The instrument will make its initial settings after first power on. While this settings, the producer company information is displayed on the LCD screen. After these settings, if the day is changed since the last shut down, a query window will appear on the LCD which asks the user to delete the records of the day before or not. If the user wants to delete the records of the day before, has to choose YES, if not has to choose NO. The instrument can keep last 1000 records. If this limit exceeds in a day, instrument will start to overwrite from the first record.

3.2.4 Patient Entry Menu

It is used to enter patient ID when no barcode reader is used. By using this menu, patient ID entry can be done here by manually. After patient ID entry, this patient's tube must be inserted to any position on the instrument. No any ID entrance is possible before inserting the tube.

If barcode reader is used, any barcode read in MAIN MENU, triggers the user to PATIENT ENTRY menu. There is no need to enter patient entry menu by manually, it is already done by the barcode reader. If operator reads another barcode before inserting the tube, the first read will be deleted. Successive reads are not allowed.

If no barcode is used, by pressing any number on keypad at MAIN MENU, it is possible to enter PATIENT ENTRY menu.

3.2.5 Control Menu

This menu is used to check if the instrument needs calibration or not. When this menu is chosen, no any other test tube is allowed on the tube holder and a warning message appears on the screen about that. Pass this screen after emptying the tube holders, and put 2 control/calibration tubes any location of the tube holder. In 3 seconds, the instrument starts to read. After reading is finished, the instrument gives a screen warning about if calibration is needed or not. If calibration is needed, use the CALIBRATION MENU to calibrate the instrument.

3.2.6 Calibration Menu

This menu is used to calibrate the instrument. When this menu is chosen, no any other test tube is allowed on the tube holder and a warning message appears on the screen about that. Pass this screen after emptying the tube holders, and put 2 control/calibration tubes any location of the tube holder. In 3 seconds, the instrument starts to read. After reading is finished, calibration is done.

3.2.7. Setup Menu

Setup ⇨ Result

The results the instrument will give can be chosen with this menu. This setup is for printout if any external printer is used.

Setup ⇨ Level Correction

The level of the blood in test tubes can not be the same. This state can be tolerated by choosing this menu option ON. Choosing ON never affects the result.

Setup ⇨ Temperature Correction

If this option is chosen ON, the sedimentation value will be converted automatically to standard sedimentation rate of Westergren's method at 18°C. Temperature correction range is between 15°C and 32°C. If the temperature is below 15°C, the correction is the same as that below 16°C. If the temperature is above 32°C, the correction is the same as that between 27°C and 32°C.

It is recommended that the analyzer work at temperature of 15°C - 30°C.

Setup ⇨ Printer

If this option is ON; printer gives a printout for every finished test. If it is OFF, the printer is disabled. If this option is ERR, the printer gives a printout if the test has any kind of error. In this case, the printout gives information about the error and gives no printout for normally ended tests. (If any external printer is used.)

Setup ⇨ Barcode

Choose this option ON, if you will use a barcode reader.

Setup ⇒ Host

If you want to send results to LIS (Laboratuary Information System), turn this option ON.

Setup ⇒ Language

You can select the instrument's interface language here: TR: Turkish, ENG: English

Setup ⇒ Date

It is used to set the date. The format is dd-mm-yyyy.

Setup ⇒ Time

It is used to set the time. If the internal clock stops working for any reason, the instrument will stop working too.

Setup ⇒ Show

The result will be shown at display after the measurement is completed can be chosen with this menu.

3.2.8. Archieve Menu

The finished test results can be searched in this menu by using arrow buttons. On this menu, you can select successive records by pressing ENTER button. Press ENTER at the start and end of the successive records. The successive records you checked can be send to the printer or the host.

3.2.9. Service Menu

This menu can be used by authorized persons with password.

4. Measuring Procedure

4.1. Measuring Principle

The infrared transmitter – receiver system in the instrument can monitor 20 test tubes simultaneously. It will record a reading every 0.2mm of vertical distance of the test tube. This is the resolution of the instrument. It will measure once every 3 minutes. When the test tube is inserted, the analyzer starts to measure automatically (if there is no problem with barcode entry). The first measuring is assumed “0” for the timing and the height of the blood in the test tube will be judged by the analyzer automatically. The acceptable blood height range by the analyzer is between 50mm and 64mm. If the blood height is between this range, the test will continue. Otherwise the analyzer will refuse to measure, and warns the user about that.

4.2. Sample Preparation

Every sample needs to contain 1.28ml of whole blood. The sample blood can be absorbed directly to the vacuumed test tube, which already has 0.32ml of anticoagulant material (sitrane) in it. Slowly bottom up and down the tube 5 to 7 time to mix the anticoagulant and the blood well. Make sure no bubbles are produced.

4.3. Tag

A tag is stuck to every test tube to identify each sample in the test tube. The tag must be pasted evenly and tightly to avoid any error in case the tube cannot be inserted into the hole of the holder plate or reach the bottom of the hole which is required by the measurement. The length of the tag is also important. There must be some space between the end of the tag and the top level of the blood (approx. 1mm).

4.4. Sample Mixing

Sample must be mixed well before measurement. It is recommended to bottom up and down the test tube at least 5 times or use a specialized mixer.

4.5. Sample Inserting

The well mixed sample must be inserted into the analyzer immediately. It is recommended to mix the sample near the analyzer. After the tube inserted, in PATIENT ENTRY menu, you can see the position number of the test tube and the barcode number of it. You can hear two short beeps after this appointment procedure. In MAIN MENU, you can also check the scroll bar at the position of the test tube. This scroll bar gives an information about the remaining test time.

4.6. Taking the Sample Off

During measurement process, it is prohibited to take the sample off. Otherwise, the whole process must repeat from step 4.2. If the measurement is ended by the user, the result will be shown under the position number at the MAIN MENU. There is no restriction to take the measured samples off. The position will be ready for new sample as soon as the measured sample is taken off.

4.7. Printing Results

If an external printer attached to ESR analyzer, and the measurement is over and the printer is on (setup > printer > ON), the ESR result (mm/h), date, time, patient ID, record position, sample position, will be printed out automatically.

5. Maintenance

No special care and maintenance is required for “bt – sedi 20” . Keep the working environment dry and clean. Keep the holes of the holder plate clean and free of dust, which may affect the transmitter or receiver parts. Keep the analyzer away from direct sunlight. It is recommended to keep close the protective cover when not in use.

Do not use wet cloth or corrosive fluid to wipe the upper surface of the analyzer in case the fluid flows into the analyzer from holes of the test tube holder 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.
- The result is “E”, as soon as the tube inserted; Inserting tubes without barcode but barcode option is ON. If you will work without barcode turn barcode option OFF at the setup menu. If you will work with barcode, enter barcode before inserting the tube.
- Motor doesn't stop running with noise of clushing; The gag detector of the measure plate is damaged. Please contact the manufacturer.
- No display; Pull out the power plug, check the fuses, change if necessary. Please contact the technical service .

7. Warnings

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

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- Installation, expansion, modification and repairment made by authorized personel of “Bilimsel Tıbbi Ürünler”,
- 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

Dimension :Length 265mm * Width 265mm * Height 160mm
Weight : 7 Kg

Appendix 1. 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.

Appendix 1.1 Features

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

Appendix 1.2 Host Format

Every data train consists of 28 bytes + cr + lf (carriage return + line feed). Whole data is text and the format of it as follows:

AAABBBCCDDDEEEFFFGGGGGGGGGG(lf)(cr)

AAA : Position number on plate
BBB : Memory position number
CCC : Sedimentation result after 30 minutes
DDD : Sedimentation result after 1 hour
EEE : Sedimentation result after 2 hours
FFF : KATZ value
GGGGGGGGGG : 10 characters for patient ID

lf : 0AH line feed
cr : 0DH carriage return

Appendix 1.3 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).

Appendix 2. 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