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ELITechGroup

MICROSED-SYSTEM®

Automated ESR Analyzer

USER'S MANUAL

57-0202-01A
Release Date 2022-01-17

MICROSED-SYSTEM®

Automated ESR Analyzer

User's Manual

57-0202-01A

REF

INSTRUMENT NAME	Microsed-System® Automated ESR Analyzer
INSTRUMENT PART NUMBERS	PRD-MSS-EL-08TKNE
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1 INTRODUCTION

1.1 USING THIS MANUAL

Prior to operating the Microsed-System Automated ESR Analyzer, carefully read the instructions in this manual for proper use of the instrument.

> ⚠ Before installing and working with the **Microsed-System Automated ESR Analyzer**, read this manual carefully and observe the safety precautions and regulations stated. Safety comes first!

Understanding Warnings

This manual uses the following warning levels to alert the user to important information as shown in the following examples.

⚠ **WARNING!**

A Warning alerts to the possibility of personal injury, death, or other serious adverse reactions stemming from the use or misuse of this instrument or its components.

⚠ **CAUTION:**

A Caution alerts to possible problems with the instrument associated with its use or misuse. Such problems include instrument malfunction, failure, damage, damage to the sample, or damage to other property. Where applicable, a Caution may include precautions to be taken to avoid the hazard.

1.2 SPECIFIC CAUTIONS AND WARNINGS

Pay particular attention to the following safety precautions. If these safety precautions are ignored, injury or damage to the instrument may occur. Each individual precaution is important.

⚠ **Caution:**

When operating the Microsed-System Automated ESR Analyzer, national guidelines and regulations must be observed, as in the normal lab routine.

⚠ **Caution:**

Power supply cords (cables/plugs) must be installed in such a way that sources of danger (overheating of cables, short circuit due to incorrect fuse ratings, loose cables etc.) are eliminated.

⚠ **Caution:**

The user should be aware that if the Microsed-System Automated ESR Analyzer is not used in the manner specified by the manufacturer, the protection provided by the equipment and the measurement results may be impaired. This manual should be kept with the instrument for consultation when necessary.

⚠ **Caution:**

Do not open the instrument. Moving parts may be damaged or may cause injury.

Caution:

This instrument complies with the emission and immunity requirements described in the IEC 61326 series. In an electromagnetic environment, the environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

WARNING!

As with all electrical equipment, the power supply is a potential source of danger. To prevent the risk of electrical shock to the user and/or damage to the instrument, the operator should not open the covers of live electrical parts of the instrument. Only authorized and trained personnel may open the instrument to perform maintenance or repair. Comply with the power requirements described in section 11.1. For the correct replacement parts, see section 14 Spare parts.

Specimens (patient samples and controls) and liquid waste should be considered potentially infectious and capable of transmitting human immuno-deficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimize risk to laboratory staff. This includes wearing applicable personal protective equipment. Contact with skin and mucous membranes must be avoided. This also applies to all components of the instrument that are exposed to these substances. If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant, such as, 0.5% sodium hypochlorite solution. Compliance with local regulations pertaining to the disposal of waste is the responsibility of the operator. Refer to local sources for additional information on correct biohazardous waste disposal. Qualified technical operators must apply the same warning procedures for instrument maintenance.

1.3 IMPROPER USE

The following uses are considered improper:

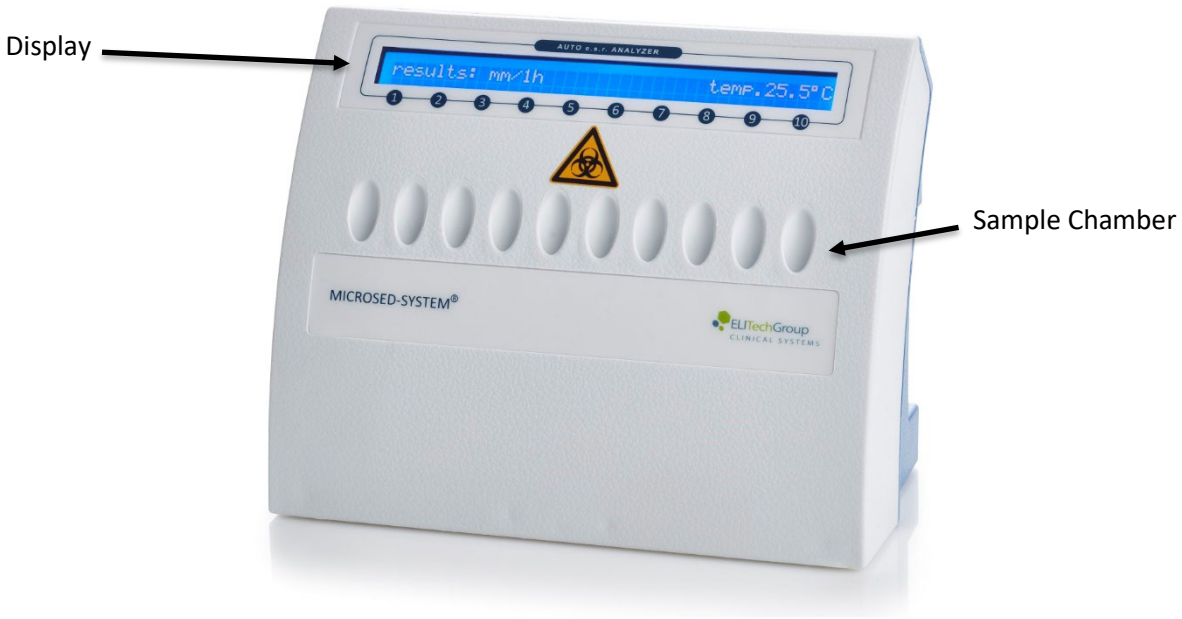
1) Use of the device to obtain results other than erythrocyte sedimentation rate (ESR)
2) Use of ESR tubes other than those specified in this manual
3) Use of the device to analyze samples other than those specified in this manual

Any use of the Microsed-System Automated ESR analyzer other than what is specified as its intended use is considered improper use of the device.

1.4 INTENDED USE

The ESR analyzer is an automated, microprocessor controlled, in vitro diagnostic device that is intended for the quantitative determination of erythrocyte sedimentation rate (ESR) in human whole blood samples by laboratory professionals. Elevated ESR results indicate degrees of inflammation or disease present in the human body.

1.5 INSTRUMENT DESCRIPTION



The Microsed-System Automated ESR Analyzer is an automated instrument controlled by a microprocessor and exclusively employed for analysis of the erythrocyte sedimentation rate (ESR). Its total absence of commands, its precision and its ability to obtain results corrected to a temperature of 18 ˚C (according to Manley) in only 15 or 30 minutes, make the Microsed-System Automated ESR Analyzer an innovative and versatile system for this kind of analysis. It simultaneously scans 10 test tubes which are custom-made for use with this system. The exclusive sample type for the Microsed-System is whole human blood.

The Microsed-System Automated ESR Analyzer follows the sedimentation of each sample independently, memorizing levels for the whole period of analysis. This allows the instrument to be used for random loading of the samples and for a continuous loading up to a capacity of 10 test tubes at a time. When the first sample is analyzed, it can be replaced by another one, so it is possible to achieve up to 40 tests per hour.

The Microsed-System Automated ESR Analyzer has been developed to simplify ESR analysis as much as possible, avoiding sample handling and operator's infection risk. To perform the analysis, the operator places the sample test tube into the instrument. The result appears on the display in only 15 or 30 minutes. When the temperature compensation of the result is active, the Microsed-System surveys the room temperature and converts the result to the reference temperature of 18 ˚C (Manley). This is necessary in order to avoid considerable variations of values due to different room temperatures.

1.5.1 DISPLAY

An LCD display with back-lighting allows constant monitoring of the analyses and visualization of the results. Sample or system error messages may also be displayed.

1.5.2 READING PLATE

One row of 10 test tube positioning channels, numbered from 1 to 10.

1.5.3 PRINTER (OPTIONAL)

An optional printer can be connected to the instrument to print ESR results and sedimentation graphs, according to the loading sequence, whenever an analysis is completed. It is external so it can be easily replaced.

Printer Technical Data: Type DPT-100

Power supply	Direct powered from Microsed-System
Input	serial RS232
Printing type	thermal
Columns	24
Conformity	CE

To enable the printer:

- Make sure that the dip-switches 4 and 8 are in the **ON** position (see section 4.3).
- Connect the printer cable to the RS232 port on the back of the instrument using Cable B-1/ B-2.

1.5.4 BARCODE READER (OPTIONAL)

An external barcode reader can be connected to the instrument with a special cable. The cable can be requested with the code: EEE30-099 – "Cable MSS10C04 printer, barcode". The barcode reader must be an RS232 port standard model, with its own power supply unit. The barcode scanner configuration must be set with the following serial port setting:

- 9600 bps, 8 data bits, no parity, 1 stop bit, no handshake control signals.

1.5.5 ESR TUBES

Specially designed MONOSED® vacuum tubes supplied by ELITechGroup Inc. must be used to ensure accuracy of measurement for the Microsed-System:

- PRD-PRV11B-50 MONOSED® ESR Vacuum Tube (50/box)
- PRD-PRV11V-H12 MONOSED® ESR Vacuum Tube - High Altitude (50/box)

Both tube types contain 3.2% sodium citrate solution and are designed to draw 1.28 mL of blood. For instructions on how to use these tubes, consult the specific instructions for use.

1.5.6 CONTROLS

It is recommended that Accu-Sed® Plus Bi-Level ESR Controls be used with the Microsed-System Automated ESR Analyzer.

- DS-71006 Accu-Sed® Plus Normal / Abnormal ESR Control, 2x4x8.5 mL

Two levels of fresh controls should be run each day of use, in accordance with CLIA and local regulatory guidelines. Results obtained should fall within the limits defined by the day-to-day variability of the system as determined in the user laboratory. If the results fall outside the laboratory's established limits, refer to the troubleshooting information in this manual. Refer to Accu-Sed® Plus instructions for use for more detailed information.

1.6 INSTRUMENT CALIBRATION

Each instrument is pre-calibrated by the manufacturer, and it does not require a user re-calibration. The calibration of each instrument is traceable from the serial number of the instrument.

1.7 OPERATORS

The instrument should only be used by qualified and trained personnel. For clinical tests, the instrument should be used under the management of a doctor or qualified laboratory technician/technologist in compliance regulations.

1.8 UNPACKING DEVICE

1. Carefully open cardboard box using a knife.
2. Remove device from packaging and place in a suitable location.
3. Keep packaging for safe storage or possible return.
4. Ensure packaging contains the following items:
    - Instrument, Qty: 1
    - Certificate of quality Qty: 1
    - Accessories kit, Qty: 1 (see below)
    - User's Manual, Qty: 1

    Accessories Kit Content
    - Power adapter, 1.8 A 100 – 240 V ≈50-60 Hz Class I, Qty: 1
    - Compatible cord and plug, Qty: 1
    - RS232 Split cable, Qty: 1
    - Dust Cover, Qty: 1

2 SAFETY PRECAUTIONS

2.1 NOTES ON SAFETY MEASURES

⚠ **Caution:**

The operator must pay a special attention to the sample collection and must use the correct vacuum test tubes described for this equipment in this manual, since these tubes have been studied to aspirate the right level of blood. Every attempt to put the blood into test tubes different to the one described brings serious dangers of infection due to the risk of sample coming out, and this, moreover, will damage the optical part inside the instrument and provoke the loss of the guarantee. Refer to the MONOSED tube instruction for use for additional details.

2.2 USER PRECAUTIONS

⚠

Before using the analyzer, the operator should be trained in universal precautions[1] when potentially handling infectious materials, as well as handling electro-mechanical systems.

To ensure proper instrument performance, ELITechGroup Inc. requires the use of MONOSED® ESR Vacuum Tubes. This instrument is designed as a system. Results obtained from the system may vary depending upon the specific characteristics of disposables, controls, and operator expertise. Control kits and the test parameters for each control have been optimized and tested to ensure compatibility

and performance with the instrument. ELITechGroup Inc. assumes no responsibility for erroneous test results caused by disposable tubes or controls not supplied by ELITechGroup Inc., or due to inappropriate use.

The analyzer and accessories are shipped in transport boxes and should be unpacked and installed using instructions supplied by ELITechGroup Inc. If these instructions are not observed, ELITechGroup Inc. assumes no responsibility for consequential damage or improper operation of the analyzer.

Analytical results depend upon not only the correct operation of the analyzer but also a variety of external influences beyond the control of the manufacturer. Therefore, a qualified clinician must carefully examine the test results obtained with this instrument before any diagnostic or therapeutic measures are taken based on the analytical results.

⚠ WARNING!

An incorrectly measured result may lead to an error in diagnosis.

2.3 EXPLANATION OF SYMBOLS

Symbol	Symbol Ref. No.	Symbol Title	Symbol Explanation	
	ISO 15223-1 5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	
	ISO 15223-1 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	
	ISO 15223-1 5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified	2498
	IEC TR 60878 5031	Direct Current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	
	ISO 15223-1 5.5.1	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	N/A
	ISO 15223-1 5.4.3	Consult Instructions for use	Indicates that need for the user to consult the user's manual	
	N/A	European Conformity Mark	Indicates that the product conforms to the European IVD Directive 98/79/EC	
	N/A	WEEE wheeled Bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or	N/A

			recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.	
	ISO 15223-1 5.1.1	Manufacturer	Indicates the medical device manufacturer	
	ISO 15223-1 5.1.1	Country and date of manufacture	Indicates the date and the country the medical device was manufactured.	
	ISO 15223-1 5.1.2	Authorized representative in the European Union	Indicates the authorized representative in the European Union	
	N/A	Warning; Biological hazard	Indicates that there is potential biological hazard associated with the medical device	
	ANSI/ESD S8.1	ESD Susceptibility Symbol	Indicates susceptibility to electrostatic discharge	
	N/A	General Warning Sign	Indicates a general warning	ISO 7010 – W001

2.4 RESIDUAL RISKS

Despite measures taken in the design of the device to allow for safe use, there remain risks that were able to be reduced, but could not be eliminated completely.

RESIDUAL RISKS	PROTECTION MEASURES
Biological contamination	Operators should practice universal precautions including wearing gloves and protective glasses, as prescribed by laboratory regulations. Do not uncap tubes.
Tubes breaking	Insert and remove tubes from holes maintaining a vertical position, without applying lateral forces.

2.5 TRANSPORT

For transport and storage conditions, see chapter 11 Technical specifications.

3 DISPOSAL AND RECYCLING

Herewith we declare that this instrument is subject to the European Directive 2012/19/EU (WEEE Directive). Therefore the instrument must be disposed separately, not as urban waste and delivered to the specific collection center in according to the Directive 2012/19/EU. The user can ask to the dealer the collection of the instrument if a new instrument is ordered to replace the old one.
On the instrument there is a label with the symbol shown in this page. The symbol means that the instrument cannot be disposed as urban waste.

Appropriate decontamination shall be performed prior to removal from use and/or disposal, see document *Decontamination Instruction ESR Instruments* for details.

4 INSTALLATION

4.1 POSITIONING OF THE ANALYZER

The Microsed-System Automated ESR Analyzer must not be placed near centrifuges, oscillating agitators or other vibrating instruments which might cause movement of the bench. Please keep in mind that the ESR analyzer is very sensitive to vibrations, which could cause a false increase in results.
The workbench must be flat and level. Keep a free area of at least 15 cm around the instrument to allow the instrument to cool. The power supply cable and power switch must be accessible at all times. Direct light on the instrument and sudden changes of temperature should be avoided.

4.2 INSTRUMENT STARTUP

Instrument configuration is controlled through dip-switches on the backside of the analyzer. See section 4.3 for dip-switch information and defaults.

Connect power supply outlet to the instrument. Insert the power supply plug into the electrical socket. If the instrument has an optional printer and/or a barcode scanner, they should be connected to the Microsed-System Automated ESR Analyzer with the appropriate cable and plugged in. Connect and switch-on first the printer, then the MICROSED-SYSTEM Automated ESR Analyzer using the switch situated at the rear side of the instrument. Each time it is turned on, the system carries out an electronic initialization and an instrument self-test. The following messages will appear:

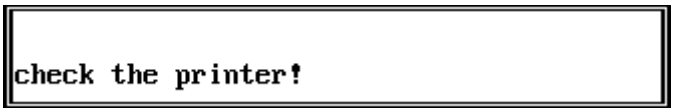
```
Self Test Start...
```

During the self-test, the instrument checks electronics parts and configurations.

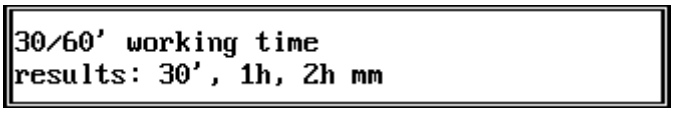
If the printer is connected and switched on, the display shows:

```
print curve ON...
printer OK...
```

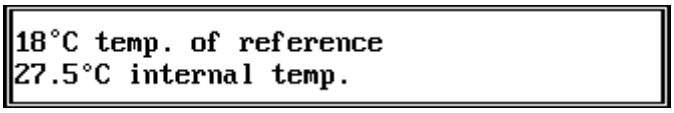
If the printer is not connected to the device, this message will appear.



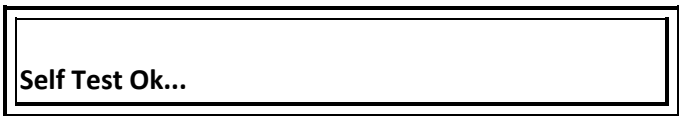
The following message shows the working time and time of results in mm/hr.



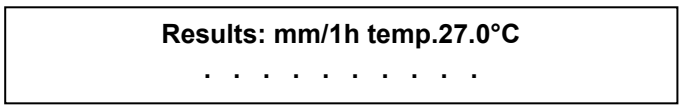
If the temperature compensation is active, the display will show:



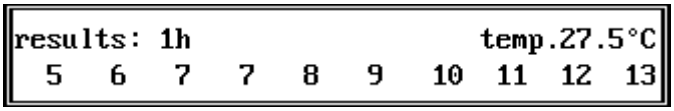
Once the self-test is finished, the following message will appear:



Now the instrument is ready for the analysis and the display will show a screen similar to the following:



The result type and temperature are always shown on the display. The bottom line of the display shows result values. The following screen is an example:



4.3 INSTRUMENT SETUP THROUGH DIP-SWITCH CONFIGURATION

1 – 30-minute Westergren. Enable results mm/30 minutes Westergren. **Default OFF.**

2 – Working time selection. Off = 30-minute working time correlated to a 1-hour Westergren. ON= 30- and 60-minute working time, with results correlated to a 1-hour and 2-hour Westergren respectively. **Default OFF.**

3 - Enable temperature compensation at 18 °C. **Default ON.**

4 - Printer output enable. **Default OFF.**

5 - Enable sedimentation graphic printout. **Default OFF**.

6 - Enable 15' of working time with results mm/h Westergren only. **Default OFF**.

7 - Internal fan enable. **Default ON**.

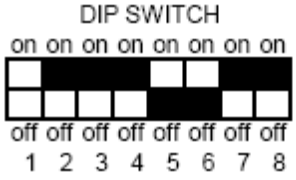
8 - Enable DC power supply for external DPT100 thermal printer. **Default OFF**.

NOTE: the function is active if the dip switch is on "ON" position.

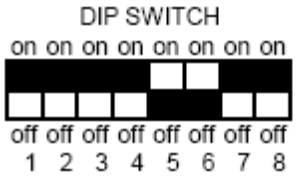
DIP SWITCH CONFIGURATION EXAMPLES

dip switch on: 3,4,7,8
configuration : working time 30'
results= mm/1h Westergren
temperature compensation ON
printer enable ventilation ON
power supply printer ON

dip switch on:3,4,6,7,8
configuration : working time 15'
results= mm/1h Westergren
temperature compensation ON
printer enable ventilation ON
power supply printer ON



dip switch on: 2,3,4,7,8
configuration : working time
30/60 results= mm/1h and 2/h
temperature compensation ON
printer enable ventilation ON
power supply printer ON



dip switch on: 1,2,3,4,7,8
configuration : working time
30/60' results= mm1/2h; 1h; 2h
temperature compensation ON
printer enable ventilation ON
power supply printer ON

5 BRIEF OPERATING INSTRUCTIONS

5.1 SETUP THE INSTRUMENT

- Connect the power supply.
- Connect optional printer and scanner if applicable.

5.2 POWER ON

- Turn on the instrument by pressing the button located at the rear side of the instrument.
- After the self-test is complete, the analyzer is ready for use.

5.3 SAMPLE INSERTION

Choose one of the following:

- Insert a well-mixed sample into any free channel
- Scan the barcode and insert well-mixed sample into any free channel

5.4 RECORD RESULTS AND REMOVE SAMPLES

- After 30 (or 15 minutes), record the result:
  - Results will print if the printer is correctly configured in the setup menu.
  - If Host is connected and configured under setup, the data will be sent to the host according to the set-up configuration.
- After results have been recorded, remove tubes carefully, maintaining tubes in vertical position, in order to avoid tubes breaking.
- Follow the above for additional samples.

5.5 POWER OFF

- The device is powered down by toggling the power switch located on the back of the device to the off position.

6 WESTERGREN METHOD

6.1 INTRODUCTION

ESR is primarily affected by the balance between pro-sedimentation factors, mainly fibrinogen, and those factors resisting sedimentation, namely the negative charge of the erythrocytes. Inflamation is a pilar of inate imunity in humans and is characterized by the release of molecules whose function is to protect the body from damage. Among the molecules released are these pro-sedimentation fibrinogen molecules. The high proportion of fibrinogen in the blood due to the inflamatory response causes red blood cells to stick to each other. The red cells form stacks called *rouleaux* which settle faster, due to their increased density.

The Westergren Method for measurement of erythrocyte sedimentation rate is considered the reference method per the Clinical and Laboratory Standards Institute (CLSI)[2]. It consists of Westergren tubes and a support that keeps the Westergren tubes containing anti coagulated blood perfectly vertical and hermetically sealed.
Westergren tubes have a diameter of 2.5 mm and are graduated up to 200 mm. As soon as the sample is taken, the venous blood is mixed with a sodium citrate solution at 3.8% (0.13 M), in a ratio of respectively four to one (1.6 ml + 0.4 ml of sodium citrate). The blood, once prepared and well mixed, is drawn into a Westergren tube up to the zero mark. The tube is placed in the support and the erythrocyte level is read after 60 min.

6.2 REFERENCE RANGES FOR NORMAL ESR VALUES

Normal ESR Values [3]		
	male	female
After 1 hour mm	0 - 15	0 - 20

6.3 ESR IN DISEASE STATES

ESR - 100 mm or more per hour

Multiple myeloma and Waldenstrom macroglobulinemia
Malignant lymphoma
Leukemia
Serious anemia
Carcinomas
Sarcomas
Serious bacterial infections
Collagenosis
Biliary or portal cirrhosis
Ulcerous colitis
Serious nephrosis
Broken ectopic pregnancy
Menstruation
Normal pregnancy after the third month
Oral contraceptives taken
Tuberculosis
Post commissurotomy syndrome
Dextran administered intravenously

ESR – Moderate increase

Acute and chronic contagious diseases	Hyperthyroidism
Acute localized infections	Hypothyroidism
Reactivation of a chronic infection	Lead or arsenic poisoning
Rheumatic illness	Nephrosis
Rheumatoid arthritis	Internal hemorrhage
Myocardial infarction	Acute hepatitis
Malignant tumor with necrosis	Ectopic pregnancy unbroken after the third month

ESR - Normal values

First stage acute appendicitis	Viruses without complications
Precocious integral ectopic pregnancy	Peptic ulcer
Malarial paroxysm	Typhoid fever
Cirrhosis of the liver	Undulant fever
Arthrosis	Rheumatic carditis with cardiac decompensation
Mononucleosis	Whooping cough
Acute allergies	

6.4 PRINCIPALS OF OPERATION

Although the sedimentation rate of red blood cells is a very complex phenomenon influenced by many factors, it follows, with many limits and exceptions, the Stokes' law, which describes the sedimentation velocity of spherical particles suspended in a fluid:

$$V = 2r^2 (d_1 – d_2) g / 9 \eta$$

Where V is the sedimentation velocity, r is the radius of the spherical particles, d1 and d2 are the density of the spheres and the suspension fluid respectively, g is the force of gravity and η is the liquid viscosity.

Red blood cells of healthy subjects remain suspended in plasma and do not tend to descend or aggregate as they all have a negative charge and repel each other. On the contrary, in patients affected by one of various diseases, they tend to aggregate and form stacks called rouleaux. The formation of rouleaux in unhealthy patients is due to the chemical composition of plasma that is altered by pathologies and modifies the electrical charge of erythrocytes, which therefore tend to aggregate. The formation of rouleaux leads to the increase of particles dimension and subsequently, according to Stokes' law, to the increase of their sedimentation velocity in the plasma.

7 OPERATING PROCEDURE

7.1 SAMPLE COLLECTION

Samples must be collected following the procedures outlined in the instructions for use for the Monosed® ESR Vacuum Tubes.

The following external factors can alter the ESR value after blood collection:

- Dilution ratio
- Bubbles
- Strongly hemolyzed samples
- Sudden agitation
- Temperature
- Time after sample-taking
- Direct sunlight
- Foam
- Lipemic samples
- Tube inclination

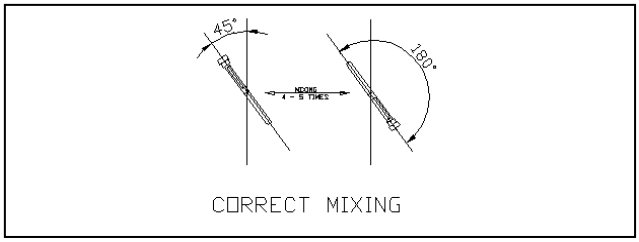
⚠ **Caution:** In accordance with the recommendations of the Clinical and Laboratory Standards Institute (CLSI), blood samples collected in this manner should be tested within 4 hours if left at room temperature, or within 6 hours if stored at 2-8 °C. Samples must be brought to room temperature prior to analysis.

7.2 SAMPLE INSERTION

After mixing, the well-mixed sample must be promptly transferred to the analyzer. It is also advisable to follow numerical sequence when loading channels. Every time a sample is inserted into a free channel an acoustic signal informs the user that the instrument recognized the tube. After loading the tenth, wait for the results and then remove analyzed samples from their channels before inserting new tubes. The sample positions on the plate are numbered from 1 to 10 but numbering is intended progressively in groups of 10. So when the tube in channel one is analyzed and removed, this position automatically becomes number 11 and so on.

7.2.1 SAMPLE MIXING

If it is not possible to analyze samples immediately after the collection, samples must be mixed manually by delicately overturning at least ten times. As an alternative, the use of an automatic rotating mixing with an RMP value of 15-20 can be used.



7.2.2 SAMPLE IDENTIFICATION

If samples are identified by a barcode label, they can be identified using an external barcode scanner. The maximum ID length readable by the instrument is 12 digits. Do not overrun this limit. To perform this procedure correctly, follow these steps:

- Read the barcode label
- Insert the tube in the first free channel within 15 seconds from reading
- The instrument will automatically detect the position of the new inserted tube and the ID will be automatically associated to that position. The display will show for some seconds:

```
+--------------------------------------+
|New sample...                         |
|Pos: 1   Pat.ID: 012345678912         |
+--------------------------------------+
```

If a printer is connected, once the instrument finishes an analysis, the following information will be printed out:

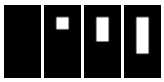
```
Smpl.Chan.PatID#              ( no ID present )
1    1     ...................
30'  1h    2h
3    5     11              mm

Smpl.Chan.PatID#              ( ID: 123456789012 )
1    1     123456789012
30'  1h    2h
3    5     11              mm
```

If the barcode is not available, identify the sample by writing the sample ID on the label. Prepare a report detailing sample ID and the corresponding instrument channel where the sample has been inserted.

7.3 ANALYSIS

7.3.1 REMAINING TIME

During sample analyses, the display shows the following symbol for each sample as indication of the remaining analysis time.



time remaining symbols

7.3.2 RESULTS PRE-INDICATION

Approximately 10 minutes after tubes insertion, the following symbols will appear on the display, giving a pre-indication of the results:

% of Sedimentation at 10 minutes	Symbol
< 16	--
< 40	+-
>= 40	++

This is only a pre-indication and cannot be used as final result.
Please note, pre-indication is shown only on 30-and 60-minutes reading mode.

7.4 FINAL RESULTS

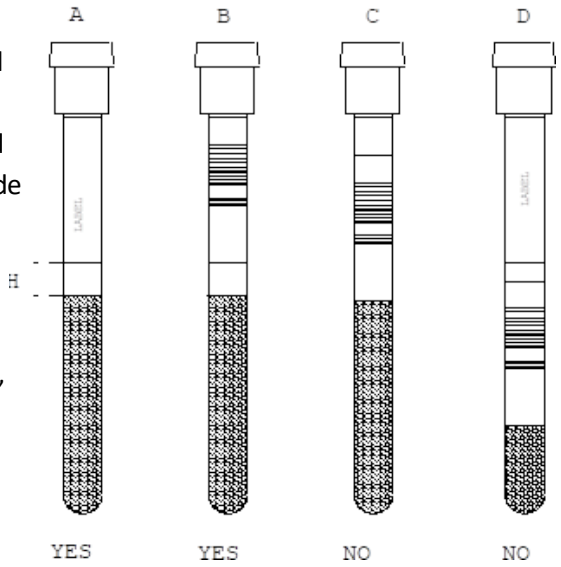
- After 30 (or 15 minutes), record the result:
  - Results will print if the printer is correctly configured in the setup menu.
  - If Host is connected and configured under setup, the data will be sent to the host according to the set-up configuration.
- Remove tubes carefully, maintaining tubes in vertical position, in order to avoid tubes breaking.

  If the tube is removed before the end of the analysis, the instrument prints "**rem**" (removed) error.

7.5 TUBE HANDLING

7.5.1 TUBE LABELING

Identify the sample by writing on the original test tube label or by applying a barcode label. Follow the scheme to carry out this action correctly. Figure "A" shows the correct blood level and the original label on which to write the patient code or any other relevant data if the barcode label is absent. The part marked "H" shows the transparent zone that must be absolutely free and clear to allow the infrared rays to recognize the end of the blood column. Figure "B" shows the correct position for the label. Figures "C" and "D" illustrate how erroneous applications of the labels obstruct the reading of the analysis.



7.5.2 TUBE HANDLING REQUIREMENTS

The vacuum test tube needs to be inserted properly into its holder to obtain the automatic draw of blood required for the analysis. Tubes are removed from the holder only after the draw has been terminated completely, i.e. the required amount of blood for the analysis has been properly evacuated.

If an incorrect blood collection occurs, Microsed-System Automated ESR Analyzer will not analyze the sample and will be indicated by a "**lev"** (level) error. Samples are not measured due to an erroneous ratio with the anticoagulant present in the tube. All vacuum test tubes need to be mixed gently immediately after blood collection, to ensure a proper mixing of the sodium citrate with the freshly drawn blood.

Tubes are gently turned completely upside down ten times, ensuring that the air-bubble floats correctly from one end of the tube to the other. ESR tests should be carried out no later than 4 hours after blood collection, if samples are kept at room temperature. Refer to tube instructions to perform this operation correctly.

8 TEMPERATURE CORRECTION

The results of the analyzer are correlated to the Westergren reference method, taking into account the ambient temperature of the testing area. Microsed-System Automated ESR Analyzer constantly measures the internal temperature and normalizes the values to a temperature of 18 °C based on the Manley[4] table. This automated temperature adjustment process ensures better reproducibility when compared to instruments which provide results without temperature compensation.

Manley table

Correct T	Analysis Temperatures				
18°C	15°C	18°C	20°C	25°C	30°C
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

Microsed-System Automated ESR Analyzer converts results to an equivalent measurement at 18 °C if room temperature is between 15 and 32 °C.

9 ERRORS AND WARNINGS

9.1 WARNINGS INFORMATION

These messages may appear on the display:

LEV: Indicates that the sample level is not into the range permitted by the instrument.

REM: Indicates that the test tube has been removed from the position in which it had been placed. On rare occasions, when there is both a high ESR and a very low hematocrit, the level of red blood cell sediment can fall below the lowest position of the IR board. In such a situation, the instrument may interpret this as a removed tube. An ESR >140 mm/h should be reported, with the added remark that the hematocrit is most likely very low.

The test tubes are checked in their positions every second. Do not touch the test tubes during the analysis period to avoid REM errors.

9.2 SYSTEM ERROR WARNINGS

"MEC ERROR: system stopped..." or "ERROR: call service..."

These warnings will be given if the instrument should find problems with the mechanical movement of the reading plate. After this indication the instrument will stop its operation and technical service must be called.

10 SERVICE

Service on the instrument must be performed by a local distributor service representative.

Technical support is offered by local distributors or can be provided by contacting ELITechGroup Inc. at 1-800-435-2725 (English) or at service.ebs@elitechgroup.com.

Service provided by other person(s) will invalidate the warranty.

11 SPECIFICATIONS

11.1 INSTRUMENT SPECIFICATIONS

Requirement	Specification
Instrument Size	Height: 140 mm Width: 180 mm Depth: 100 mm
Weight	≈ 0.9kg
Software	v 4.0
Instrument Power Rating	1.5 A, 12 Vdc
External AC Adapter Power Rating	Input: 1.8 A 100 – 240 V ≈50-60 Hz Class I Output: 12 Vdc, 5.0 A LPS
Operating Conditions	Temperature: 15 to 32 °C Humidity: 45 to 85% Altitude: up to 2000 m
Transport and Storage Conditions	Temperature: -10 to 45 °C Humidity: 0 to 95%
Overvoltage	Category II
Sound Level	< 80 dbA
Tube Type	8 x 120 mm glass tubes
Reading Channels	10
Sample Capacity	10 with option to run samples in random mode
Analysis Time	Option to select 15, 30, or 60 min analysis time
Instrument Run rate	Maximum 20 test/hour
Results Units	Westergren mm/hr (by interpolation)
Reading Method	Infrared beam
Reading Resolution	+/- 0.2 mm
Results Resolution	+/- 1.0 mm
Display	Graphic LCD with backlight
Connections	RS232
Temperature Correction	Automatic compensation referenced to 18 °C using Manley table

11.2 PERFORMANCE SPECIFICATIONS

Mechanical / optical resolution of detection:	0.2 mm
Automatic temperature conversion to 18 °C (Manley table)	Accepted range: 15° - 32°C
Level range for correct analysis:	From 50 to 60 mm from the bottom of the MONOSED ESR tube
2 measuring points:	Initial and Final
Measuring range:	1 - 140 mm/h
Results pre-indication:	After about 10 minutes
Precision, within run:	CV ≤ 10% (for samples with an ESR > 30 mm/h)

Correlation:

	R value	n	Regression line
30 minutes working time	0.98	55	y = 1.0129x - 0.7772
15 minutes working time	0.97	55	y = 1.1309x - 3.3716

11.3 LIMITATIONS

- Strongly lipemic or hemolytic samples may alter reading capability.
- Sed rate values > 140 mm/h will be indicated as ">140"
    - On rare occasions, when there is both a high ESR and a very low hematocrit, the level of red blood cell sediment can fall below the lowest position of the IR board. In such a situation, the instrument may interpret this as a removed tube. An ESR >140 mm/h should be reported, with the added remark that the hematocrit is most likely very low

11.4 POWER SUPPLY

The analyzer is provided with an external power supply with low voltage output. The power supply is supplied with the analyzer.

WARNING!
For user's security and instrument safety, use only original power supply unit.

Caution: In case of power supply cord substitution, use only power supply cord listed/certified minimum 18 AVG, 3C VW-1 Min. 75°C, minimum SVT type.

12 HOST

12.1 RS232 CONNECTOR DESCRIPTION AND I/O DATA FORMAT

NOTE: Data format is: 9600 bps, 8 data bit, 1 stop bit, no parity, hardware protocol RTS-CTS for printer, no protocol for barcode scanner.

Instrument 9 pin female connector:

PIN	DIRECTION	NAME	DESCRIPTION
1	---	---	(Do not connect!)
2	INPUT	RXD	Barcode data input
3	OUTPUT	TXD	Printer / Host data output
4	OUTPUT	DTR	Data Terminal Ready
5	---	GND	Ground
6	---	---	(Do not connect!)
7	OUTPUT	+12	Power supply for external custom printer
8	INPUT	CTS	Clear to send
9	---	---	(Do not connect!)

DIRECT HOST CONNECTION CABLE EXAMPLE

Note: The connectors of the cable are 9 pin.

Male (instrument) Female (to host)

2 ---------- 3
3 ---------- 2
4 ---------- 8
8 ---------- 4
5 ---------- 5

13 MAINTENANCE

The Microsed-System Automated ESR Analyzer does not require special maintenance, due to the simplicity of the instrument and the component parts. The most sensitive parts are the infrared sensors inside the instrument.

13.1 CLEANING INSTRUCTIONS

Dust can be removed using an ordinary vacuum cleaner. It is recommended to clean the instrument externally once a month with a disinfectant solution (e.g. 70% isopropyl alcohol) to reduce possible microbial contamination.

⚠

Please pay attention to the cleanliness of the test tube positioning plate (reading plate). When not in use, the positioning plate must be covered with the dust cover.

Do not clean the reading plate with liquids or damp cloths; the ingress of liquids or solid material into the channels can cause considerable damage to the instrument.

⚠

Pay particular attention to the test tube. The cap must be tightly closed, and the label must be positioned correctly and completely adhered to the test tube surface. If not, label fragments could fall into the test tube channel and obstruct the correct reading function of the analyzer.

14 SPARE PARTS

Part number	Description
EEE20-039	Board MSS-IR rev.2.0 cod.MSS20A03
3367-129	Board MSS-CPU 4.0 for Blue Display
EEE30-021	Cable MSS-10C02 - IR plate MSS
ELE10-029	Power supply unit EA1050A-120
MEE10-234	Front label MSS-EL-DISP-20 - Display
MEE10-323	Front label MSS-EL-LOGO-20 - Logo
MEE20-061	Back panel MSS-GREY-SWITCH
MEE20-061	Back panel MSS-BLUE
MEE48-049	Guide for MSS-IR plate
MEE48-091	Encoder wheel MSS
MEE48-171	Motor group kit MSS 12V version
SEM30-009	Fan 12 Vdc 40x40x10 assembled
ELE30-025	MSS Blue LCD display kit with cables
MEE20-057	MSS-EL front panel +violet label kit
MEE20-057	MSS-EL front panel +blue labels kit

> ⚠ **WARNING!**
> In order to ensure the safety and performance of the instrument do not use spare parts other than the ones specified above.

15 TROUBLESHOOTING

Before calling for a service technician, please check sample collection procedures, mixing procedures and operating instructions.

ALARM OR ERROR	CAUSE	REMEDY
LEV	a) Sample level high or low b) The label was not placed in its proper position.	a) Repeat sample collection b) Replace label and repeat analysis
REM	a) Sample has been removed b) Sample has very high ESR and very low hematocrit (rare)	Repeat analysis
T.ERR	"Temperature error" sensor malfunction	Data-analysis is not converted to 18 °C. Call service assistance
MEC. ERROR or ERROR call service	Motor or mechanical malfunction	Call service assistance
Data result is not printed	a) Printer power b) Printer cable c) Instrument printer configuration	a) Check power supply b) Check cable c) Check instrument configuration d) Replace printer

ALARM OR ERROR	CAUSE	REMEDY
Data result seems not correct	a) Sample clot b) Sample has foam c) Sample measured after 4 hours from sample collection d) Sample short mixing e) Temperature conversion is OFF	a) Repeat sample collection b) Remix gently c) Check instrument configuration
One or more samples are shown on the display without tubes introduced	a) Paper pieces or dust on sensors b) Internal cable problem	a) Call service assistance
Barcode reading not work	a) Adapter cable problem b) Scanner power problem c) Wrong ID procedure	a) Check adapter cable b) Check power of the scanner c) Read the user manual
No info on display	a) Instrument switch problem b) Instrument power problem c) Internal problem	a) Check instrument switch b) Check power supply unit c) Call service assistance
PRINTER NOT READY..... Message	a) Printer is not connected b) Printer out of paper c) Printer cable problem	a) Connect the printer or turn off printer configuration. b) Load a new roll of paper c) Check the printer cable
Analysis end delay on display	a) Printer is not connected but enabled b) Printer out of paper c) Printer cable problem d) Random samples inserted, the reading plate is moving	a) Connect the printer or turn off printer configuration. b) Load a new roll of paper c) Check the printer cable d) NO PROBLEM, results are always correct
Analysis end delay on printer	Random samples inserted, the reading plate is moving	NO PROBLEM, results are always correct

In case further technical assistance is required please complete the *Malfunction Report* and send to your local distributor.

16 REFERENCES

The following is a list of literature citations and other reference material regarding erythrocyte sedimentation rate testing.

1) CDC Universal Precautions; U. S. Department of Health and Human Services: Recommendation for Prevention of HIV Transmission in Health Care Settings. MMW Report, Aug 21, 1987, Vol. 36, No. 2S.

2) CLSI. "Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard – Fifth Edition." H02-A5, Vol. 31 No. 11.

3) GREER, JOHN P., MD., et al. (2004). Wintrobe Clinical Hematology (11th ed. Vol. 2, pp. 2697). Philadelphia: Lippincott Williams & Wilkins.

4) MANLEY, R.W. (1957). The effect of room temperature on erythrocyte sedimentation rate and its corrections. Journal of Clinical Pathology, 10, 354

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