EXCYTE® MINI

AUTOMATED ESR ANALYZER

USER'S MANUAL

ELITechGroup
EMPOWERING IVD

EXCYTE® MINI

Automated ESR Analyzer

User's Manual

57-0204-01A
Release Date: 2022-12-01

INSTRUMENT NAME	EXCYTE® MINI Automated ESR Analyzer 10 measuring channels
INSTRUMENT PART NUMBER	EX-10310 [PRD-MSS-VD-08UKN] EP-10610 [PRD-MSS-VD-09UKN]
Manufactured in The Netherlands for INSTRUMENT MANUFACTURER	 ELITechGroup Inc. 370 West 1700 South Logan, UT 84321 United States (800) 453 2725 (435) 752-6011 General Inquiries: info@elitechgroup.com Service / Applications: service_ebs@elitechgroup.com www.elitechgroup.com

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1. INTRODUCTION

1.1. USING THIS MANUAL

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

> ⚠ Before installing and working with the **Excyte Mini 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 Excyte Mini 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 Excyte Mini 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.

⚠ **WARNING!**
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.

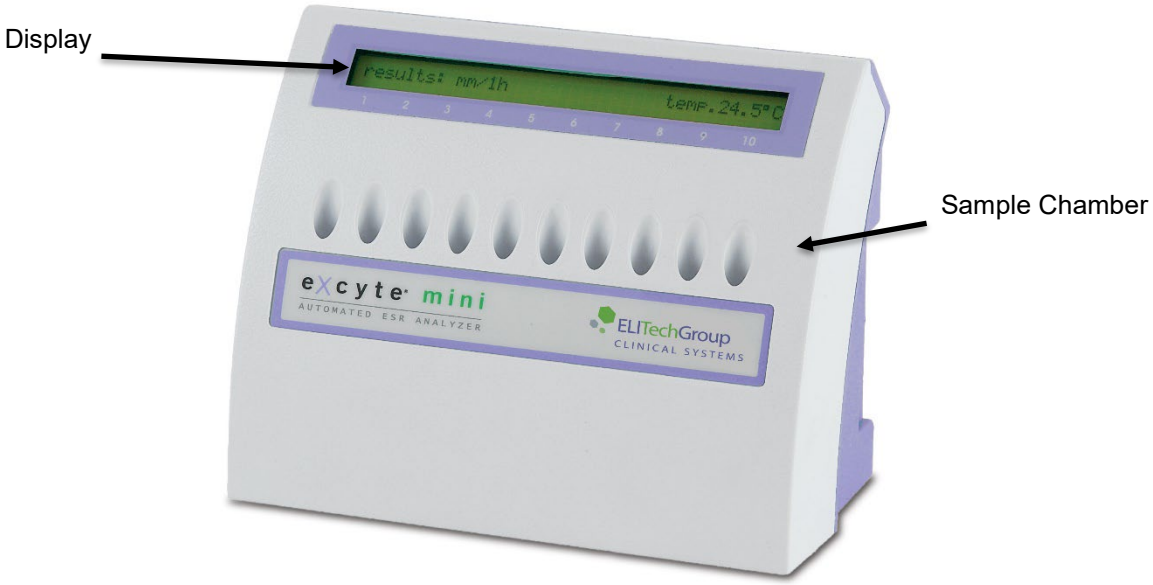
1.3. IMPROPER USE
The following uses are considered improper:

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 Excyte Mini 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 Excyte Mini 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 Excyte Mini 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 Excyte Mini is whole human blood.

The Excyte Mini 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 Excyte Mini 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 Excyte Mini 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 Excyte Mini
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, item number EEE30-099. 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 Excyte ESR tubes supplied by ELITechGroup Inc. must be used to ensure accuracy of measurement for the Excyte Mini:

- EP-10605 EXCYTE® Plastic ESR Vacuum Tube (50/box)
- EP-10605-H1 EXCYTE® Plastic ESR Vacuum Tube High Altitude (50/box)
- EX-50100 EXCYTE® Glass ESR Non-Vacuum Tube (50/box)
- EX-50205 EXCYTE® Glass ESR Vacuum Tube (50/box)

All tube types contain 3.2% sodium citrate solution and are designed to draw 1.0 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 Excyte Mini Automated ESR Analyzer.

- DS-71002 Normal Accu-Sed® Plus ESR Control Kit 5 x 8.5 mL
- DS-71003 Abnormal Accu-Sed® Plus ESR Control Kit 5 x 8.5 mL
- DS-71005A Accu-Sed® Plus ESR Bi-Level Control Set 5 x 2 x 8.5 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 Excyte tube instruction for use for additional details.

2.2. USER PRECAUTIONS

⚠ CAUTION:

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 Excyte ESR 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 7000 Reg. No.
	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	0434A
	ISO 15223-1 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	2493
	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.	N/A
	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	1641
	N/A	European Conformity Mark	Indicates that the product conforms to the European IVD Directive 98/79/EC	N/A

Symbol	Symbol Ref. No.	Symbol Title	Symbol Explanation	ISO 7000 Reg. No.
	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 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.	N/A
	ISO 15223-1 5.1.1	Manufacturer	Indicates the medical device manufacturer	3082
	ISO 15223-1 5.1.1	Country and date of manufacture	Indicates the date and the country the medical device was manufactured.	6049
	N/A	Warning; Biological hazard	Indicates that there is potential biological hazard associated with the medical device	ISO 7010 – W009
	ANSI/ESD S8.1	ESD Susceptibility Symbol	Indicates susceptibility to electrostatic discharge	N/A
	N/A	General Warning Sign	Indicates a general warning	ISO 7010 – W001
	ISO 15223-1 5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	0621
	ISO 15223-1 5.3.4	Keep Dry	Indicates a medical device that needs to be protected from moisture	0626
	ISO 15223-1 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	0632

Symbol	Symbol Ref. No.	Symbol Title	Symbol Explanation	ISO 7000 Reg. No.
	ISO 15223-1 5.3.8	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed	2620
	N/A	This way up	To indicate correct upright position of the transport package	0623
	N/A	Recycle symbol	Indicates that packaging is a corrugated fiberboard and may be recycled	N/A

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 section 11.1, Instrument 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.

4 INSTALLATION

4.1. POSITIONING OF THE ANALYZER

The Excyte Mini 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.

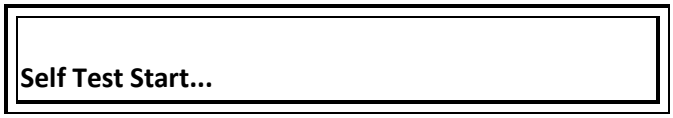
4.2. INSTRUMENT STARTUP

Excyte Mini will be supplied factory configured. Instrument configuration is controlled through dip-switches on the backside of the analyzer. See section 4.3 for dip-switch information and defaults.

4.2.1. POWER ON

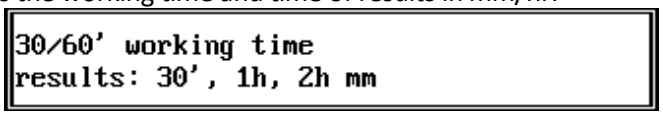
- Connect power adapter to the instrument.
- Insert the power supply plug into the electrical socket.
- If using the optional printer or scanner, connect to the RS232 port on the Excyte Mini using the appropriate cable. Then, plug the power supply for the scanner into an electrical outlet.
- Once connected, turn on the Excyte Mini using the switch situated at the rear side of the instrument.

Each time the Excyte Mini is switched on, it performs an electronic initialization and self-test to check for proper operation.

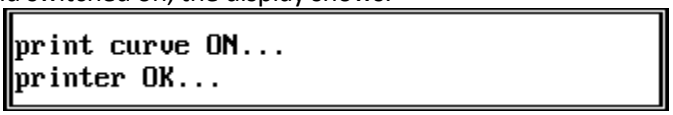


During the self-test, the instrument checks electronic parts and configurations.

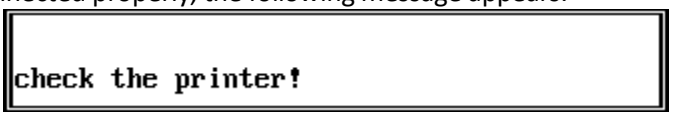
The following message shows the working time and time of results in mm/hr.



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

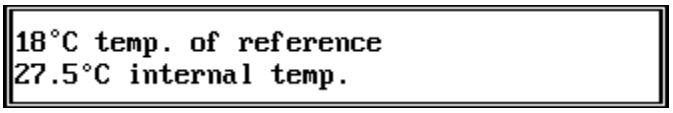


If the printer is off or not connected properly, the following message appears:

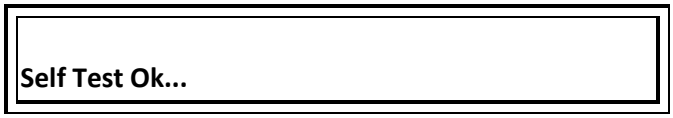


If after 5 seconds the printer is not connected, the instrument automatically disables the printer.

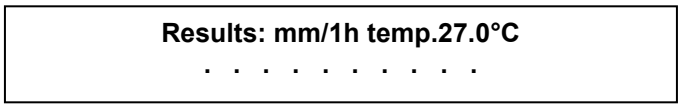
If the temperature compensation is active, the display will show:



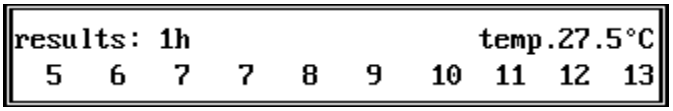
Once the self-test has successfully finished, the following appears:



The instrument is now ready for 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. DEFAULT DIP-SWITCH SETTINGS

The standard factory settings are as follows:

a) Analysis time: 30-minute working time with results correlated to a 1-hour Westergren (dip-switch 2 OFF).
b) Automatic adjustment of temperature with result related to the reference temperature of 18 °C in accordance with MANLEY (dip-switch 3 ON).
c) Printer is disabled (dip-switches 4 and 8 OFF).
d) Pre-indication is on (no dip-switch).

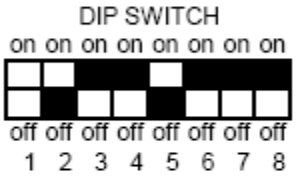
The dip-switch configurations are as follows:

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 minutes 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**.

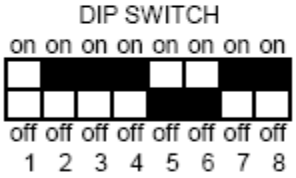
NOTE: the function is active if the dip switch is on “ON” position.

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

Sample must be inserted within 15 seconds. The instrument will detect the tube insertion position and will display the position and ID on the screen for 2 seconds.

5.4. RECORD RESULTS AND REMOVE SAMPLES

When analyzer is set for a 30-minute working time and pre-indication is on, pre-indication of results will show after 10 minutes, and will continue to show until the results are populated at 30 minutes.

After 30 (or 15 minutes), record the result:

- Results will print if the printer is connected and 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. Free channels will appear with " . ", indicating that the channel position is free for introduction of next tube.

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. Inflammation is a pilar of innate immunity 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 inflammatory 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

Ulcerous colitis

Malignant lymphoma
Leukemia
Serious anemia
Carcinomas
Sarcomas
Serious bacterial infections
Collagenosis
Biliary or portal cirrhosis
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
Acute localized infections
Reactivation of a chronic infection
Rheumatic illness
Rheumatoid arthritis
Myocardial infarction
Malignant tumor with necrosis
Hyperthyroidism
Hypothyroidism
Lead or arsenic poisoning
Nephrosis
Internal hemorrhage
Acute hepatitis
Ectopic pregnancy unbroken after the third month

ESR - Normal values

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

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 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 READING PRINCIPLE

Ten pairs of infrared sensors vertically monitor and measure the sample tubes in 60 second cycles. The measurement of light transmittance is performed in 0.2 mm increments.

Newly inserted samples are detected on each cycle provided the sample tubes contain the recommended volume. At the first rising (when the instrument has ensured that the meniscus is clearly distinct), the software recognizes any positions occupied by samples containing the right level of blood. The level of the sample collection just inserted is checked and analysis begins.

The computer records the "zero" time for each sample, and all the following readings, until 30 minutes have elapsed. During this phase, the instrument monitors the presence of the sample.

7.2 SAMPLE COLLECTION

Samples must be collected following the techniques shown in the Excyte ESR Vacuum and Non-Vacuum package insert. The following external factors can alter the ESR value after blood collection:

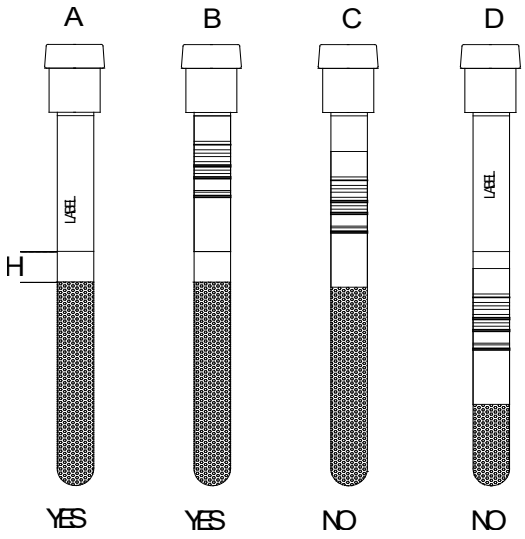
a) Dilution ratio
b) Bubbles
c) Strongly hemolyzed samples
d) Sudden agitation
e) Improper mixing
f) Temperature
g) Time after sample-taking*
h) Direct sunlight
i) Foam
j) Lipemic samples
k) Tube inclination

⚠ **CAUTION:** In accordance with the recommendations of the Clinical and Laboratory Standards Institute (CLSI), blood samples collected in this manner and stored in an EXCYTE tube should be tested within 4 hours if left at room temperature (18 to 25 °C). The specimen may be kept refrigerated (2 to 8 °C) for up to 12 hours, but must be brought to room temperature and mixed thoroughly prior to analysis.

Blood used for ESR testing and stored in an EDTA tube is stable for up to 24 hours if refrigerated (2 to 8 °C), but must be brought to room temperature and mixed thoroughly prior to analysis.

7.3 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. In Figure A, the tube has 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 and analysis.



7.4 SAMPLE MIXING

When it is not possible to analyze the sample immediately after sample collection, the sample must be mixed manually by gently overturning at least 10 times. As an alternative, we suggest the use an automatic rotating mixer with an RPM value of 15-20.

7.5 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. For example, when the tube in channel one is analyzed and removed, this position automatically becomes number 11 and so on.

7.6 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:

1) Scan the barcode label
2) Insert the tube in the first free channel within 15 seconds after scanning

The instrument will automatically detect the position of the newly inserted tube and the ID will be automatically associated to that position. After the sample has been inserted, the display will show:

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

7.7 Sample Printout

If a printer is connected, the following information will be printed out once the analysis is complete.

```
Smpl.Chan.PatID#                    ( no ID present )
 1   1 ............
  1h
  5       mm

Smpl.Chan.PatID#                    ( ID: 123456789012 )
 1   1  123456789012
  1h
  5       mm
```

To identify sample ID's in the absence of a barcode label, write the ID on the label of each sample. On a separate report, write the sample ID, the corresponding channel, and result.

7.8 DISPLAY

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

The display also shows the symbols shown below:

Meaning of symbol on display	
"xxx"	Result = xxx
" . "	Awaiting sample
">xxx"	Sample value higher than "xxx"
"lev"	Error: initial level error
"rem"	Error: removed sample

Time remaining symbols

These symbols appear for each sample and indicate the remaining time to the end of the analysis.

7.9 RESULTS PRE-INDICATION

Approximately ten minutes after inserting the sample in the instrument, each sample will be analyzed and the result will appear on the screen with an indication such as + or -. This semi-quantitative value gives an anticipated indication of the result expressed in mm/h Westergren. Remember, this value is ONLY a pre-indication; the final results will display after 30 minutes.

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

NOTE: Pre-indication is shown only on 30 and 60 minute working time modes.

7.10 REMAINING TIME

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

time remaining symbols

7.11 SAMPLE REMOVAL

As soon as sample has been analyzed, the result will be automatically printed out if a printer is connected. Results will stay on the display until the tube removal. Remove tubes carefully, maintaining tubes in a 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.

7.12 FINAL RESULTS

When the analysis is finished, the result will be shown on the display and printed (when connected and switched on). After removing the test tube, the displayed data will disappear within one minute. **Removal of the tube causes the displayed result to clear**. Once cleared, the operator may insert a new sample into the channel.

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

> ⚠ **CAUTION:** Remove tubes carefully, maintaining tubes in a vertical position in order to avoid tubes breaking.

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. The Excyte Mini Automated ESR Analyzer constantly measures the internal temperature and normalizes the values to a temperature of 18 °C, according to the Manley[4] table. This automated temperature adjustment ensures better reproducibility when compared to instruments which provide results without temperature compensation.

Manley table

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

Excyte Mini Automated ESR Analyzer converts the results to 18 degrees according to the table if the internal temperature is between 15 - 32°C. For lower or higher room temperatures, the instrument converts temperature in this way: 15°C for lower and 32°C for higher temperature.

9 ERROR INFORMATION AND WARNINGS

9.1 SAMPLE ERRORS

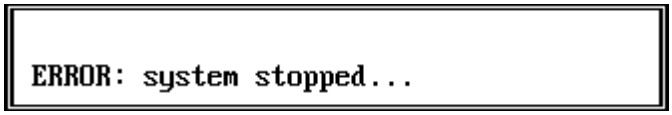
These messages may appear on the display:

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

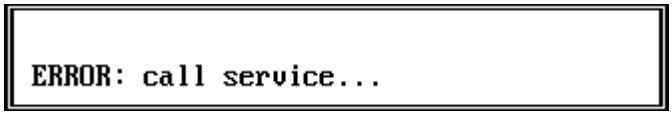
REM: Indicates that the test tube has been removed from the position in which it had been placed. On rare occasions, when there is both a high ESR and a very low hematocrit, the level of red blood cell sediment can fall below the lowest position of the IR board. In such a situation, the instrument may 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.

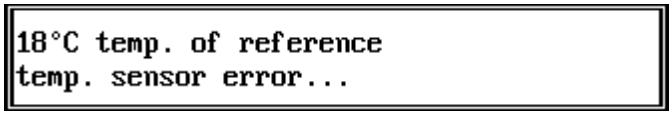
9.2 SYSTEM ERROR WARNINGS



This warning will be given if the instrument finds problems with the mechanical movement of the reading plate during the initial self-test. After this indication, the instrument will stop and the operator will need to call Technical Service.



This message can appear if there is a mechanical problem during analysis.



This message can appear if the internal thermometer has problems. In this case, analysis results are displayed without temperature compensation.

10 SERVICE

In the rare case that an Excyte Mini malfunctions, please call Technical Support at 1-800-453-2725 or email service.ebs@elitechgroup.com. Service can be made by authorized ELITechGroup Inc. personnel only. Work performed by unauthorized personnel invalidates the warranty.

11 SPECIFICATIONS

11.1 INSTRUMENT SPECIFICATIONS

Instrument size:	Height 5 7/8” (149 mm) Width 7 7/10” (196 mm) Depth 4” (102 mm)
Weight:	Approximately 2 lbs. (0.91 kg)
Voltage:	External power supply: 100 - 240 Vac +/-10%, 1.8A, 50/60 Hz
Power consumption:	12 Vdc 1.5 A
Operating Conditions:	Temperature: 15 – 32 °C Relative humidity: 10% - 95% Altitude: up to 2000 m Overvoltage: category II Pollution: degree 2 For indoor use only Sound level: < 80dB(A)
Transport and storage conditions:	Temperature: -10 °C – +45 °C Relative humidity: 0% – 95%
Tube employed:	8 x 120 mm glass tubes 9 x 120 mm plastic tubes
Results (selectable):	in Westergren mm/30 minutes, mm/1h, mm/2h (by interpolation)
Reading time (selectable):	15, 30 or 60 minutes
Pre-indication results:	10 minutes
Reading channels:	10
Analytical capacity:	Maximum 40 tests/h
Loading pattern:	Random
Acceptable blood draw level:	45 – 55 mm from the bottom of the tube
Measuring method:	Infrared beam
Reading resolution:	+/- 0.2 mm
Results resolution:	+/- 1 mm
Wave length:	900 nm
Temperature correction:	Automatic compensation referred to 18 °C (Manley)
Interface:	Single RS232 port for printer output and barcode scanner input

11.2 PERFORMANCE SPECIFICATIONS

Mechanical/Optical precision of detection:	+/- 0.2 mm (Software controlled by encoder resolution)
Automatic temperature conversion to 18 °C (Manley table):	Accepted range: 15 °C - 32 °C
Level range for correct analysis:	Accepted range: 45 - 55 mm from tube bottom
Measuring points:	2 reading points, initial and final
Measuring range:	1 – 140 mm/h
Pre-indication of results before end of analysis:	After 10 minutes

Precision:

Within run precision (total precision)
30 minutes working time

	Mean	1SD	CV
Glass ESR tubes, Normal (n=40)	6.2 (6.2)	0.6 (0.8)	10.2% (13.0%)
Glass ESR tubes, Abnormal (n=40)	47.8 (47.5)	3.5 (3.8)	7.4% (7.9%)
Plastic ESR tubes, Normal (n=45)	7.4 (7.2)	0.5 (0.6)	7.4% (7.9%)
Plastic ESR tubes, Abnormal (n=45)	60.0 (67.6)	2.2 (6.0)	3.7% (8.9%)

Correlation:

Blood samples from patients with ESR's ranging from 1 to 140 mm/hr on the EXCYTE-MINI and EXCYTE-20 automated ESR analyzers and Westergren (modified) method were compared by least squares regression and the following statistics were obtained:

	R value	*n*	*Regression line*
Glass ESR tubes, 30 minutes working time	0.989	108	y = 1.0664x + 0.7896
Glass ESR tubes, 15 minutes working time	0.972	55	y = 1.2257x - 2.2715
Plastic ESR tubes 30 minutes working time	0.993	61	y = 0.983x - 0.380
Plastic ESR tubes 15 minutes working time	0.982	55	y = 1.2071x - 4.0364

11.3 LIMITATIONS

- Strongly lipemic or hemolytic samples may alter reading capability.
- Sedimentation 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

- Anemia under 2.5 million/cubic mm RBC can give reading problems.

- As with all ESR analyzers, abnormally high or low hematocrits, along with other hemoglobinopathies, may affect results.

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 INTERFACING (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!)

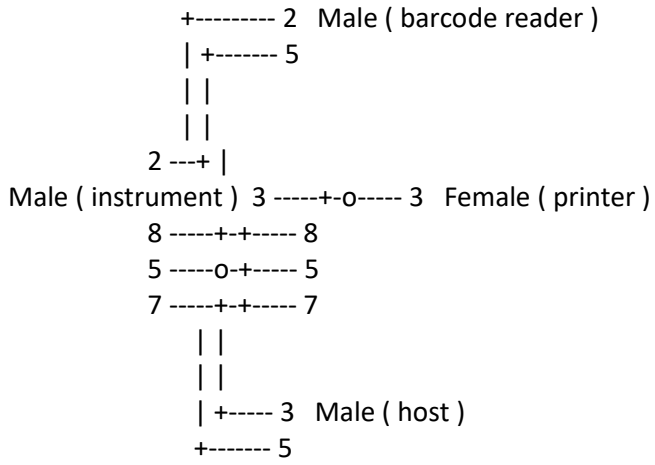
DIRECT HOST CONNECTION CABLE EXAMPLE

Note: The connectors of the cable are 9 pin.

Male (instrument)	Female (to host)
2	3
3	2
4	8
8	4
5	5

HOST, PRINTER AND BARCODE CONNECTION CABLE EXAMPLE

Note: The connectors of the cable are 9 pin.
The printer must be connected and ready to print.



13 MAINTENANCE

13.1 MAINTENANCE

The Excyte Mini 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.

13.2 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 the microbial contamination.

⚠ **CAUTION:**

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

⚠ **CAUTION:**

Pay particular attention to the test tube. The cap must be tightly closed. 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 a correct reading function during analysis.

The entry of liquids or solid material into the channels can cause considerable damage to the instrument, so use caution when cleaning.

14 SPARE PARTS

Part number	Description
EEE20-039	Board MSS-IR rev.2.0 cod.MSS20A03
EEE20-078	Board MSS-CPU 4.0 for Green Display
EEE20-138	Board MSS-CPU 4.0 for Blue Display
EEE30-021	Cable MSS-10C02 - IR plate MSS
ELE10-029	Power supply unit EA1050A-120
MEE10-210	Front label MSS-EL-DISP-20 - Display
MEE10-211	Front label MSS-EL-LOGO-20 - Logo
MEE20-059	Back panel MSS-GREY-SWITCH
MEE20-061	Back panel MSS-BLUE
MEE48-049	Guide for MSS-IR plate
MEE48-091	Encoder wheel MSS
MEE48-124	Mechanical group kit MSS-EL
MEE48-171	Motor group kit MSS 12V version
SEM30-009	Fan 12 Vdc 40x40x10 assembled
SEM30-020	MSS Green LCD display kit with cables
SEM30-030	MSS Blue LCD display kit with cables
SEM50-032	MSS-EL front panel +violet label kit
SEM50-066	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 GUIDE

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

ALARM OR TROUBLE	CAUSE	REMEDY
LEV	a) Sample level high or low b) The label was not placed in its proper position. Refer to Section 6.3	a) Repeat sample collection b) Replace label and repeat analysis
REM	Sample has been removed	Repeat analysis
T.ERR	"Temperature error" sensor malfunction	Data-analysis is not converted to 18°C. Call Technical Support
MEC. ERROR or ERROR call service	Motor or mechanical malfunction	Call Technical Support
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
Data result is not credible	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) Repeat sample collection and promptly process d) Check instrument configuration
One or more samples are shown on the display without tubes introduced	a) Possible obstruction of infrared barrier by external materials (label pieces, etc.) b) Internal cable problem	Call Technical Support
Barcode scanner not working	a) Cable adapter problem b) Scanner power problem c) Wrong configuration codes	a) Check adapter cable b) Check power of the scanner c) Reprogram scanner, refer to section 17
No information on display	a) Instrument switch problem b) Instrument power problem c) Internal problem	a) Check instrument switch b) Check power supply unit c) Call Technical Support
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 b) 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) Wait a moment for the reading plate to stop moving
Analysis end delay on printer	a) Random samples inserted, the reading plate is moving	a) Wait a moment for the reading plate to stop moving

In case further technical assistance is required please contact ELITechGroup Inc. Technical Support:

Phone:	1 (800) 453-2725 +1 (435) 752-6011
Email:	service_ebs@elitechgroup.com

In case you want to return the instrument please decontaminate it prior to shipment as prescribed in the Decontamination Instruction provided by ELITechGroup Inc. Technical Support.

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

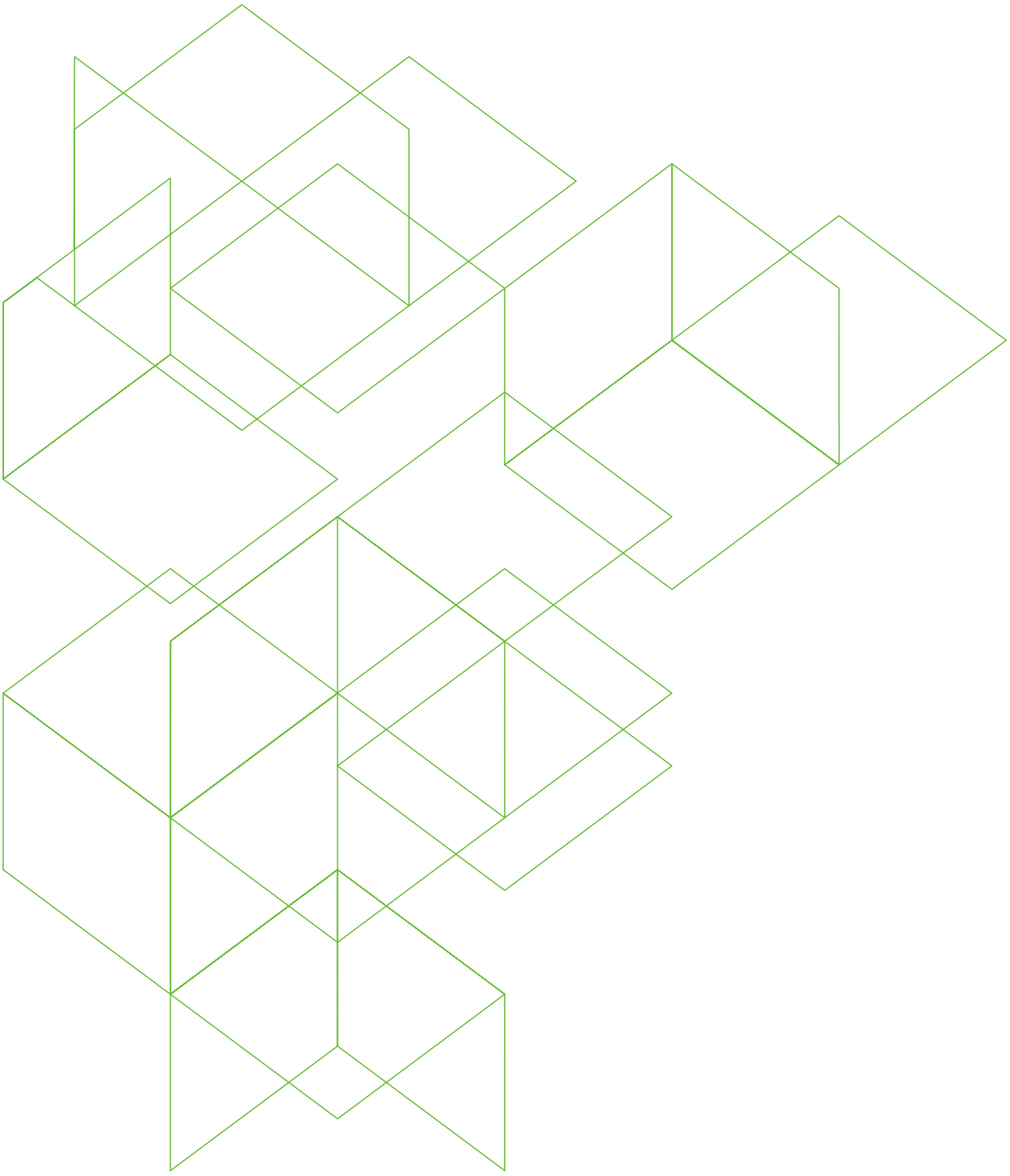
17 BARCODE SCANNER CONFIGURATION

In case of barcode reading problems, this page can be used to reset the barcode scanner.

Turn on the instrument, wait for the self-test to complete and then read all barcodes in table 1, from top to bottom. Then in table 2, from top to bottom.

Table 1
$%+PRO
3AE Baud rate
/0 0
/5 5
%% Finish
%$$ Exit

Table 2
$%+PRO P
EAK
/0 0
/0 0
%% Finish
%$$ Exit



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