

EXCYTE® 20

AUTOMATED ESR ANALYZER

USER'S MANUAL



EXCYTE[®] 20

Automated ESR Analyzer

User's Manual

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INSTRUMENT NAME	EXCYTE® 20 ESR Automated Analyzer 20 measuring channels
INSTRUMENT PART NUMBER	EX-10318 EP-10618
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1. INTRODUCTION

1.1. Using This Manual

Prior to operating the EXCYTE 20 Automated ESR Analyzer, carefully read the instructions in this manual for proper use of the instrument.

 Before installing and working with the **Excyte 20 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 20 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 20 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 until it is disconnected from the power supply. If the power is on, damage can be caused by moving parts. Do not try to stop the agitator manually or inserting something between the moving part and the device. This could cause instrument damage. The operator cannot be injured by the agitator because the moving part is driven by a low power motor and the motor is software controlled in order to stop its movement every time an external object/force blocks its movement.

⚠ 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 service personnel may open the instrument to perform maintenance or repair. For the correct replacement parts, see the spare parts list, Section 17.0.

⚠ 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
- 4) Attempting to open the mixing panel when it is closed, or to hinder its movement

Any use of the EXCYTE 20 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.



The EXCYTE 20 Automated ESR Analyzer is an automated instrument controlled by a microprocessor and exclusively employed for analysis of the erythrocyte sedimentation rate (ESR). Its precision and its ability to obtain results corrected to a temperature of 18 °C (according to Manley) in only 15/30 minutes make the EXCYTE 20 Automated ESR Analyzer an innovative and versatile system for this kind of analysis. It simultaneously scans 20 test tubes which are custom-made for use with this system. The exclusive sample type for EXCYTE 20 is whole human blood.

The EXCYTE 20 Automated ESR Analyzer follows the sedimentation of each sample independently. When a sample has been analyzed, it can be replaced by another, making it possible to analyze up to 80 tests per hour.

The EXCYTE 20 Automated ESR Analyzer has been developed to simplify ESR analysis as much as possible, avoiding sample handling and the operator's infection risk. To perform the analysis, the operator places the sample test tube into the instrument. The results are complete in as little as 15 minutes, correlated to one (1) hour Westergren. This feature allows the instrument to be used directly in the blood sample collection department and in small to medium laboratories.

In performing the analysis, the EXCYTE 20 Automated ESR Analyzer 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. Keypad

The EXCYTE 20 Automated ESR Analyzer is equipped with a numerical keypad that can be used for several purpose like sample identification, QC lot entry, change set up features, etc.

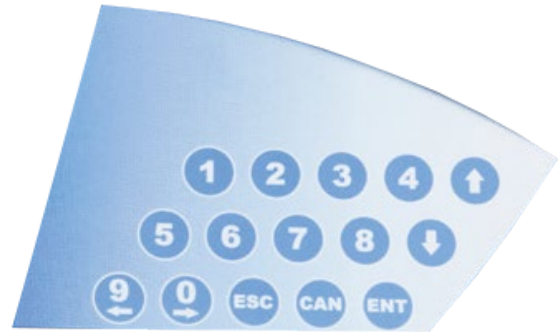
Besides numbers (from 0 to 9), there are additional buttons on the keypad that perform the following functions:

ARROWS: allows the operator to move the cursor UP and DOWN and LEFT or RIGHT

ESC: allows the operator to skip the mixing procedure and to exit a menu

CAN: allows the internal printer paper to advance when the operator is in the MAIN MENU, and the deletion of “memory full” message from the display (Section 5.2)

ENT: allows the operator to confirm /accept



1.6. Printer, barcode reader, and host

The EXCYTE 20 Automated ESR Analyzer is fitted with an internal printer and an internal barcode reader. If desired, an external printer and/or barcode reader can be used. To enable an external printer and/or barcode reader, connect its cable to the RS232 port on the back of the instrument. This RS232 port can also be used as HOST port.

If using the external ELITechGroup DPT100 printer, use Cable A, power supply and gender changer supplied with the printer.

1.7. Tubes and Controls

Specially designed EXCYTE ESR tubes supplied by ELITechGroup Inc. must be used to ensure accuracy of measurement for the EXCYTE 20:

- 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.

1.8. 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.

1.9. 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.

1.10. 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.

1.11. 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
- Thermal Paper Roll 57x25mm, Qty:1
- Paper Roll Support, Qty: 1

2. SAFETY PRECAUTIONS

2.1. Notes on safety measures

CAUTION:

The operator must pay a special attention to the sample collection. EXCYTE ESR tubes must be used with the equipment in this manual since these tubes have been designed to aspirate the correct level of blood. Any attempt to use tubes different to the one described brings serious dangers of infection due to the risk of sample spilling, and this, moreover, will damage the optics inside the instrument and provoke the loss of the guarantee. Refer to the EXCYTE ESR Tube instruction for use for additional details.

2.2. User precautions

CAUTION:

Before using the analyzer, the operator should be trained in universal precautions¹ 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 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 instrument failure due to inappropriate use.

The analyzer and accessories are shipped in transport boxes and should be unpacked and installed using




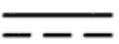


instructions supplied by ELITechGroup Inc. If these instructions are not observed, ELITechGroup Inc. assumes no responsibility for consequential damage or improper operation of the analyzer.










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 <i>symbol</i> 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

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, risks remain that were reduced, but not eliminated completely.

RESIDUAL RISKS	PROTECTION MEASURES
Biological contamination	Operators should practice universal precautions ¹ 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. Do not try to open the mixing panel in order to avoid breaking tubes.
Mixing panel stop	Do not try to stop the mixing panel while it is moving. Do not try to insert any object between the mixing panel and the device in order to avoid mixing panel damage and/or tubes breaking. Do not try to touch the internal moving parts when the mixing panel is open, in order to avoid user and/or instrument damage.

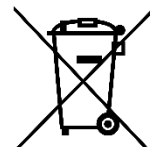
2.5. Transport

For transport and storage conditions, see section 14.1.

Appropriate decontamination shall be performed prior to transportation, see document Decontamination Instruction ESR Instruments for details.

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 of separately, not as urban waste and delivered to a specific collection center according to Directive 2012/19/EU. The user may ask the distributor about the collection of the instrument if a new instrument is ordered to replace an 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.

4. INSTALLATION

4.1. Positioning of the analyzer

The EXCYTE 20 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 leveled. Keep a free area of at least 15 cm around the instrument to allow instrument cooling by the internal back panel fan. Direct light on the instrument and sudden changes in temperature should be avoided.

4.2. Instrument startup

- Connect power supply outlet to the instrument.
- Insert the power supply plug into the electrical socket.
- Once connected, turn on the **EXCYTE 20** using the switch situated at the rear side of the instrument.

Each time the EXCYTE 20 is switched on, it carries out an electronic initialization and an instrument self-test to check for proper operation.

After initialization, the main menu will be displayed (see Figure 1).

The numbers from 1 to 20 on the screen indicate the positions (channels) for samples to be placed, while indications relative to the status of the analysis appear above channels 1 through 10, and below channels 11 through 20. See Section 4.3 for complete symbol descriptions.

On the top of the display there are six (6) functions. They can be accessed by pressing the appropriate number on the keypad.

Main-Menu Functions:

- ID: Register the identification number for each sample
- MEMORY: Display and edit data stored in memory
- QC: Quality Control program
- PRINT: Print a work list, or print the results of the analysis
- HOST: Transfer data to the host computer
- SETUP: Initial setup and configuration of the instrument

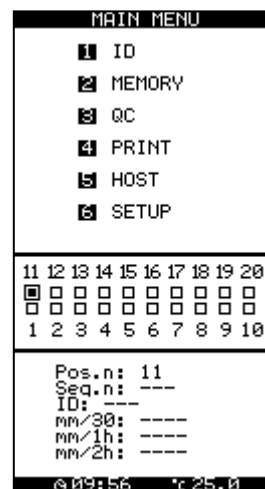


Figure 1

5. INSTRUMENT SETUP: MAIN MENU - FUNCTION (6)

Instrument setup can be accessed by pressing 6 on the main menu (Figure 1).

The operating parameters of the EXCYTE 20 are factory set to the default values shown in Figure 2. The parameters may be changed by using the UP and DOWN arrows to move the cursor through the menu options.

5.1. Result (RES. XX)

The default factory setting of the EXCYTE 20 is Result 1h, with a 30-minute working time. This setting provides results which are displayed and printed in 30 minutes for each measurement, referenced to one-hour Westergren.

To change the default, set the desired setting to Yes. More than one result may be chosen. For example, by selecting “30”, “1h”, and “30/60”, the operating time remains at 30 minutes and the results are reported for both “30 minutes” and for “1 hour” referencing the Westergren method. By selecting “2h”, the operating time is one hour for each measurement referencing the 2-hour Westergren. All three combinations are possible with a 2-hour operating time and all three results reported.

If the 15-minute working time is selected “W. Time: 15”, results are displayed and printed in 15 minutes, referenced to one hour Westergren. Results can only be correlated to a one-hour value; results cannot be correlated to 30 minutes or 2 hours in the 15 minute working time mode.

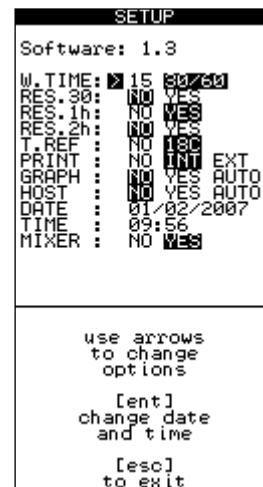


Figure 2

NOTE! Changing the operating time with results stored in memory requires a reset of the memory, and stored results will be deleted!

After the operating time has changed, a message will appear indicating that the results stored in memory will be deleted (see Figure 3). Press [ENT] to accept and ESC to abort.

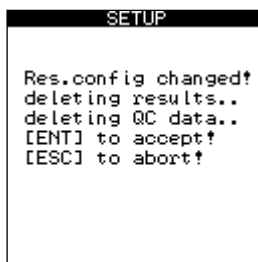


Figure 3

5.2. T REF

The EXCYTE 20 features an automatic adjustment of temperature related to the reference temperature of 18°C in accordance with Manley (see Section 12, Temperature Compensation for further details). To change this setting, select No.

5.3. Print

The default printer is an internal printer, as indicated by the “INT”. If you wish to connect an external printer, select “EXT”. Select “NO” if a printer will not be connected, and you do not wish to use the internal printer.

5.4. Sedimentation Graph

It is possible to monitor the state of the sedimentation by viewing the sedimentation graph (Figure 4). Select the sample to monitor from the main menu by moving the arrows, and then press Enter to view the graphic. Pressing enter a second time enables you to print. Moving the arrows up and down allows you to pass to the next or previous samples.

The graph can only be viewed if the Graph Setting is set to Yes or Auto in the Setup menu (see Figure 4). To view the sedimentation graph, set Graph to either Yes or Auto. If Auto is set, the sedimentation graph will print with each result.

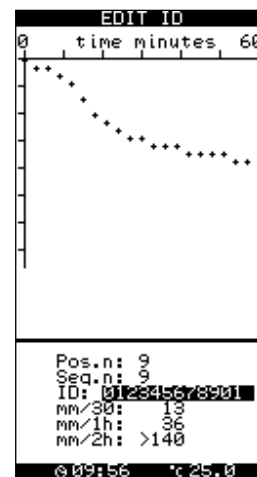


Figure 4

5.5. Host

The instrument may be connected to a Laboratory Information System (LIS). To transfer the results to a laboratory computer, it is necessary to select YES or AUTO on the HOST line.

5.6. Date and Time

If needed, register the date and local time by moving the cursor to the desired line and pressing enter. Use the numeric keypad to enter the numbers. The date format is month/day/year. Additionally, a 24-hour clock is used, e.g. 2:00 p.m. would appear as 14:00.

5.7. Mixer

The default factory setting for the on-board mixer is "YES." With the mixer function set to Yes, the cover, when closed, begins the five-minute mixing process.

To disable the mixer operation, select No. With the mixer function set to No, the cover will function as a cover only, and tubes can be inserted at any time without remixing.

After any adjustments are made, press the ESC button to return to the main menu.

6. MAIN MENU

6.1. ID Function (1): Samples Identification

After selecting (1) ID, the instrument shows two options (ID1 and ID2) to the data (see Figure 5).

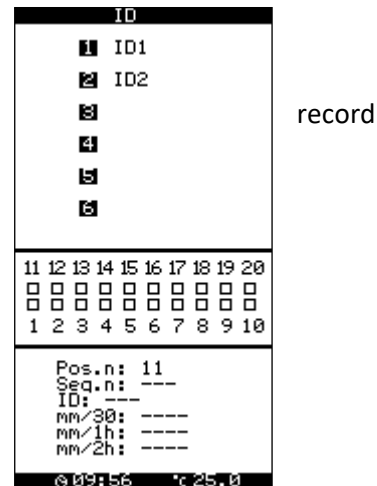


Figure 5

6.1.1. ID1 sub-menu function (1)

After selecting (1) ID1, enter a patient’s code by either entering the number on the keyboard and pressing enter, or scanning the barcode by passing the tube in front of the CCD scanner window located on the right side of the analyzer. The tube should be swiped at a distance of approximately 6”. If the barcode does not scan, move the tube side-to-side (left to right) in the path of the LED until you hear a beep and the ID code is accepted. If desired, an external barcode reader can be connected to the BARCODE port.

CAUTION: If the keyboard is used to key the barcode ID, enter must be pressed after the ID code is input. If enter is not pressed, then the instrument will not recognize the ID.

CAUTION: The CCD scanner is made up of red LED’s and emits visible red light. The light emitted by the scanner does not pose a danger to the operator.

After the barcode is accepted, the operator will be instructed to insert the tube into any open position (see Figure 6). The analyzer will detect the channel in which the tube was placed.

After inserting the sample, a beep will confirm that the sample has been recognized, and the instrument is ready to accept the next identification code (see Figure 7).

If all twenty channels are used and the analyzer is full, the operator will not be able to input additional ID’s, and an Analyzer Full message will appear (see Figure 8). To exit the screen, press the ESC key.

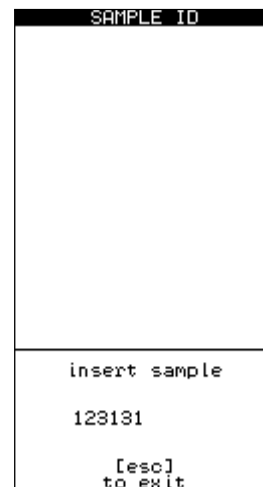


Figure 6

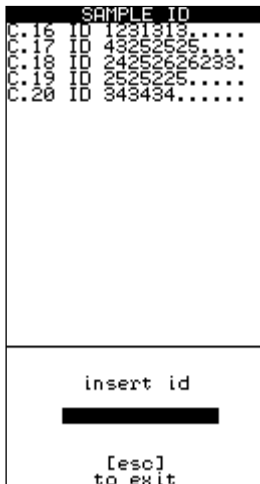


Figure 7

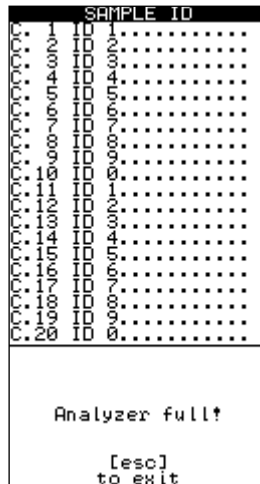


Figure 8

After all ID's are entered, return to the main menu to monitor the status of the analysis or before closing the cover to start the mixing process. If the cover is closed while the analyzer is still in the ID mode, mixing will not occur.

During analysis, symbols are shown on each channel to indicate time remaining (see Section 9.6.1).

6.1.2. ID2 Sub Menu Function (2)

This function enables the operator to insert a series of sample identification codes following a work list. Once the codes are entered, the operator must transfer the samples to the channels relative to the identification codes. This procedure is ideal when one has to transfer many samples from the external mixer to the instrument quickly, so that results are not affected.

Once the samples have been inserted, return to the main menu to monitor the status of the analysis by pressing ESC. During analysis, symbols are shown on each channel to indicate time remaining (see Section 9.6.1).

6.2. Memory Function

Up to 500 results can be stored in memory at one time. It is recommended to clear the memory at least every other day. When the instrument is turned on at the start of a new day, the user is prompted to delete results (see Figure 9). Pressing enter will erase all records in memory. ESC aborts this action.

When the memory is full, a warning message will be displayed, and the analyzer will emit a beep (see Figure 10). Press CAN key to clear this message.

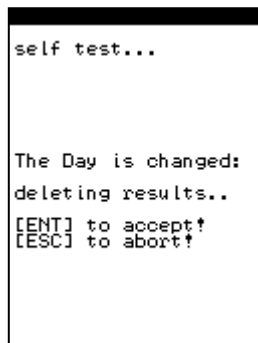


Figure 9

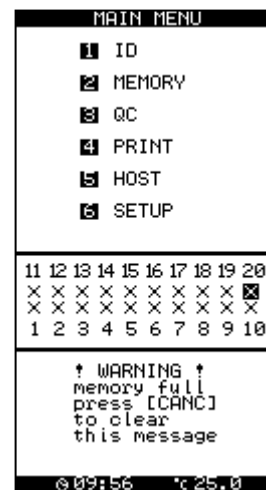


Figure 10

⚠ WARNING! If the memory is full, the instrument will overwrite samples already in memory, starting with the first sample stored, sample 1.

Use option 1 to clear the memory. This will delete all data stored in memory, so caution should be used. After 1 is pressed, a warning message will appear (Figure 11). To continue, press [ENT] to accept, or press ESC to abort.

6.2.1 View Memory Sub-Menu Function (2)

This function allows the operator to view the results and ID codes stored in memory (see Figure 12).

6.2.2 Edit Memory Sub-Menu Function

This function allows the operator to edit ID codes, along with the respective results. Move the cursor to the sample to be changed, press enter, and then edit the ID code or the results (Figure 13).

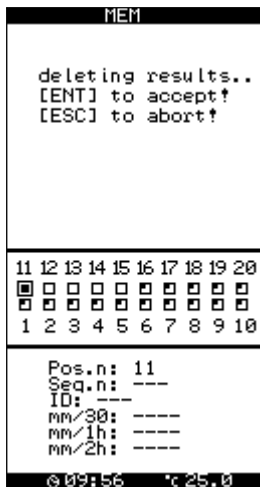


Figure 11

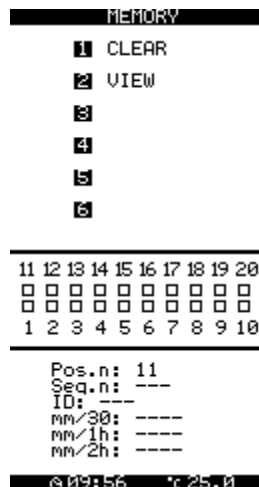


Figure 12

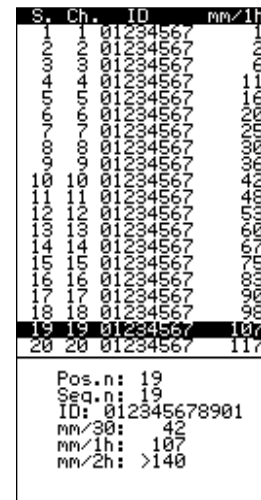


Figure 13

6.3. Quality Control Function (3)

The screen shown in Figure 14 will be displayed when Function 3 is pressed at the Main Menu.

6.3.1 QC INP Sub-Menu Function (2)

This Function precedes Function 1. The QC ID number for the ESR control is entered using (2) QC INP. This should be done every time a new lot of controls will be used. Press 2, enter the QC ID number for both the normal and abnormal controls (found on the package insert), then press ESC to exit. Alternatively, the QC ID barcode found on the package insert can be scanned.

This function is designed to be used specifically with Accu-Sed Plus Normal/Abnormal ESR Controls. The QC ID number has a “checksum” character to ensure that it is entered correctly. Be certain to enter QC ID number exactly as written or the code will not be accepted.

When the new QC ID code is entered, a screen similar to Figure 15 will appear.

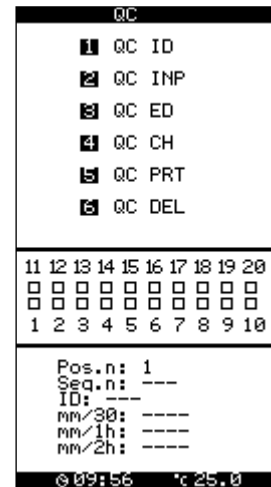


Figure 14

⚠ CAUTION: When a new lot is entered and accepted, the stored QC data will be erased. Therefore, before deleting stored QC data, “1” must be pressed in order to confirm the deletion of this stored data. If you wish to print out this data, and do not wish to delete at this time, press ESC to exit now.

If “1” is pressed the screen shown in Figure 16 will appear.

Press [ENT] to confirm the entry of the new control information and the deletion of the old data. This will return you to the QC menu.

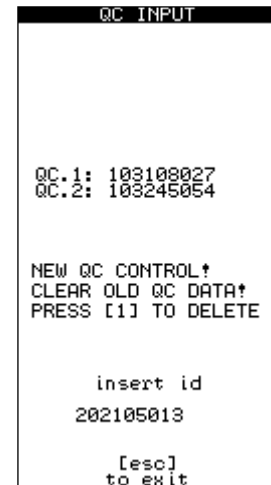


Figure 15

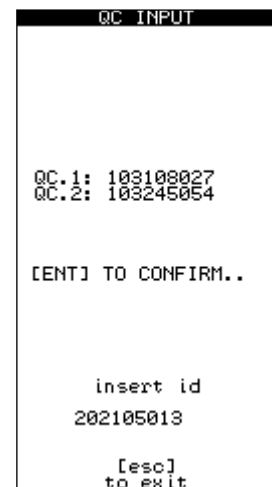


Figure 16

6.3.2 QC ID Sub-Menu Function (1)

Once the QC ID numbers for the QC controls are entered using Function 2 “QC INP”, the EXCYTE 20 is now ready to measure QC controls and store the results. To identify that a control is being measured, enter or scan the QC ID number using the QC ID, Function 1, before inserting the control samples into the instrument.

Entering or scanning the QC ID number will indicate to the EXCYTE 20 that the next sample placed in the instrument is a control sample. The QC ID number can be found on the package insert.

Control samples may be inserted in any channel as there are no specially assigned positions for the controls. When the control results are ready, the instrument will print the data and store the results in the QC memory. When the control samples are being analyzed, the individual channel display will show “C.” (see Figure 17).



Figure 17

⚠ CAUTION: ELITechGroup Inc. recommends using control solutions with known values for each test and running two levels of fresh controls 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.

6.3.3 QC ED Sub-Menu Function (3)

The calculated QC values are shown on the right side of the screen, and may be used to replace the theoretical values inserted at beginning of the lot. To adjust the theoretical values of the graph, press (3) to enter into QC ED.

The theoretical values are displayed to the left of the screen, while the instrument’s calculated values are display to the right of the screen. To replace the theoretical values with the new values, select the QC type (either 1 or 2), press enter, and then replace the MEAN and SD with new values. Once done, press ESC to exit the menu (see Figure 18).

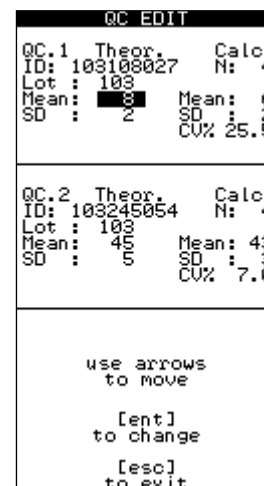


Figure 18

6.3.4 QC CH Sub-Menu Function (4)

This function allows the operator to view a Yuden Plot graph detailing the QC results over the last 30 days. Press 4 from the QC menu to display the graph (see Figure 19). To print, see Section 6.3.5.

6.3.5 QC PRT Sub-Menu Function (5)

To print a list of recent QC results, press 5 from the QC menu. The QC results will print.

6.3.6 QC DEL Sub-Menu Function (6)

To delete all of the QC data, press 6 from the QC menu. The operator will hear four short beeps, followed by the message shown in Figure 20. Press ENT to delete the data or press ESC to abort and exit the menu.

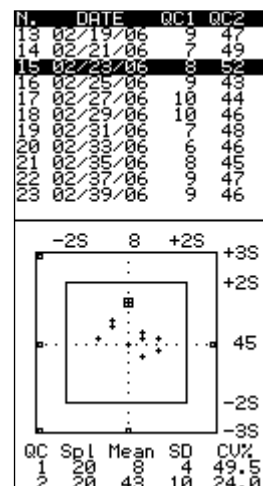


Figure 19

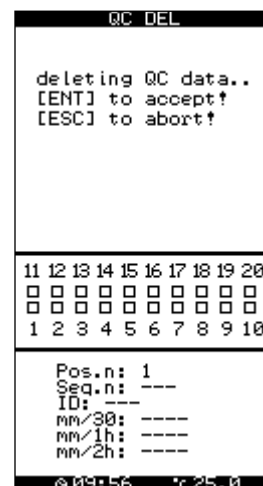


Figure 20

6.4. PRINT FUNCTION (4)

From the main menu, press 4 to enter the print menu. Using this command displays three options (see Figure 21).

6.4.1 W.LIST Sub-Menu Function (1)

The W.LIST enables the operator to retrieve a summary printout list of the samples currently being analyzed. Press 1 to print.

6.4.2 Memory Sub-Menu Function (2)

Pressing 2 prints out a list of all samples analyzed and held in memory.

6.4.3 Memory Range Sub-Menu Function (3)

Pressing 3 allows the user to enter a range of results to print from memory (see Figure 22). Insert the sample number to start from in the “From” field and press ENT. Insert the ending sample number in the “To” field and press ENT. Printing will start automatically. Pressing ESC without entering the From and To fields aborts the function.

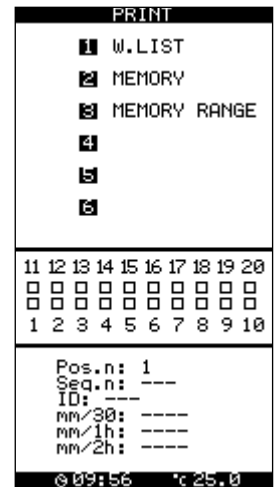


Figure 21

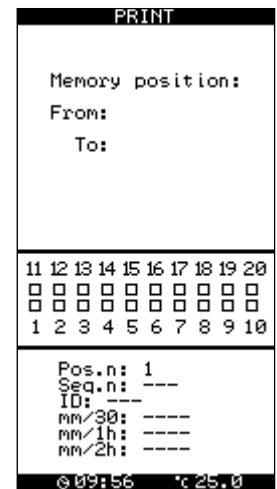


Figure 22

6.5. Host Function (5)

To transmit data, press 5 from the Main Menu. Press ENT to send the data, or ESC to exit the menu (Figure 23).

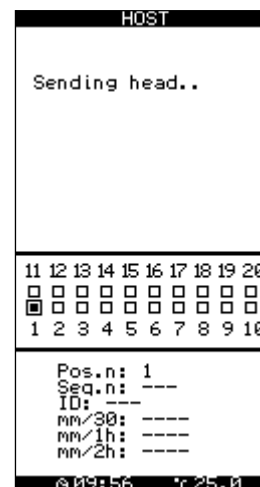


Figure 23

7. BRIEF OPERATING INSTRUCTIONS

7.1. Set up instrument.

- Connect the power supply.
- Insert paper in the internal printer.

7.2. Power On

- Turn the instrument on by pressing the switch located at the rear side of the instrument. The display will show free channels to insert samples as indicated by this symbol: [].

7.3. Sample insertion

choose from one of the following:

- Insert well-mixed sample into any free channel.
- Insert unmixed samples into free channels and close the cover to begin the mixing process.
- ID1: Scan the barcode and insert well-mixed sample into any free channel.
- ID1: Scan the barcode and insert sample into free channel. Close the cover to begin the mixing process.
- ID2: Scan the bar-coded samples in sequence or enter the ID's using the keyboard. Then insert well-mixed samples into any free channel.
- ID2: Scan the bar-coded samples in sequence or enter the ID's using the keyboard. Then insert samples into any free channel and close the cover to begin the mixing process.

7.4. Record Results and Remove Samples

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

- 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 the tubes. The [] symbol will appear, indicating that this position is free for introduction of next tube.

- Follow points 3 – 5 for additional samples.

7.5. Power Off

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

8. Westergren method

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 pillar 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 non 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, in a ratio of four to one (4-1). 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 minutes.

8.1. Reference Ranges For Normal ESR Values

The following table lists the reference ranges for normal ESR values for both males and females.

Normal ESR Values ³		
	Male	Female
After 1 hour mm	0 - 15	0 - 20

8.2. ESR in Disease States

ESR – 100 mm or more per hour

- | | |
|-----------------------------|--|
| Multiple myeloma | Waldenstrom macroglobulinemia |
| Internal hemorrhage | Etopic pregnancy |
| Acute hepatitis | Malignant lymphoma |
| Leukemia | Oral contraceptives |
| Serious anemia | Carcinomas |
| Menstruation | Serious bacterial infections |
| Sarcomas | Normal pregnancy after the third month |
| Collagenosis | Biliary or portal cirrhosis |
| Tuberculosis | Ulcerative colitis |
| Nephrosis | Dextran administration |
| Postcommissurotomy syndrome | |

ESR – Moderate increase

Acute and chronic contagious diseases

Acute localized infections

Reactivation of a chronic infection

Rheumatoid arthritis

Malignant tumor with necrosis

Hypothyroidism

Nephrosis

Rheumatic illness

Myocardial infarction

Hyperthyroidism

Lead or arsenic poisoning

ESR – Normal values

First stage acute appendicitis

Malarial paroxysm

Arthritis

Acute allergies

Peptic ulcer

Rheumatic carditis with cardiac decompensation

Whooping cough

Cirrhosis of the liver

Mononucleosis

Virus infections without complications

Typhoid fever

8.3. Principles 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 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.


9. OPERATING PROCEDURE

9.1. Sample Collection

Samples must be collected following the techniques shown in the **EXCYTE ESR Vacuum and Non-Vacuum** package inserts.

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) Temperature
- f) Time after sample-taking*
- g) Direct sunlight
- h) Foam
- i) Lipemic samples
- j) Tube inclination

 **CAUTION:** In accordance with the recommendations of the Clinical and Laboratory Standards Institute (CLSI)², blood samples collected in this manner 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, but must be brought to room temperature and mixed thoroughly prior to analysis.

9.2. Batch Mode With Sample Mixing

Sample Identification should follow the procedures outlined in Section 6.1.

To utilize onboard mixing, the EXCYTE 20 MIXER functionality must be set on YES. See Section 5.7 for instructions on MIXER settings.

Check the set-up menu to verify the MIXER is enabled. When the MIXER is enabled, the analyzer will detect the state of the cover position.

To initialize integrated sample mixing, simply close the plastic cover after samples have been inserted into the analyzer. Once the cover is closed, samples are automatically mixed for five minutes. Time remaining is shown on the screen during the mixing. When the mixing feature is used, samples are run in a batch mode.

When the MIXER is enabled, the cover position is detected by the analyzer. If the operator opens the cover, the instrument will automatically bypass the mixing procedure in order to avoid tubes being damaged which could interfere with the analyzer.

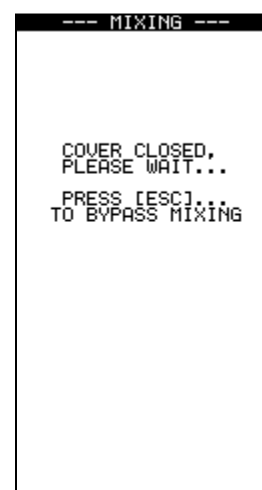


Figure 24

The mixing process can be bypassed when the cover is first closed. To bypass the mixing process, press ESC (Figure 24). A “Please Wait” message will appear while the analyzer resets itself (Figure 25).

If the operator bypasses the mixing procedure, a new message will be displayed.

This message will be displayed while the analyzer returns the reading plate to the position required to start the normal sample reading sequence. Once the reading plate is in the right position, the instrument will start to read the inserted samples.

This message will be displayed while the analyzer returns the reading plate to the position required to start the normal sample reading sequence. Once the reading plate is in the right position, the instrument will start to read the inserted samples.

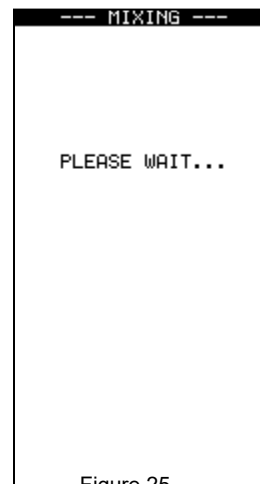


Figure 25

9.3. Random Mode

For sample identification, follow the instructions in Section 6.1.

There are two options to work in random mode:

9.4. Mixer Function Off

In this setting the cover position will not be detected by the instrument. If the operator closes the cover, the instrument won't start the mixing procedure. See Section 4.3.7 on how to set MIXER settings.

Due to MIXER option being disabled, samples should be correctly mixed prior to being introduced into the analyzer (Figure 26). It is recommended to follow a numerical sequence when loading samples into individual channels in the reading chamber.

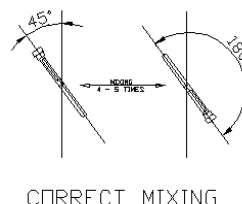


Figure 26

The analyzer will display the sample location into which the tube was placed when ID function 2 is selected. See Section 5.1 for more information related to ID function.

9.5. Mixer Function On

Samples can be run in Random mode when the MIXER function is selected. In order to run samples in Random mode with the MIXER function selected, the cover needs to remain open through the entire run of samples. As long as the cover remains open, every time a tube is inserted the instrument will begin the reading sequence. With the MIXER function selected, the cover position is detected by the analyzer. If the cover is closed, the instrument will start the mixing procedure as described in Section 9.5 and any analyses that were in process will be re-started once the mixing step has concluded.

Channel positions on the support plate are numbered from 1 to 20. Numbering is increased progressively in groups of 20 samples. When the analysis of the sample in channel number 1 is complete, a new sample inserted in channel 1 automatically becomes sample number 21, and so on.

After insertion of the twentieth sample, wait for the results of the first loaded sample. Once complete, remove the analyzed samples and insert new test tubes in these channels to continue the analysis.

After pre-mixing, the sample must be promptly transferred to the analyzer. It is recommended to follow a numerical

sequence while loading the channels. The operator can check the display for the proper location in which to put the new test tube, if ID function 2 is used.

9.6. Sample Removal

During the analysis, the display on the EXCYTE 20 shows the operative state of the instrument via time remaining symbol (see Section 9.6.1), and already concluded analysis. Before the final result is shown on the display, the operator is advised by two short beeps.

9.6.1 Symbol Description / Time Remaining

When a sample is being analyzed the display shows the status of testing. The symbols that show status are described below (Figure 27).

- 1 – Tube inserted, start time
- 2 – Tube inserted, ¼ complete
- 3 – Tube inserted, ½ complete
- 4 – Tube inserted, end time
- 5 – Empty position
- 6 – Position with ID, no tube
- 7 – Test finished (X)



Figure 27

9.6.2 Final Results

When the analysis is finished, the results are printed. The “X” symbol will remain on the display until the operator removes the corresponding test tube from the analyzer. After removing the tube, the displayed “X” 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.

10.TUBE LABELING

Sample information can be added to the ESR Tubes by writing relevant information on the label that is provided. If a barcode or other label will be applied to the tube, ensure that the label placement matches Figure 28. Incorrect label placement will affect the analyzer reading sequence.

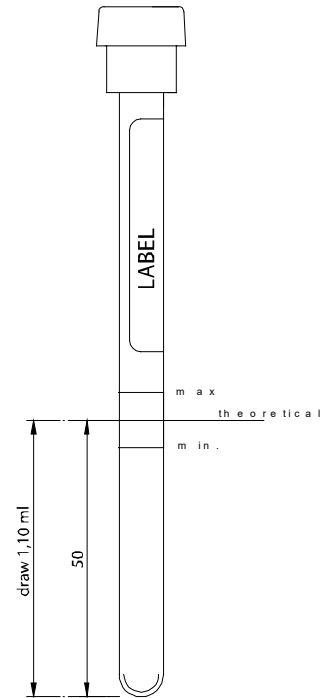


Figure 28

11. BARCODE CONFIGURATION

The instrument is supplied with a default barcode configuration that enables the reading of the most commonly used barcode label formats.

The barcode scanner manual, supplied with the instrument, can be used to enable or change configuration for other formats.

⚠ WARNING! Wrong configuration codes may lead to barcode scanner malfunction.

Use the barcode scanner to change settings.

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

Turn on the instrument, wait for the self-test to complete and then read all barcode labels on this page, from top to bottom.

The factory default configuration is automatically saved in the barcode scanner.

DEFAULTS



%%\$+/2

START



%%\$+/3

RS232



%00U8

FLASH



%0276

CR



%750+

ALL



%1A/+

END



%%\$+/4

SAVE



%%\$+/0

12. TEMPERATURE COMPENSATION

The results of the analyzer are correlated to the Westergren reference method, taking into account the ambient temperature of the testing area. The **EXCYTE 20** constantly measures the internal temperature and normalizes the values at the temperature of 18 °C, according to the Manley table (Figure 29). This automated temperature adjustment process guarantees better reproducibility when compared to instruments which provide results without temperature compensation.

Manley Table

correct values	-----Analysis Temperatures-----				
	18°C.	15°C.	18°C.	20°C.	25°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

Figure 29

The EXCYTE 20 converts results to an equivalent measurement at 18 °C if room temperature is within the range of 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.

13.ERROR DISPLAYS

13.1. Result Data Error

There is invalid data stored in memory. Contact Technical Support (Figure 30)

13.2. QC Data Error

There is invalid data within the QC memory. Contact Technical Support.

13.3. Check Printer

If the printer was enabled in the setup function, then the printer must be connected and ready to print. Check the printer connection, or turn off the printer in the setup function.

13.4. Check Host Connection

If the host option is enabled in the setup function, then the host system must be connected and ready to receive data. If this error message is received, check the host connection, or turn on hosting in the setup function.

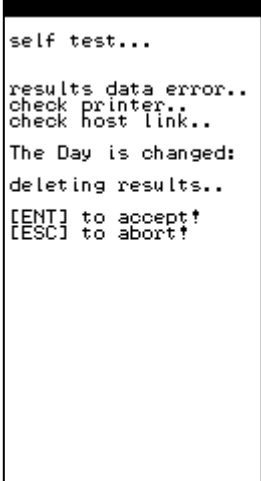
13.5. Error: System Stopped

This message will be displayed if the instrument is not functioning, and has completely stopped due to mechanical problems with the reading plate movements. Contact Technical Support.



```
ERROR: system stopped...
```

Figure 31



```
self test...  
  
results data error..  
check printer..  
check host link..  
  
The Day is changed:  
deleting results..  
  
[ENT] to accept!  
[ESC] to abort!
```

Figure 30

14.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 1-800-453-2725 (English) or at service_ebs@elitechgroup.com.

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

15. TECHNICAL SPECIFICATIONS

15.1. Instrument Specifications

Instrument Size:	Height 7 7/8", Width 12", Depth 12 13/64" (Height 200 mm, Width 330 mm, Depth 310 mm)
Weight:	11 lbs.
Software:	V 1.3
Instrument Power Rating:	3.5 A 12 Vdc
Input:	1.8 A 100 – 240 Vac, 50-60 Hz Class 1
	Output: 12 Vdc, 5.0 A LPS
Operating Conditions:	Temperature: 15 to 32 °C Relative humidity: 10% - 95% Altitude: up to 2,000 m
Transport and storage conditions	Temperature: -10 °C to 45 °C Relative humidity: 0% – 95%
Overvoltage:	Category II
Sound level:	< 80dbA
Pollution:	degree 2 For indoor use only
Tube type:	8 x 120 mm glass tubes; 9 x 120 mm plastic tubes
Reading channels:	20
Analysis time:	Option to select 15, 30 or 60 minute analysis time
Instrument run rate:	Maximum 40 tests/hour (30 minute working time) Maximum 80 tests/hour (15 minute working time)
Result units:	In Westergren mm/hr (by interpolation)
Temperature correction:	Automatic compensation referenced to 18 °C (Manley)
Measuring method:	Infrared beam
Reading resolution:	+/- 0.2 mm
Results resolution:	+/- 1 mm
Display:	GRAPHIC LCD with backlight
Connections:	RS232 for printer, host and barcode scanner

15.2. Performance Specifications

Real-time detection measuring points:	10 point intervals
Measuring range:	1 – 140 mm/hr
Graphic curve:	On printer and display
Short time analysis:	15 minutes
Mechanical/optical precision of detection:	+/- 0.2 mm
Automatic temperature correction to 18 °C.:	15 °C to 32 °C
Precision:	CV ≤ 10%

Within run precision (total precision)
30 minutes working time

	<i>Mean</i>	<i>1SD</i>	<i>CV</i>
Glass ESR tubes, Normal (n=150)	8.2 (9.2)	0.4 (1.7)	5.1% (18.3%)
Glass ESR tubes, Abnormal (n=150)	60.9 (59.7)	1.4 (2.6)	2.3% (4.4%)
Plastic ESR tubes, Normal (n=45)	7.2 (8.5)	0.4 (1.1)	6.2% (12.9%)
Plastic ESR tubes, Abnormal (n=45)	59.8 (72.7)	0.8 (6.6)	1.4% (9.1%)

Correlation:

We compared 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. Results were compared by least squares regression and the following statistics were obtained:

	<i>R value</i>	<i>n</i>	<i>Regression line</i>
Glass ESR tubes, 30 min. working time	0.979	98	$y = 0.97x + 2.50$
Glass ESR tubes, 15 min. working time	0.974	55	$y = 1.1405x - 0.6009$
Plastic ESR tubes 30 min. working time	0.988	66	$y = 0.850x - 1.692$
Plastic ESR tubes 15 min. working time	0.976	55	$y = 1.1603x - 0.7916$

15.3. Limitations


- Strongly lipemic or hemolytic samples may alter reading capability.
- Sedimentation rate values > 140 mm/h will be indicated with this mark: > 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
- Temperatures outside the given range will be accepted as 15°C minimum and 32°C maximum.
- 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.

15.4. Hardware Specifications

15.4.1 Power Supply Unit Specification

Input: 100 - 240 V, 50 - 60 Hz
Output: +12Vdc, 5.0A

 **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.

15.4.2 Power Connector Description

PIN	DIRECTION	NAME	DESCRIPTION
1	internal	+12V	Power supply 12Vdc, 5.0A
2	external	GND	Ground

15.4.3 Printer Connector Description

Instrument 9 pin female connector:

PIN	DIRECTION	NAME	DESCRIPTION
1	---	---	(Do not connect!)
2	---	---	(Do not connect!)
3	OUTPUT	TXD	Serial data output
4	OUTPUT	DTR	Data Terminal Ready
5	---	GND	Ground
6	---	---	(Do not connect!)
7	---	---	(Do not connect!)
8	INPUT	CTS	Clear to send
9	---	---	(Do not connect!)

16.HOST SPECIFICATIONS

16.1. Host Connector Description

Instrument 9 pin male connector:

PIN	DIRECTION	NAME	DESCRIPTION
1	---	---	(Do not connect!)
2	INPUT	RXD	Serial data input
3	OUTPUT	TXD	Serial data output
4	OUTPUT	DTR	Data Terminal Ready
5	---	GND	Ground
6	---	---	(Do not connect!)
7	---	---	(Do not connect!)
8	INPUT	CTS	Clear to send
9	---	---	(Do not connect!)

16.2. Barcode Connector Description

Instrument 9 pin male connector:

PIN	DIRECTION	NAME	DESCRIPTION
1	---	---	(Do not connect!)
2	INPUT	RXD	Serial data input
3	---	---	(Do not connect!)

4	OUTPUT	DTR	Data Terminal Ready
5	---	GND	Ground
6	---	---	(Do not connect!)
7	---	---	(Do not connect!)
8	---	---	(Do not connect!)
9	---	---	(Do not connect!)

16.3. Host Connection Specifications - Communications Protocol

EXAMPLE OF A CONNECTION TO A PC IBM COMPATIBLE COMPUTER

Note: Connectors are 9 pin female.

```

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

16.3.1 Host Connector Signals Description

1. Data format is: 9600 bps, 8 data bit, 1 stop bit, no parity, hardware protocol RTS-CTS.
2. In order to make this document clear the character tilde ("~") is used in place of a space (" ") when there is more of one space and spaces are important for data collection.
3. Control characters sent by the instrument are:
 - STX code (2 decimal) in this document, replaced by the string "[STX]";
 - ETX code (3 decimal) in this document, replaced by the string "[ETX]";

16.3.2 Host/Data Transmission" Request From Host Computer

The host computer could require data transmission by sending the character "?". Data transmission starts only if the operator is not using the instrument. If the instrument still executing a command menu, characters will not be transmitted.

16.3.3 Messages Sent In The Beginning

Instrument model: **"MODEL: xxxxxxxx V.X.X"**

Note: The model name and version of the software can be different.

Device configuration: **"MODE: 15' T.CORRECTION ON"**, **"MODE: 30' T.CORRECTION ON"** or **"MODE: 60' T.CORRECTION ON"**

NOTE: Values 15, 30 and 60 depend on the analysis time mode, respectively 15', 30' or 60'. The string "~T.CORRECTION ON" is transmitted only if the temperature correction is enabled.

Date and Time: "DATE: GG/MM/AAAA~~HH:MM"

Operating temperature: "TEMPERATURE: gg.rC"

where: gg.r is the operating temperature value with one decimal. Transmitted only if the temperature correction is enabled.

16.3.4 Message Sent For Any Result Stored In Memory And Transmitted Results

"sss pp cccccccccc mmmm 30mm 60mm"

where: sss = is the sequential sample number (~1 - 999).

pp = sample location identified by a number (from ~1 to 20).

ccccccccc = patient ID - code ("....." if not present).

mmmm = 30' analysis result whose values can be shown as:

"~~~0" sample under analysis.

"~LEV" if error level.

"~REM" if sample error.

"~mmm" mmm = result in millimeters. (on the right).

">140" result more than 140 millimeters.

30mm = 1h analysis result, whose values can be shown as:

"~~~0" sample under analysis.

"~~~~" if the result of mmmm is an error or the value is higher than >140.

"~mmm" mmm = result in millimeters. (on the right).

">140" result more than 140 millimeters.

60mm = 2h the result of the analysis can have the following values:

"~~~0" sample under analysis.

"~~~~" if the result of mmmm is an error or the value is higher than >140.

"~mmm" mmm = result in millimeters. (on the right).

">140" result more than 140 millimeters.

Note: the 60mm result is present only if the instrument works in mode: 60'.

"~~~~" is sent if the instrument works in mode: 30'.

16.3.5 Description Of The Data Frame

Any string of characters is transmitted with the following frame:

<STX>string<ETX>ECC

ECC represent the checksum used to detect if a string transmitted is defective. The checksum is encoded as two characters sent after the <ETX> character. The checksum is computed by adding the binary values of the characters in a string (modulo 256) and keeping the least significant 8 bits of the result. The 8 bits can be considered as two groups of 4 bits which are converted to ASCII and represented in hexadecimal format. The two ASCII characters are transmitted as the checksum with the most significant character first.

Using the following frame as an example, the checksum for this frame is calculated.

Example:

<STX>ABCDEFGHI<ETX>70

Character ASCII value

A	065	1 st character for calculation
B	066	2 nd
C	067	etc
D	068	etc
E	069	etc
F	070	etc
G	071	etc
H	072	etc
I	073	etc
<ETX>	003	etc

Total sum value = 624

Module 256 (624) is: 112

Then 112 (decimal) is 70 (hex) ECC is: **70**.

If ECC length is 1 character, the resultant ECC is adding a zero character (ASCII 48) on the left.

Example: First ECC: **A** The resultant ECC is **0A**

16.4. Interfacing Specifications

This document contains moderately complex technical information. The reader should have an intermediate level of knowledge in the following areas:

Computer systems
 Computer communications

This manual assumes that the users of Windows® systems have logged on as Administrator.

16.4.1 Basic Procedure

The basic procedure to setup an EXCYTE 20 and a host system is:

- a) Connect the two systems together
- b) Configure EXCYTE
- c) Configure host PC

16.4.2 Configuration

The EXCYTE 20 can be interfaced to an external computer system using a 9 pin serial cable. The EXCYTE 20 host settings can be configured in 3 modes, these are:

- 1 No
- 2 Yes
- 3 Auto

In Auto mode, the EXCYTE sends data when results are ready, or the host computer can request a data dump of the complete EXCYTE memory by sending a ? character to the EXCYTE. This request will be ignored if the EXCYTE is busy.

16.4.3 Hardware Configuration

The EXCYTE 20 can be interfaced to an external computer system with a 9 pin Serial cable. The cable configuration is:

Host Side	EXCYTE Side	
Pin	Pin	
2 -----	3	Both sides use female connectors.
3 -----	2	
4 -----	8	
8 -----	4	
5 -----	5	

Press 6 from the EXCYTE main menu and set the host to AUTO.

16.4.4 Software Configuration

The host system uses a standard PC serial COM port configured with the following settings:

- 9600 bits/second
- 8 Data bits
- N No Parity
- 1 Stop bit
- Hardware handshake (RTS-CTS)

The host system must be configured to read data in the format described in Section C.6. This is the responsibility of the customer or host PC vendor. The test procedure described in section 4 will verify that the EXCYTE is transmitting data to the host PC.

16.5. Troubleshooting

- If data is not displayed in the host PC application, check the application configuration with reference to section 5. The application **must** be able to accept data in the format of section 15.
- Check the interface cable by testing it with an ohm meter or using it with a system that is known to be working. This does not need to be an EXCYTE; it can be two computer systems.
- Try using a different COM port. Check and verify COM port settings and COM port properties in Windows device manager.
- Check EXCYTE settings.
- Verify communications and cable integrity by running HyperTerminal and interrogating the EXCYTE. This procedure is described below; example screenshots are for a Windows 2000 System. Other systems may differ slightly. The EXCYTE must be ON, and it must NOT be measuring samples.

This example uses COM1 on the host LIS system.

- Verify that the EXCYTE LIS host setting is AUTO (option 6 on the EXCYTE menu).

On the Host LIS:

Launch HyperTerminal by selecting:

START...PROGRAMS...
 ACCESSORIES...
 COMMUNICATIONS...
 HYPERTERMINAL (Figure 32)

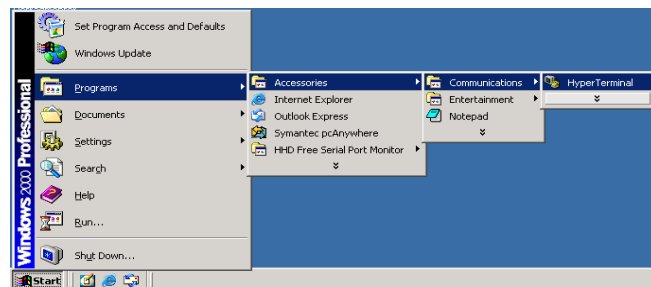


Figure 32

In the Connection description window, key in an appropriate name.

This example uses the name TEST.
 (Figure 33)

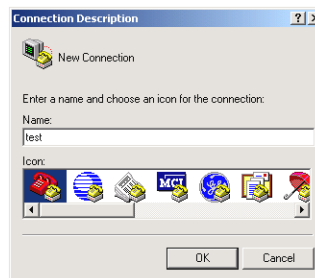


Figure 33
 Entering the name “test” in the connection description window

In the CONNECT TO window (Figure 34), select COM1 (or the COM Port connected to the EXCYTE).

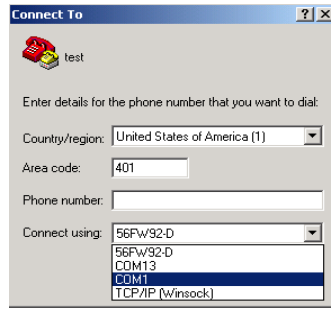


Figure 34
Selecting the COM Port

In the COM1 PROPERTIES window (Figure 35), select the following parameters:

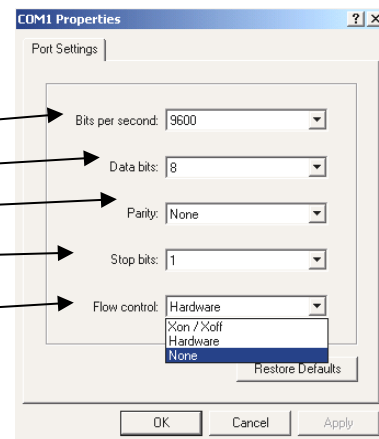
9600 bits/second

8 Data bits

No Parity

1 Stop bit

Flow Control

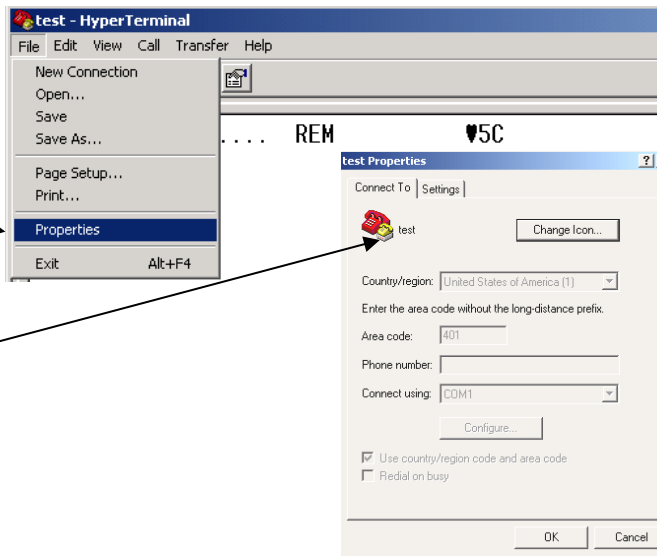


Select HARDWARE or NON if using a cable with CTS active. Click OK.

Figure 35
Selecting COM1 properties

In the HYPERTERMINAL window (Figure 36), Select

FILE...
PROPERTIES



In the PROPERTIES window, Select SETTINGS (Figure 37)

Figures 36 & 37
Setting Properties

In the SETTINGS window (Figure 38),
Select ASCII SETUP

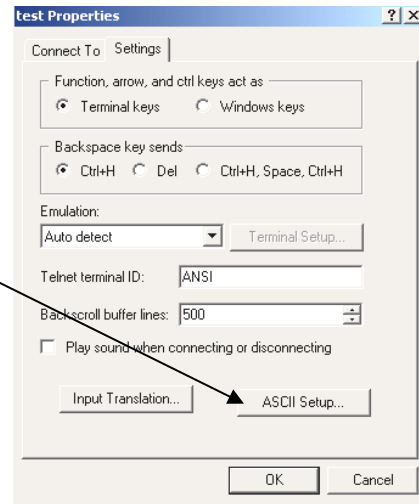


Figure 38
Selecting ASCII Properties

In the ASCII SETUP window (Figure 39), Select

ECHO TYPED CHARACTERS LOCALLY

set line and character delay

to >50mS (this example uses 100mS)

select Wrap lines that exceed terminal width

Click OK, Click OK again.

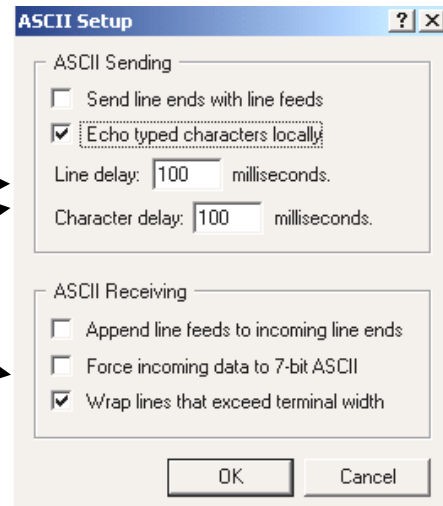


Figure 39
ASCII Setup

If this data is received by Hyperterminal, the EXCYTE is working correctly. If the LIS is not displaying the data, the problem is in the LIS configuration.

If the above data is not displayed, double check:

- Cable
- Ports
- EXCYTE Host LIS setting
- Hyperterminal settings

- Wait until the EXCYTE has transmitted all its data – the EXCYTE screen will return to the main menu screen when the data has been sent.
- Close Hyperterminal by clicking the close X at the top right of the Hyperterminal Window.

Click YES to the YOU ARE CURRENTLY CONNECTED ARE YOU SURE YOU WANT TO DISCONNECT NOW Prompt.

Click NO to the DO YOU WANT TO SAVE prompt.

16.6. Data Format & Example Data File

The data format sent out by the EXCYTE consists of the following format:

STX (message) ETX and a Checksum derived from (message) & ETX

16.6.2 Startup message

On startup, the EXCYTE transmits:

- The model number and version of software
- The device configuration – analysis time mode
- Date & time
- Operating temperature

Some of the above are optional and depend on instrument settings

The file shown in Figure 42 is an example transmission from the EXCYTE 20. For the first sample, the Sample ID number is 4037340, the sequence number is 2, 1, and the result is 62. **BOLD** = STX & ETX UNDERLINE = Checksum, Black = data

Grey = Next sample data.

Hex	ASCII
02 20 20 32 20 20 31 20 34 30 33 37 33 34 30 2E	. 2 1 4037340.
2E 2E 2E 2E 20 20 20 20 20 20 36 32 20 20 20 20 62
20 03 <u>31 39</u> 02 20 20 33 20 20 32 20 34 30 33 38	.19. 3 2 4038

EX-20614	Cable X20-10C01 - IR plate
EX-20611	Cable X20-10C02 - CPU-POWER
EX-20613	Cable X20-10C04 - X20 internal scanner
EX-20624	EXCYTE 20 keyboard layout "123-UP"
EX-20625	EXCYTE 20 keyboard layout 1234 violet
EX-20615	Power supply unit
EX-20601	LCD Display GM241230GNSWA-02 blue
EX-20631	Belt 1176 MXL
EX-20622	Label MXR-EL-ENCODER
EX-20616	Plexiglas cover for display ESR-40
EX-20620	Bottom panel
EX-20617	Plexiglas scanner protection
EX-20619	Printer cover
EX-20628	Back plastic panel
EX-20634	Paper roll support
EX-20629	EL 08 mm tube adapter plate nr.01-10
EX-20630	EL 08 mm tube adapter plate nr.11-20
EX-20609	MXR motor group kit for mixing movement
EX-20607	Crouzet motor 82924.0
EX-20610	Fan 12Vdc 60x60x25 assembled

**WARNING!**

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

17.4. Printer paper replacement

To replace the printer paper or to insert it for the first time, follow the steps below:

- 1) Remove the printer cover.
- 2) Remove the support for the printer paper from its lodging.
- 3) Remove the spacer from the end of the support.
- 4) If necessary, remove the empty paper roll.
- 5) Place the new paper roll on the support then replace the spacer.
- 6) Re-insert the support into its lodging so that the beginning of the paper roll is behind the support and pointing upward.
- 7) If analyzer is off, turn it on.
- 8) Bring the paper up to the opening just behind the padded roll under the printer.
- 9) Gently guide the paper into the opening until it catches. The printer will then automatically load the paper.
- 10) To advance the paper, push the CAN button on the keyboard. **Do not pull on the paper.**
- 11) Close the printer cover.

18. TROUBLESHOOTING

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

ERROR/ALARM	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	Sample has been removed	Re-insert sample
Temp. "T.ERR"	Temperature sensor malfunction	Call Technical Support
System stopped	Motor or mechanical defect	Call Technical Support
Data result is not printed	a) Printer setup turned off b) Printer cable c) Printer malfunction	a) Check setup and turn on b) Check cable c) Replace printer
Data results seem to be wrong	a) Sample clot b) Sample has foam c) Sample measured after 4 hours from sample collection d) Incorrect sample mixing	a) Repeat sample collection b) Re-mix gently c) Repeat sample collection and promptly process d) Follow mixing instructions found in Section 9.2
CCD Scanner does not read barcode	a) Scanner configuration wrong b) Driver board malfunction c) Scanner malfunction	a) Check setup and turn on b) Call Technical Support c) Call Technical Support
HOST communication failure	a) Host cable b) Configuration disabled	a) Check if cable is connected b) Check setup
Display background is dark	a) Power switch on? b) Power supply working? c) Internal problem	a) Switch power on b) Check power supply c) Call Technical Support
Memory error	Memory battery discharged	Call Technical Support
Keyboard malfunction	Keyboard broken	Call Technical Support
Clock error	Clock battery discharged	Call Technical Support

In case further technical assistance is required please complete the *Malfunction Report* and contact ELITechGroup Inc. Technical Support:

Phone: 1 (800) 453-2725
+1 (435) 752-6011

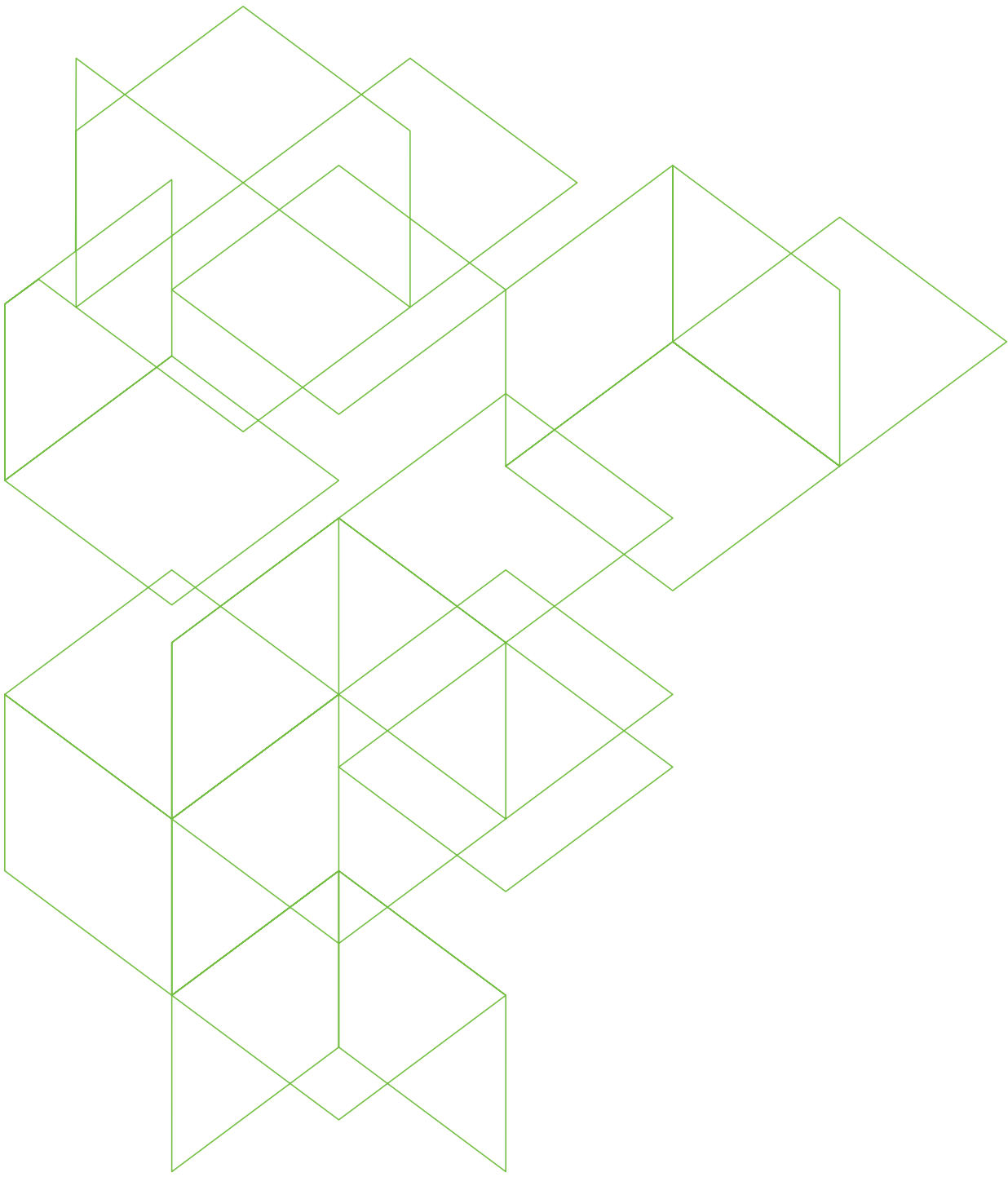
Email: service_ebs@elitechgroup.com

In case you want to return the instrument, please decontaminate it prior to shipment as prescribed in the Decontamination Instruction ESR Instruments document.

19. BIBLIOGRAPHY

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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