Mixrate-X20

USER'S MANUAL

Manual code MAN-053 – Revision 04
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CONTENTS

1. INTRODUCTION

Prior to operating the Mixrate-X20, carefully read the instructions in this manual for proper use of the instrument.

Mixrate-X20 has been designed to simplify ESR analysis, avoiding sample handling and reducing the operator's risk of infection. To perform the analysis, the operator simply places the sample in the instrument. The results are complete in 30 minutes, correlated to one (1) hour following the Westergren reference method. This feature allows the instrument to be used directly on the ward, in the blood sample collection department and in small laboratories.

Caution! Before installing and working with the **Mixrate-X20** analyzer, read this manual carefully and observe the safety precautions and regulations stated. Safety comes first!

The Mixrate-X20 was designed and manufactured to conform to various national and international standards and safety regulations. Possible known risks were eliminated or reduced. Nevertheless, all risk cannot be eliminated. When operating the Mixrate-X20, national guidelines and regulations must be observed, as in the normal lab routine. Power supply accessories (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. The user should be aware that if the Mixrate-X20 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
To assure proper instrument performance, Vital Diagnostics requires the use of Vital Diagnostics ESR Vacuum Tubes or ESR Non-Vacuum Tubes, and Precision-Rate Controls with this analytical system. 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. Vital Diagnostics assumes no responsibility for erroneous test results caused by disposable tubes or controls not supplied by Vital Diagnostics, or by inappropriate use.

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

1.1 Operator Qualification

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 with CLIA and local regulations.

1.2 Analytical Results

The 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.

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

Technical Service
Service to the instrument must be performed by local distributor service representative. Service provided by other person(s) will invalidate the warranty.

2. INTENDED USE

The MIX-Rate ESR analyzer is an automatic instrument for the analysis of the erythrocyte sedimentation rate. It constantly and simultaneously scans 10 test tubes which are custom-made for ESR analysis. The MIX-F follows the sedimentation of each sample independently, memorizing levels for the whole period of analysis.

3. IMPROPER USE

Following uses are considered improper:
1) Use of the device to obtain results different from ESR
2) Use tubes different from those specified in this manual
3) Every attempt to open tubes analyzed by the device
4) Use the device to analyze samples different from those specified
5) Every attempt to open the mixing panel when it's closed, or to block its movement

The above mentioned uses and every attempt to use the MIX-Rate X20 ESR analyzer with a purpose different from the intended use, must be considered improper.

4. INSTALLATION

4.1 Placement of the Analyzer

The Mixrate-X20 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 instrument is very sensitive to vibrations, which could cause a false increase of results.
The workbench must be flat and leveled.
Direct light on the instrument and sudden changes in temperature should be avoided.

4.2 Configuration

Mixrate-X20 will be supplied factory configured.

4.3 Power on

Connect power supply outlet to the instrument.
Insert the power supply plug into the electrical socket.
Once connected, turn on the Mixrate-X20 using the switch situated at the rear side of the instrument.

Each time the Mixrate-X20 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).

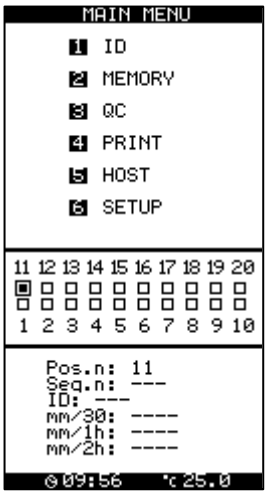


Figure 1

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

See Section 3, Functions for further details.

4.4 Setup: Main Menu - Function (6)

The operating parameters of the Mixrate-X20 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.

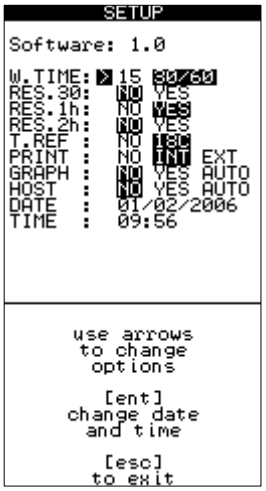


Figure 2

RESULT (Res. XX): The default factory setting of the Mixrate-X20 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. The coefficient of correlation at a 30 minute working time with the Westergren method is R=0.98.

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. The coefficient of correlation at 15 minutes working time with the Westergren method is less than R=0.92.

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

T REF: The Mixrate-X20 features an automatic adjustment of temperature related to the reference temperature of 18℃ in accordance with Manley (see Section 8, Temperature Compensation for further details). To change this setting, select No.

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.

GRAPH: To view the sedimentation graph (see Section 4.4), set Graph to either Yes or Auto. If Auto is set, the sedimentation graph will print with each result.

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.

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.

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

5. FUNCTIONS

5.1 Main Menu Function (1) ID: Samples Identification

After selecting (1) ID, the instrument shows two options (ID1 and ID2) to record the data (see Figure 4).

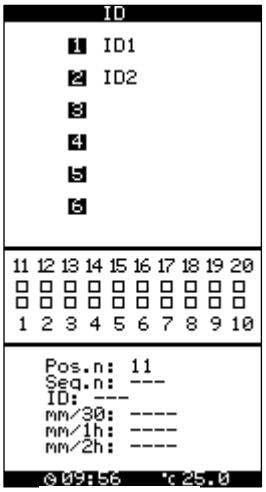


Figure 4

5.1.1 Samples Identification: Sub-Menu Function (1) ID1

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.

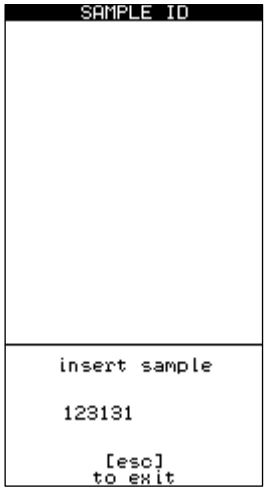


Figure 5

NOTE! If the keyboard is used to enter 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.

NOTE! The CCD scanner is made up of red LED's and emits visible red light that is not dangerous for the operator

After the barcode is accepted, the operator will be instructed to insert the tube into any open position (see Figure 5). 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 6).

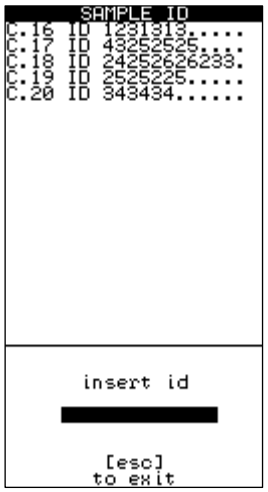


Figure 6

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 7). To exit the screen, press the [ESC] key.

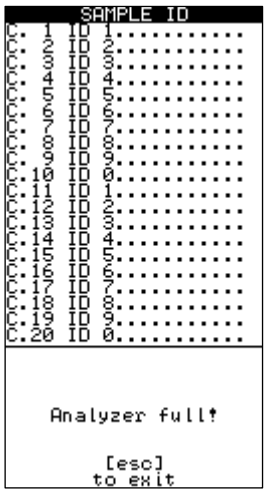


Figure 7

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 4.3).

5.1.2 Samples Identification: Sub Menu Function (2) ID2

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 4.3).

5.2 Memory: Main Menu Function (2) MEM

Up to 500 results can be stored in memory at one time, although the manufacturer recommends clearing 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 8). 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 9). Press CANC key to clear this message.

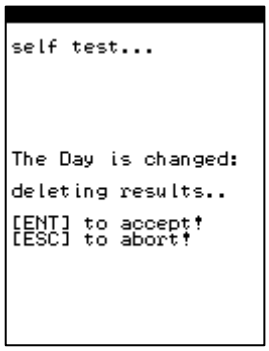


Figure 8

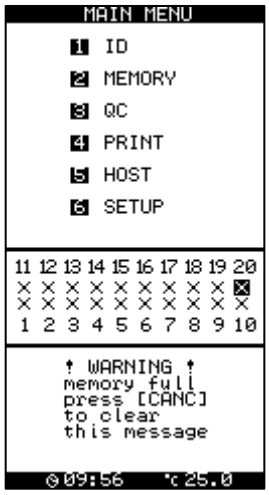


Figure 9

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

5.2.1 Memory: Sub-Menu Function (1) Clear

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 (see Figure 10). To continue, press ENT to accept, or press ESC to abort.

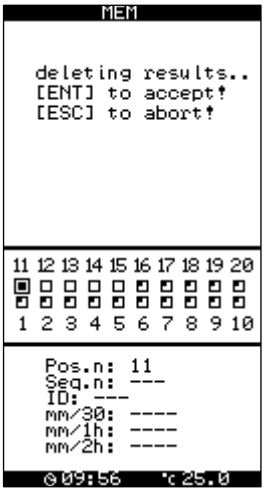


Figure 10

5.2.2 Memory: Sub-Menu Function (2) Edit

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 (see Figure 11).

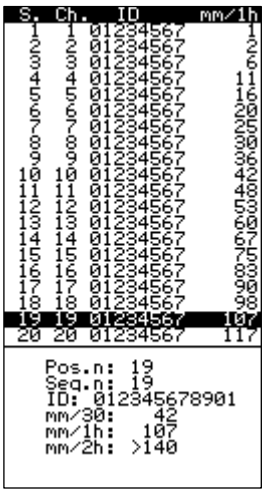


Figure 11

5.3 Quality Control: Main Menu Function (3) QC

The screen shown in Figure 12 will be displayed when Function 3 is pressed at the Main Menu.

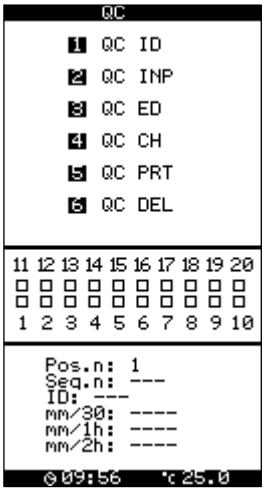


Figure 12

5.3.1 QC INP: Sub-Menu Function (2)

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

The lot number has a “checksum” character to ensure that it is entered correctly. Be certain to enter lot number exactly as written or the code will not be accepted.

When the new code is entered, a screen similar to Figure 13 will appear.

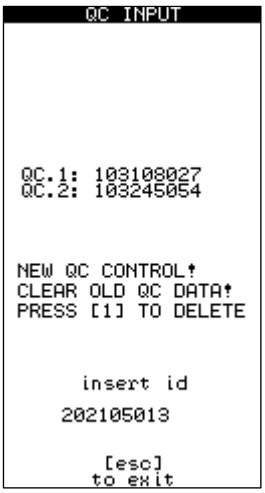


Figure 13

CAUTION! When a new code 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 14 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.

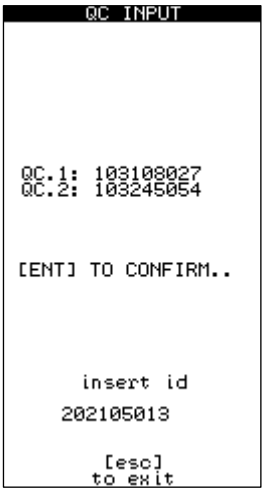


Figure 14

5.3.2 QC ID: Sub-Menu Function (1)

Once the lot numbers for the QC controls are entered using Function 2 “QC INP”, the Mixrate-X20 is now ready to measure QC controls and store the results. To identify that a control is being measured, enter the identification code using the QC ID, Function 1, before inserting the control samples into the instrument.

Entering the QC ID code will indicate to the Mixrate-X20 that the next sample placed in the instrument is a control sample. The QC identification code is the lot number found on the package insert.

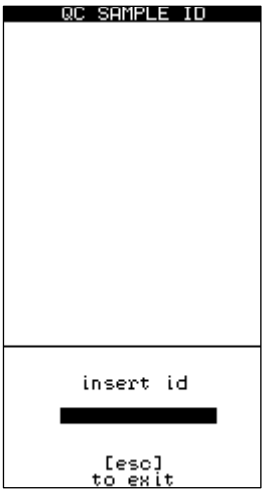


Figure 15

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 16).

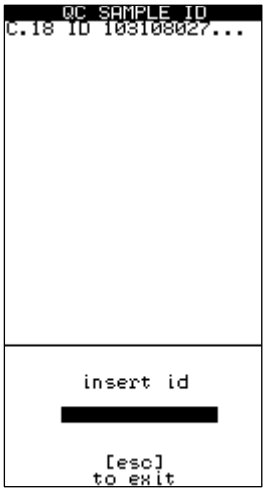


Figure 16

NOTE: Vital Diagnostics recommends using control solutions with known values for each test and running two levels 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.

5.3.3 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 17). To print, see Section 3.3.5.

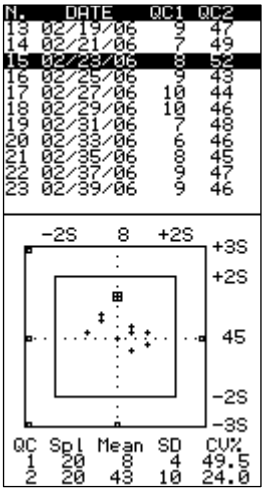


Figure 17

5.3.4 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).

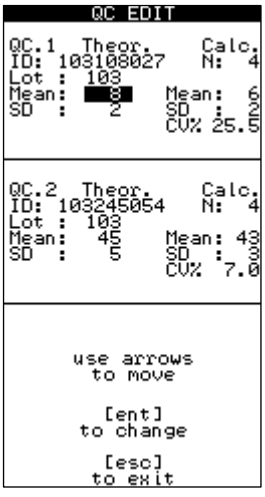


Figure 18

5.3.5 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.

5.3.6 QC DEL: Sub-Menu Function (6)

To delete all of the QC data, press 6 from the QC menu. The operator will hear four shorts beeps, followed by the message shown in Figure 19. Press ENT to delete the data, or press ESC to abort and exit the menu.

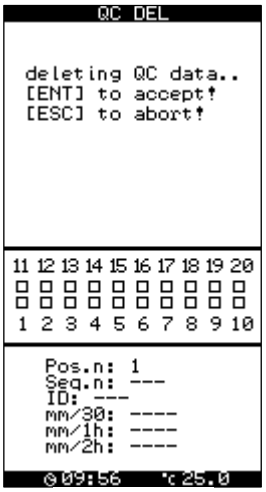


Figure 19

5.4 Printout: Function (4) Print

From the main menu, press 4 to enter the print menu. Using this command displays three options (see Figure 20).

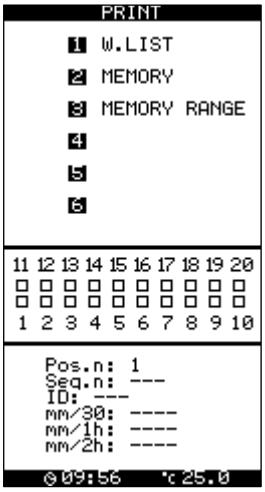


Figure 20

5.4.1 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.

5.4.2 Memory: Sub-Menu Function (2)

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

5.4.3 Memory Range: Sub-Menu Function (3)

Pressing 3 allows the user to enter a range of results to print from memory (see Figure 21). 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.

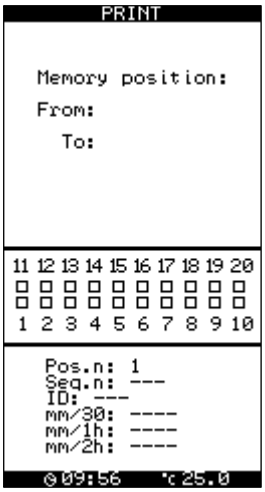


Figure 21

5.5 Host: Function (5) Host

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

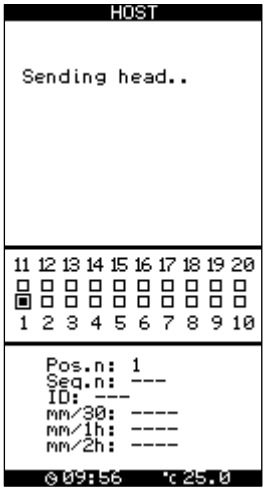


Figure 22

6. SYSTEM DESCRIPTION

6.1 Mixrate-X20 Analyzer

The Mixrate-X20 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 30 minutes, make the Mixrate-X20 an innovative and versatile system for this kind of analysis. It simultaneously scans 20 test tubes which are custom-made for ESR with this system.

Mixrate-X20 follows the sedimentation of each sample independently. The instrument can be used for random and continuous loading of samples to a capacity of 20 test tubes at a time. When a sample has been analyzed, it can be replaced by another, so it is possible to analyze up to 40 tests per hour.

Mixrate-X20 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 30 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 laboratories.

In performing the analysis, the Mixrate-X20 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.

6.2 Results in 15 minutes

Mixrate-X20 can be run in a 15 minute working time mode. If selected, results are displayed after 15 minutes, referenced to 1 hour Westergren. Results are correlated to a one hour value; results cannot be correlated to 30 minutes or 2 hours in the 15 minute working time mode. The coefficient of correlation at a 15 minutes working time referenced to the Westergren method is less than R=0.92.

6.3 Symbol Description

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)

6.4 Sedimentation graph

It is possible to monitor the state of the sedimentation by viewing the sedimentation graph (see Figure 23). 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 Section 2.4, Setup.

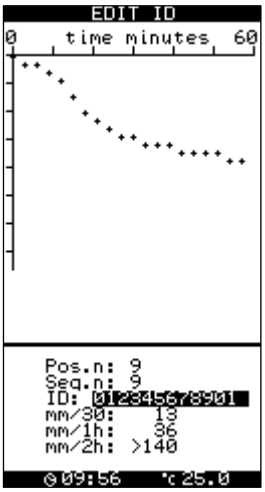


Figure 23

6.5 ESR Tubes

Specially designed vacuum and non-vacuum ESR measurement tubes supplied by Vital Diagnostics must be used to ensure accuracy of measurement for the Mixrate-X20. Both types of tubes contain sodium citrate at 3.8%. Vacuum tubes are made to draw 1.2 mL of blood. Refer to package insert for detailed instructions.

7. OPERATING PROCEDURE

7.1 Sample collection

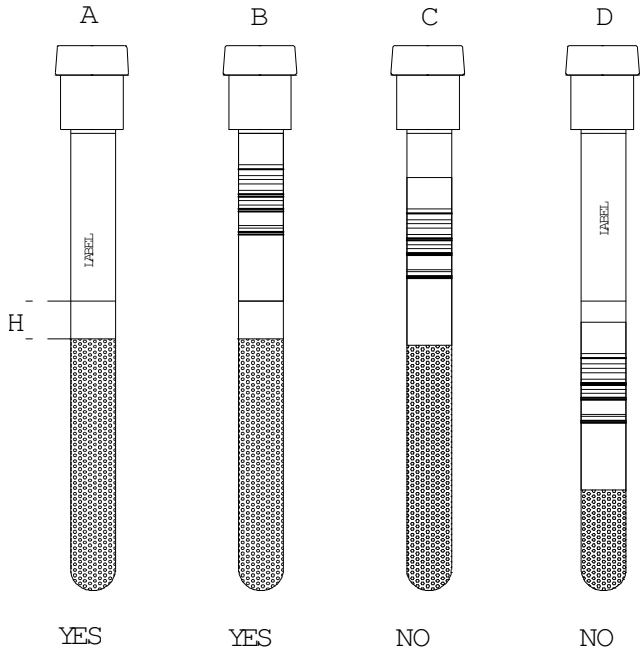
Samples must be collected following the techniques shown in the Vital Diagnostics ESR Vacuum and Non-Vacuum package inserts.

The following external factors can alter the ESR value after blood collection:
Dilution ratio
Bubbles
Strongly hemolyzed samples
Sudden agitation
Temperature
Time after sample-taking*
Direct sunlight
Foam
Lipemic samples
Tube inclination

*Time of test: In accordance with the recommendations of the International Committee for Standardization in Hematology (ICSH), blood samples collected in this manner should be tested within 4 hours if left at room temperature, or within 6 hours if stored at 4°C. Samples must be brought to room temperature prior to analysis.

7.2 Labeling

Identify the sample by writing on the original test tube label or by applying a bar code label.
Follow the scheme to carry out this action correctly. In the figure the test tube “A” has the correct blood level and the original label on which to write the patient code or any other relevant data if the bar code 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. The next test -tube “B” shows the correct position for the label. Test- tubes C and D illustrate how erroneous applications of the labels obstruct the reading of the analysis. If the Mixrate-X20 is installed in the surgery, the sample can be immediately analyzed by placing samples in a free position. Anyway the sample should be analyzed within three hours, paying attention to external agents shown below that might alter ESR in the pre-analysis phase.



7.3 Sample insertion batch mixing mode

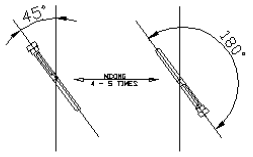
To initialize integrated sample mixing, simply close the plastic cover after samples have been inserted into the analyzer. Once the cover is closed, samples are automatically mixed for five minutes. Time remaining is shown on the screen during the mixing. When the mixing feature is used, samples are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

7.4 Sample insertion in random mode

For sample identification, follow the instructions in Section 3.1.
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.
For the random mode insertion, DO NOT CLOSE THE COVER. If the cover is closed, automatic mixing will start and analysis in process will be re-started from the beginning.

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

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.



CORRECT MIXING

7.5 Sample removal

During the analysis, the display on the Mixrate-X20 shows the operative state of the instrument, time remaining symbol (see Section 4.3), and already concluded analysis. Before the final result is shown on the display, the operator is advised by two short beeps.

7.6 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.

7.7 Brief Working Instructions

Set up instrument.
Connect the power supply.
Insert paper in the internal printer.
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 [ ].
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 samples into free channels. 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.
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. [ ] will appear, indicating that this position is free for introduction of next tube.
Follow points 3 – 5 for additional samples.

8. SAFETY MEASURES

8.1 User Precautions

Before using the analyzer, the operator must know the rules for handling potentially infectious materials and for handling the electro-mechanical systems.

8.2 Electrical equipment

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 personnel (Vital Diagnostics Service Technicians) may open the instrument to perform maintenance or repair.

8.3 Mechanical equipment

As a precaution, 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's damage. The operator can't be injured by the agitator, because the moving part is driven by a low power motor and the motor is via software controlled in order to stop its movement every time an external object/force blocks its movement.

8.4 Samples Analysis

All biological fluids must be considered potentially infectious by the operator. Even if it is not necessary to remove the cap during the analysis (and so there is no direct contact with blood), the operator must adopt the national and international standards of precautions to avoid the biological danger.

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 bloodborne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations (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.) in order to minimize risk to laboratory staff. This includes wearing of gloves, splash protection, etc. 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 of 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 disposalQualified technical operators must apply the same warning procedures for instrument maintenance.

8.5 Notes on safety measures

The operator must pay a special attention to the sample collection. 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 tubes manual to have more details.On the instrument, to assure a correct use of the instrument, may be placed the following symbols:

Attention: read use instruction

For in vitro diagnostic use only

ELECTROSTATIC DISCHARGE SENSITIVE DEVICE (ESDS):
The device could be damaged by electrostatic potentials

8.6 Residual Risks

Despite of the measures taken in the designing of the machine to guarantee a safe use of it, there might happen reasonably predictable occurrences, whose risk was possible to reduce, but not to eliminate completely.

RESIDUAL RISKS	PROTECTION MEASURES
Biological contamination	The operator must wear always gloves and protection glasses, as prescribed by laboratory regulations. Do not ever open 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 tubes breaking.
Mixing Panel stop	Do not try to stop the mixing panel. 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.

9. PERFORMANCE CRITERIA AND LIMITATIONS

9.1 Performance Criteria

Level sensor for correct blood draw 1.00 to 1.40 mL

Real-time detection measuring points: 10 point intervals

Measuring range: 1 – 140 mm/h

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 - 32°C.
(Manley table)

QC software for daily control of functionality

9.2 Limitations

Strongly lipemic or hemolytic samples may alter reading capability.
Sedimentation rate values > 140 mm/h will be indicated with this mark: > 140
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.

10. TEMPERATURE COMPENSATION

10.1 Results correction to 18°C

The results achieved are correlated to the method of reference, considering the room temperature. The Mixrate-X20 constantly measures the internal temperature and normalizes the values at the temperature of 18 degrees, according to the Manley table shown in (1) below. This process guarantees better reproducibility instead of instruments which perform results without temperature compensation.

(1) Manley Table

correct values ----------Analysis Temperatures----------

18°C.	15°C.	18°C.	20°C.	25°C.	30°C.
5	4	5	5	6	8
10	9	10	10	12	16
20	18	20	21	25	31
30	27	30	31	37	45
40	36	40	42	49	58
50	46	50	52	60	71
60	55	60	62	71	82
70	63	70	72	82	93
80	72	80	82	93	104
90	81	90	93	103	114
100	90	100	103	114	125

Mixrate-X20 converts the results to 18 degrees according to the table if room temperature is within the range 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.

11. MAINTENANCE

11.1 Maintenance

The Mixrate-X20 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.

11.2 Cleaning Instructions

Dust can be removed using an ordinary vacuum cleaner.

Please pay attention to the cleanliness of the test tube positioning plate. When not in use, the positioning plate must be covered with the Plexiglas cover. Do not clean the upper plate with liquids or damp cloths; the entry of liquids or solid material into the channels can cause considerable damage to the instrument.

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

12. ERROR DISPLAYS

12.1 Result Data Error

There is invalid data stored in memory. Contact Technical Support. (Figure 24)

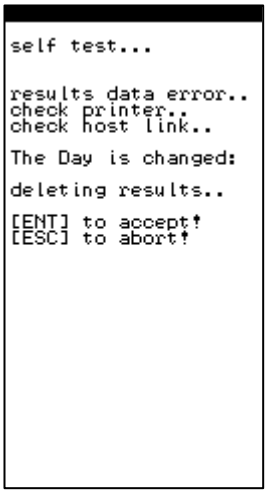


Figure 24

12.2 QC Data Error

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

12.3 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.

12.4 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.

12.5 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.

Figure 25

13. 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 5.3
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	Check if cable is connected 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

14. APPENDIX

14.1 Westergren Method

This is the selected method in accordance with the National Committee for Clinical Laboratory Standards (NCCLS). It consists of a support that keeps the Westergren tubes, containing anticoagulated 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 the ratio of respectively four to one (1.6 ml of blood + 0.4 ml of sodium citrate). The blood thus prepared and well mixed is drawn into a Westergren tube up to the zero mark. The tube is placed in the appropriate support and the erythrocyte level is read after 60 minutes.

14.2 Reference Ranges of Normal ESR Values

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

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

14.3 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
Rheumatic illness
Rheumatoid arthritis
Myocardial infarction
Malignant tumor with necrosis
Hyperthyroidism
Hypothyroidism
Lead or arsenic poisoning
Nephrosis

ESR – Normal values

First stage acute appendicitis
Whooping cough
Malarial paroxysm
Cirrhosis of the liver
Arthritis
Mononucleosis
Acute allergies
Virus infections without complications
Peptic ulcer
Typhoid fever
Rheumatic carditis with cardiac decompensation

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

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.

14.4 Hardware specifications

14.4.1 Power Supply Units Specification

Manufacturer: Dee Van Enterprises (DVE)
Model: DSA-0421S-12
Input: 100 - 240 Vac, 47 - 63 Hz
Output: +12Vdc, 3.5A

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

NOTE: 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.

14.4.2 Power Connector Description

PIN	DIRECTION	NAME	DESCRIPTION
1	internal	+12V	Power supply 12Vdc, 3.5A
2	external	GND	Ground

14.4.3 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!)

14.5 Host specifications

14.5.1 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!)

14.5.2 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!)

14.5.3 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

14.5.4 HOST CONNECTOR SIGNALS DESCRIPTION

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

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.

Control characters sent by the instrument is:

STX code (2 decimal) in this document, replaced by the string "[STX]";
ETX code (3 decimal) in this document, replaced by the string "[ETX]";

14.5.5 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.

14.5.6 MESSAGES SENT IN THE BEGINNING

Instrument model: "MODEL: xxxxxxxx V.1.0"

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.

14.5.7 MESSAGE SENT FOR ANY RESULT STORED IN MEMORY

"sss pp ccccccccccc mmmm 30mm 60mm"

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

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

ccccccccccc = 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 send, if the instrument works in mode: 30'.

14.5.8 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	1st character for calculation
B	066	2nd
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

14.6 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.

14.6.1 Basic Procedure

The basic procedure to setup an Mixrate-X20 and a host system is:

Connect the two systems together
Configure Mixrate-X20
Configure host PC

14.6.2 Configuration

The Mixrate-X20 can be interfaced to an external computer system using a 9 pin serial cable. The Mixrate-X20 host settings can be configured in 3 modes, these are:

No, Yes or Auto

In Auto mode, the Mixrate-X20 sends data when results are ready, or the host computer can request a data dump of the complete Mixrate-X20 memory by sending a ? character to the Mixrate-X20. This request will be ignored if the Mixrate-X20 is busy.

14.6.3 Hardware Configuration

The Mixrate-X20 can be interfaced to an external computer system with a 9 pin Serial cable. The cable configuration is:

Host Side Pin	Mixrate-X20 Side Pin	
2	3	Both sides use female connectors.
3	2	
4	8	
8	4	
5	5	

Press 6 from the Mixrate-X20 main menu and set the host to AUTO.

14.6.4 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 Mixrate-X20 is transmitting data to the host PC.

14.7 Data format & example data file

5.1 The data format sent out by the Mixrate-X20 consists of the following format:

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

5.2 Startup message:

On startup, the Mixrate-X20 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.

5.3 The file shown in FIG 34 is an example transmission from the Mixrate-X20. 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 31 39 02 20 20 33 20 20 32 20 34 30 33 38	.19. 3 2 4038
30 32 31 30 31 2E 2E 2E 20 20 20 20 20 20 20 37	02101... 7
20 20 20 20 20 03 30 43 02 20 20 34 20 32 34 20	.0C. 4 24
34 30 33 38 32 37 33 2E 2E 2E 2E 2E 20 20 20 20	4038273.....
20 20 20 37 20 20 20 20 20 03 32 35	7 .25

Fig 26 Sample Transmission

5.4 Checksum calculation
In the example of FIG 34, the checksum is 31 39. This is derived by:

Adding all the hex data in the data frame between ETX and STX, including ETX but not STX. This is equal to 0519 hex.

The least significant byte from 0519 is 19, the ASCII equivalent of these digits is 31 39 – the check sum data.

5.5 Host participation
IMPORTANT: There is no host intervention in the communication protocol. If the host finds the checksum does not match the data, the only thing the host can do is to request the Mixrate-X20 resend data by sending a “?” character.

15. INTERNAL BARCODE SCANNER DEFAULT 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. Use the barcode scanner to change settings.

Caution! Wrong configuration codes may lead to barcode scanner malfunction.

In case of reading problems, this page can be used to reset the scanner to the 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 configuration is automatically saved in the barcode scanner.

DEFAULTS

START

RS232

FLASH

CR

ALL

END

SAVE

16. TECHNICAL SPECIFICATIONS

Area of application:	Erythrocyte sedimentation rate analysis
Operating Conditions:	15° - 32°C room temperature Humidity: 45% - 85%
Tube employed:	Special 8 x 120 mm tubes
Reading channels:	20
Analysis time:	15, 30 or 60 minutes
Analytical capacity:	Maximum 40 tests/hour (30 minute working time) Maximum 80 tests/hour (15 minute working time)
Loading capacity:	Maximum 20 samples at a time
Loading pattern:	Random
Results:	In Westergren mm/h (by interpolation)
Temperature correction:	Automatic compensation referenced to 18°(Manley)
Measuring method:	Infrared beam
Reading resolution:	+/- 0.2 mm
Results resolution:	+/- 1 mm
Acceptable blood draw level:	0.90 to 1.20 ml
Display:	GRAPHIC LCD with backlight
Interface:	RS232 for printer, host and barcode scanner
Instrument size:	Height 200 mm Width 330 mm Depth 310 mm
Weight:	about 5 kg
Voltage:	External power supply: 100 - 240 Vac, 47 - 63 Hz 12 Vdc, 3.5A

17. EC DECLARATION

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE Dispositivi Medico-Diagnostici In Vitro
conforme all'Allegato II della Direttiva 2006/42/CE Direttiva Macchine
according to Annex III of the Directive 98/79/CE In Vitro Diagnostic Medical Devices
according to Annex II of the Directive 2006/42/CE

fabbricante *manufacturer*	**Vital Diagnostics S.r.l.**
indirizzo *address*	Via Balzella 41/G/4 47100 FORLI' ITALIA
telefono *phone* 0039 0543 721220	fax *fax* 0039 0543 796001
Identificazione dei prodotti *Product identification*	**Analizzatore Automatico della VES** ***ESR Automated Analyzer***
Nome commerciale *Brand name*	**Mixrate-X20**
Numero/i di catalogo *Part number/s*	**PRD-X20-EL-08TKN**
classificazione dei prodotti *product identification*	dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE *devices other then those mentioned in Annex II of the Directive 98/79/EC*

Si dichiara sotto la propria responsabilità che
i dispositivi sopraelencati rispettano le disposizioni applicabili delle seguenti direttive:

Hereby we declare under our sole responsibility that
the above mentioned devices meet the applicable provisions of the following Directives:

Direttiva 98/79/CE
Direttiva 2006/42/CE
Direttiva 2004/108/CE (Compatibilità Elettromagnetica)
Direttiva 2006/95/CE (Bassa Tensione)
Direttiva 2002/96/CE e 2003/108/CE (RAEE)
Direttiva 2002/95/CE (RoHs)

Tutta la documentazione tecnica comprovante il rispetto dei requisiti applicabili delle Direttive elencate, è conservata a cura del Fabbricante

All the technical documents required to demonstrate the conformity to the listed Directives, are kept by the Manufacturer

luogo e data *place and date*	Forlì, 11/03/2008	anno di immissione in commercio *year of introduction on the market*	2006
firma *signature* timbro della Società			

CE

18. DISPOSAL AND RECYCLING

Herewith we declare that this instrument is subject to the European Directive 2002/96/EC (RAEE Directive).
Therefore the instrument must be disposed separately, not as urban waste and delivered to the specific collection center in according to the Directive 2002/96/EC.
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 can not be disposed as urban waste.