miniSED®

Automated Erythrocyte Sedimentation Rate Analyzer

OPERATOR'S MANUAL & INSTRUCTIONS FOR USE

ALCOR SCIENTIFIC

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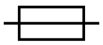
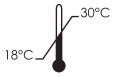
Symbol Reference

The following is a list of symbols and their meaning used on the instrument, consumables, and accessory labeling.

Symbol	Meaning
CE	Instrument satisfies requirements of European directive on in vitro diagnostic medical devices (98/79/EC)
	Date of Manufacture
	Manufacturer
SN	Serial Number
IVD	In Vitro Diagnostic Medical Device
REF	Product/Reference Number
	Fuse Rating (located on serial number label, replace with same value and type)
	AC Single Phase Alternating Current
	Consult instructions – Refer operator to the instruction manual for additional information
	Temperature limitation – Indicates storage requirements range
	WEEE: Disposal of Waste Electrical and Electronic Equipment
	**Biological Hazard:** Universal Precautions Should be Followed
	**Caution:** Moving Parts
	**Caution:** Sharp Needle
	**Warning:** Consult Operator Manual and Observe Safety Warnings
	**Caution:** May Cause Electrical Shock
	**Caution:** Object is Heavy – Use care and/or assistance in lifting

Notes, Precautions, Warnings, and Biological Warnings: Interpretation Guide

The Instructions for Use include information and warnings. These need to be observed by the operator to ensure safe operation of the instrument. There are 4 types of messages: Notes, Cautions, Warnings, and Biological Warnings.

Notes

NOTE: Highlights important facts, gives helpful information and tips, and clarifies procedures.

Cautions

CAUTION: Electrical caution! Unplug before handling.

CAUTION: Important information on the proper operation of the instrument. This information is crucial in preventing instrument damage and maintaining the system.

Warnings

WARNING: Identifies potentially hazardous situations that could result in serious injury to laboratory personnel.

Biological Warnings

WARNING: Universal precautions should be followed. Always wear gloves to prevent exposure to pathogens.

Precautions and Safety Information

Please pay close attention to the instructions, notes and symbols as well as the standard laboratory practices outlined by your facility and local regulatory agencies.

Always keep a distance of at least 4 inches (10 cm) between the rear of the instrument and the wall to allow for proper ventilation.

Do not use power frequencies or voltage other than those specified in this document. Connection to an inappropriate power source may cause injury or fire.

Do not disassemble or modify the instrument. Doing so may cause injury and/or instrument malfunction and void the warranty.

Place the instrument on a stable and level surface free of vibration. Failure to do so may cause injury or malfunction of the unit.

CAUTION: To reduce the risk of electrical shock, do not remove any panel unless under the direction of qualified personnel.

Do not block any ventilation openings.

Do not place instrument in water.

Do not drop or throw the instrument.

Operate the instrument on a dry, level surface.

Do not move the instrument while specimens are processing.

Plug the instrument into a grounded power source.

Tubes must be tightly capped prior to loading them onto miniiSED.

WARNING: For continued protection against risk of fire and hazard, replace fuse only with the same type and rating fuse.

WARNING: The instrument's main power entry port is used as the main disconnect device.

WARNING: Observe Universal Precautions. Discard contaminated materials according to applicable regulations.

Contents

1. Intended Use

miniiSED Erythrocyte Sedimentation Rate Analyzer is an automated in vitro diagnostic (IVD) device for the determination of an erythrocyte sedimentation rate (ESR) expressed in mm/hr. Testing is performed using EDTA whole blood samples obtained by venipuncture or capillary blood collection. The analyzer is intended to be used in a professional clinical laboratory setting. The analyzer directly measures the aggregation of red blood cells by photometric rheology technology which does not require the use of reagents. Results are reported in units of mm/hr and correlate with the Westergren method of ESR determination. The quantitative results for sedimentation rate produced by the analyzer are considered non-specific and are used by a clinician to aid in assessing the general health status of a patient. Results from the device are to be used in conjunction with other laboratory results and with the patient condition known by the ordering clinician.

2. Methodology

2.1 History

In 1897, Polish physician Edmund Faustyn Biernacki (1866–1911) was the first to observe the phenomenon of erythrocyte sedimentation. He discovered that blood sedimentation rates varied between different individuals, the number of cells affected sedimentation, and blood sedimentation rate directly correlated to levels of plasma fibrinogen. The findings presented by Biernacki clearly showed the clinical significance of ESR.

In 1921, Swedish internist Alf Vilhelm Albertsson Westergren (1891–1968) presented a similar description of ESR as those given by Biernacki and Swedish hematologist Robert Sanno Fåhraeus (1888–1968). Westergren defined the standard measurement of the ESR test to which nearly all automated ESR analyzers are referenced today. The traditional Westergren method of ESR testing, still considered the gold standard for ESR testing, uses a standardized tube and assesses the degree of gravity-based blood sedimentation after a period of 60 minutes.[1, 2, 3]

2.2 Principle of Procedure

ESR is a simple non-specific screening test that indirectly measures the presence of inflammation in the body. It reflects the tendency of red blood cells (RBCs) to settle more rapidly in some disease states, usually because of increases in plasma fibrinogen, immunoglobulins, and other acute-phaseproteins. Changes in red cell shape or numbers may also affect ESR.[4]

With the traditional Westergren method of ESR testing (to which miniiSED is correlated), anticoagulated whole blood is allowed to stand in a narrow vertical tube (known as a Westergren tube) for a period of 60 minutes, and the RBCs settle out from the plasma. The rate at which they settle is measured as the number of millimeters of clear plasma present at the top of the column after 1 hour (mm/hr). The RBCs come together to form aggregates known as rouleaux, and these aggregates sediment because their density is greater than that of the surrounding plasma.[1] Rouleaux formation is determined largely by increased levels of plasma fibrinogen and globulins, so ESR mainly reflects changes in the plasma proteins that accompany inflammatory disease states such as infections, some cancers, rheumatoid arthritis and other autoimmune diseases, kidney disease, and inflammatory bowel disease among others.[5] In these disease states, ESR values are typically elevated. ESR can denote the presence of tissue damage or disease but not the severity. ESR may also be used to help monitor disease progression or the effectiveness of treatment.

While the traditional Westergren method relies on gravity-based RBC sedimentation, the miniiSED analyzer uses photometric rheology technology to measure RBC aggregation during rouleaux formation. Rouleaux formation occurs during the earliest phase of the erythrocyte sedimentation process, and the aggregation of RBCs during the rouleaux formation ultimately determines the length at which the red cells sediment in the Westergren tube.

The technical innovation of the miniiSED analyzer consists of directly measuring the aggregation of the RBCs, while gravity-based ESR methods indirectly measure the aggregation of the RBCs by recording the length at which the red cells settle in a Westergren tube.

> **NOTE:** ESR is a nonspecific result. It is highly recommended to use ESR results in conjunction with other laboratory tests and patient history.

3. General Information

Read this manual carefully prior to operating the instrument.

This document is the Instructions For Use for the instrument. It is intended to explain the instrument operation in detail and can be used as a basis for training new operators. It is an information guide and troubleshooting reference. Retain this manual for future use.

3.1 For In Vitro Diagnostic Use Only

3.2 Sample Requirements

- Whole blood collected in a capped 13 x 75 mm tube with K3-EDTA or K2-EDTA anti-coagulant (lavender top tube) must be used
- Sample tube MUST have a pierceable cap/stopper and only be run on miniiSED when tightly capped
- Sample volume for testing is approximately 500 µL whole blood (only 100 µL of sample volume is aspirated)
  - If using false bottom/pediatric tubes, sample volume is approximately 350 µL (see note below)
- Sample should be free of clots and not grossly hemolyzed or lipemic upon visual inspection (DO NOT mix vigorously!)
- Sample should be tested within 28 hours from venipuncture when stored at room temperature (18-25°C) and within 48 hours if stored refrigerated (4-8°C)
- If sample has been refrigerated, sample must be brought to room temperature for at least 15 minutes before testing

NOTE: To ensure accurate results patient samples must be well mixed prior to testing. If automated mixing is not available (or enabled) on the analyzer, samples must be mixed manually or by mechanical rocker for a minimum of 3 minutes before testing. Testing should occur immediately after mixing to ensure accuracy of the results.

NOTE: The sample tube is inverted within the instrument while the sample is aspirated, therefore the total testing volume is larger than the aspirated volume, and total volume required to perform a test varies by tube make/model. Contact ALCOR Scientific Technical Support for the most updated information on specific sample tube compatibility.

NOTE: The instrument requires no additional or special sample preparation. As with all anticoagulant collection tubes, the sample should be well mixed after collection to help avoid clotting or other aggregates that may alter ESR test results.

NOTE: Although infrequent, a small amount of sample (<50 µL) may be needed for priming the system in addition to the 100 µL aspirated sample volume.

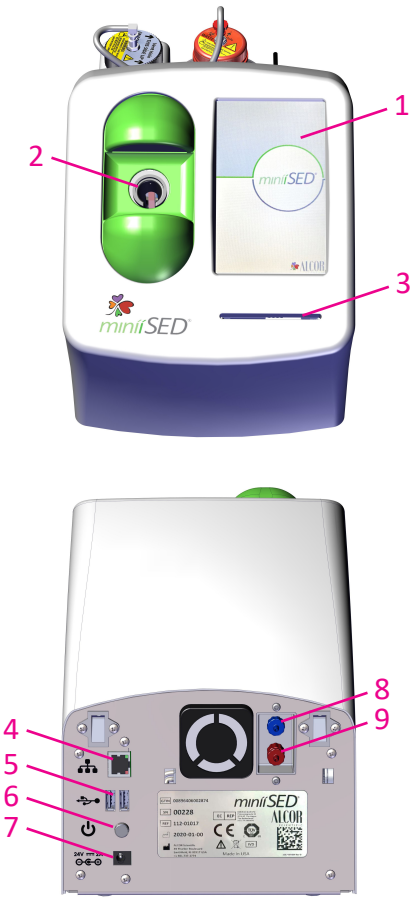
WARNING: Do not run sample if tube cap/stopper is missing. Use only tightly capped samples.

4. Instrument Overview

The miniiSED analyzer is a compact automated ESR analyzer for processing single samples. Capped whole blood EDTA samples can either be mixed prior to insertion into the analyzer via a mechanical rocker, or the user can opt to activate onboard mixing depending on workflow preference. miniiSED automatically scans the sample ID via an onboard barcode scanner, aspirates the sample, and analyzes the sample before returning the sample tube to the Loading Port. Results can be automatically transmitted to the LIS or manually exported.

miniiSED uses photometric rheology to monitor light transmission through a whole blood sample after the RBCs have been disaggregated. This produces a signal that is a direct representation of RBC aggregation. As RBCs aggregate in the rouleaux formation, light transmission through the sample increases. The greater the RBC aggregation, the greater the change in light transmission. The analyzer's micro-flow cell captures the critical kinetics of RBC aggregation in a highly controlled testing environment which helps reduce the impact of environmental factors that can contribute to result variability. The analyzer is designed to sample directly from capped, primary EDTA blood collection tubes and produce an ESR result in 15 seconds after appropriate homogenization. Results are reported in units of mm/hr, and miniiSED performance is correlated to the Westergren ESR method.

4.1 Parts Identification



1	Touch Screen
2	Sample Loading Port
3	Smart Card Reader
4	Ethernet Connection Port
5	USB Connection Ports (2)
6	On/Off Switch
7	Power Connection Port (24VDC, 2A)
8	miniiWASH® Connection Port (Blue)
9	miniiWASTE® Connection Port (Red)

4.2 Consumables

Consumables can be purchased by contacting ALCOR Scientific Customer Service Department or your local authorized ALCOR Scientific distributor.

Item	Description	Configuration	Reference Number
iSED® Test Card	Preloaded Test Card with Test Credits available with tests in various quantities	250 Test Credits	112-00250
		1,000 Test Credits	112-01000
		2,000 Test Credits	112-02000
		5,000 Test Credits	112-05000
miniiWASH Wash Fluid (4 pack)	250 mL bottle with screw cap, pre-filled with wash fluid	4 x 250 mL	112-12-003
miniiWASTE Waste Container (4 pack)	Waste bottle with screw cap	4 x 300 mL	112-12-004
deepCLEAN® Cleaning Solution	Sodium hypochlorite solution for the Deep Cleaning procedure	3 x 2.0 mL	112-12-020
SEDiTROL® Quality Control, Levels 1 & 2	Human red cell-based, bi-level, external controls for the iSED family of analyzers	1 x set of 2 tubes	DSC01
		3 x sets of 2 tubes	DSC06
ALCOR Thermal Printer	External thermal printer	1 each	DS-05240
ALCOR Thermal Printer Paper	Paper for the ALCOR Thermal Printer	5 pack	DS-05233

NOTE: Only use consumables that are within their expiration date.

NOTE: Use of any other product could affect the performance of the instrument and will void the warranty.

4.3 Continuous Operation Mode

It is recommended that the instrument always remain on and ready for use. Should the instrument need to be powered off for any reason, the On/Off Switch on the back of the instrument shall be used.

NOTE: The instrument is programmed to perform self-cleaning after being idle for 15 minutes following the last sample tested. The process takes approximately 1 minute and utilizes approximately 2.5 mL of miniiWASH for each wash cycle. Once completed, testing can resume as normal.

5. Unpacking and Installation

It is recommended that the instrument always remain on and ready for use. Should the instrument need to be powered off for any reason, the On/Off Switch on the back of the instrument shall be use

CAUTION: The instrument weighs approximately 10 lbs. Use safe lifting techniques when handling heavy objects. If necessary, obtain assistance to safely lift the instrument.

CAUTION: If using a utility knife, extend the blade to appropriate length to avoid cutting internal components.

5.1 Unpacking the Instrument

Inspect the shipping container for any obvious signs of mishandling or shipping damage. If damage is found, retain all package materials and immediately file a claim with your shipping carrier.

1. Position the box upright and open the top flaps (Figure 1).
2. Remove the Power Supply and set aside (Figure 2).
3. Remove the miniiWASH and miniiWASTE Bottles and Bottle Tray and set aside (Figure 2).
4. Rotate the box on its side (Figure 3).
5. Slowly slide the instrument and surrounding foam out of the box using the brown tube found between the foam panels (Figure 3).
6. Remove the Accessory Bag and set aside (Figure 3).
7. Remove the foam panels from the sides of the instrument (Figure 4).
8. Place the instrument on a secure, flat surface.
9. Remove the instrument from the protective bag.
10. Save the box and foam pieces for future use.

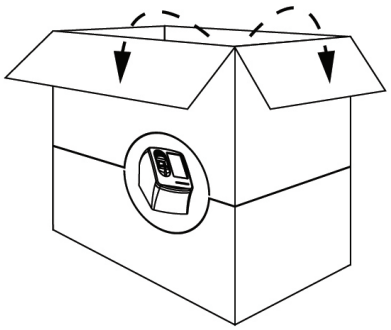


Figure 1

5.2 Contents of the Box

Refer to Figure 4.

a. miniiSED analyzer (1)
b. Power Supply (1)
c. Accessory Bag (1), containing:
   - Power cord (1)
   - miniiWASH connection tube (blue) and miniiWASH Bottle Cap (1 each)
   - miniiWASTE connection tube (red) and miniiWASTE Bottle Cap (1 each)
   - Warranty and Quick Start Guide (1 each)
d. Bottle Tray (1)
e. Pre-filled miniiWASH Bottle (1)
f. Empty miniiWASTE Bottle (1)

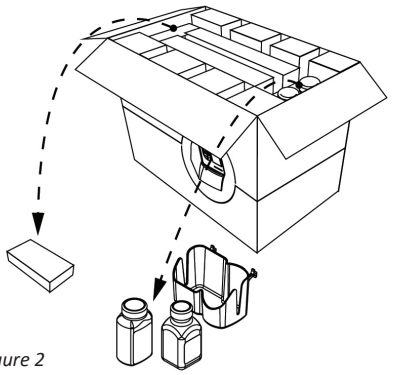


Figure 2

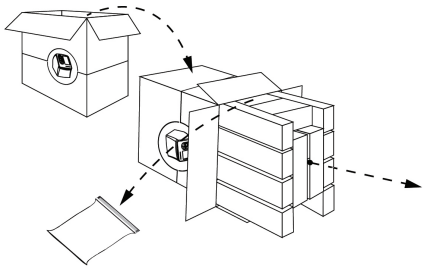


Figure 3

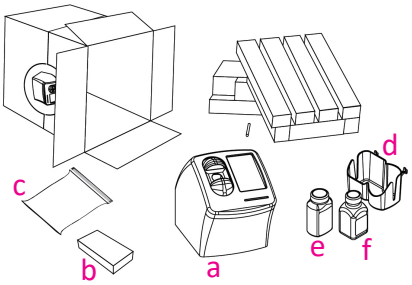


Figure 4

5.3 Bottle Connections

Attach the Bottle Tray to the back of the miniiSED.

Connecting the miniiWASTE Bottle (Figure 5, 6):

1. Connect the non-connector end of the miniiWASTE connection tube (has red connector at other end) to the red miniiWASTE Connection Port on the back of the miniiSED.
2. Connect the other end of the miniiWASTE connection tube to the miniiWASTE Bottle by replacing the original cap with the miniiWASTE Bottle Cap supplied.

Connecting the miniiWASH Bottle (Figure 5, 6):

1. Connect the non-connector end of the miniiWASH connection tube (has white connector at the other end) to the blue miniiWASH Connection Port on the back of the miniiSED.
2. Connect the other end of the miniiWASH connection tube to the miniiWASH Bottle by replacing the original cap with the miniiWASH Bottle Cap supplied.
3. Place both connected bottles into the Bottle Tray.

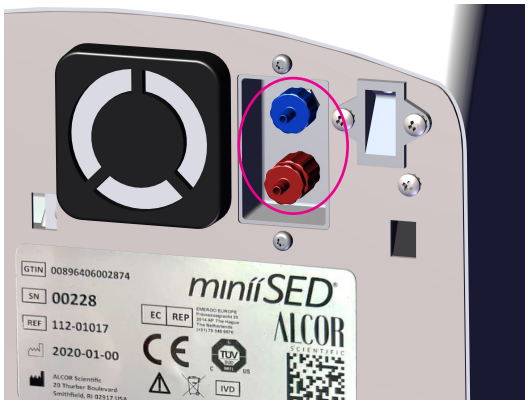


Figure 5

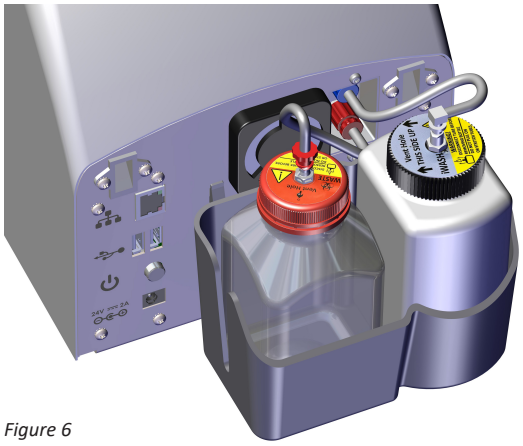


Figure 6

5.4 Power Connection

Precautions and warnings.

CAUTION: Operate the instrument on a dry, level surface.

CAUTION: Always keep a distance of at least 4 inches (10 cm) between the rear of the instrument and the wall to allow for proper ventilation.

CAUTION: Place the instrument on a stable and level surface free of vibration. Failure to do so may cause injury or malfunction of the unit.

Connecting the power supply

1. Connect the Power Cord to the Power Supply (Figure 7).
2. Connect the Power Supply to the Power Connection Port located on the back of miniiSED.
3. Place the instrument in its permanent operating location (indoor use only) and plug the Power Cord into a standard wall outlet.
4. To power the unit on, press the On/Off switch located on the back of the instrument.

Powering on

1. To power the unit on, press the On/Off switch located on the back of the instrument (Figure 7).
2. Once the power button has been pressed the instrument will produce an audible beep, after which the instrument is non-functional while the operating system boots up. This boot-up process takes about 10-15 seconds.

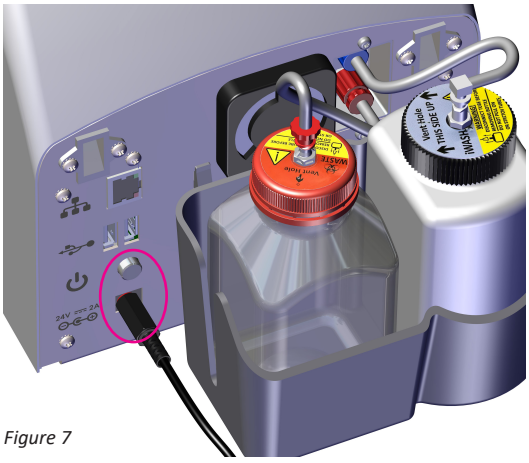


Figure 7

5.5 Ethernet Connection

The analyzer is equipped with an RJ-45 Ethernet connector for Factory use and for connection to network-based LIS systems using the LIS2-A2 standard. For more information, Document 1017-09-018 Communication Protocol is available upon request.

5.6 USB Connection

The analyzer is equipped with 2 USB 2.0 interface connectors to facilitate the export of test results or to connect an optional USB printer. Please call ALCOR Scientific Technical Support Department or your local authorized ALCOR distributor for more information.

6. User Interface & Operating Instructions

6.1 Initial Set Up

Selecting the language and date/time format

miniiSED will recognize when it is being powered up for the firs time and will guide the user through the initial set up process of selecting a language (Figure 8) and the date/time format (Figure 9, 10). Once set up is complete, the analyzer is ready for basic operation (Figure 11).

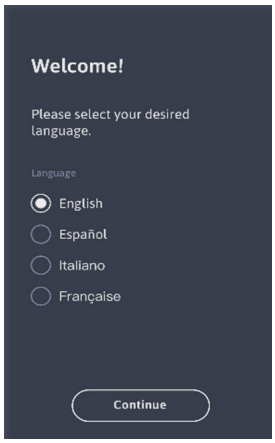


Figure 8

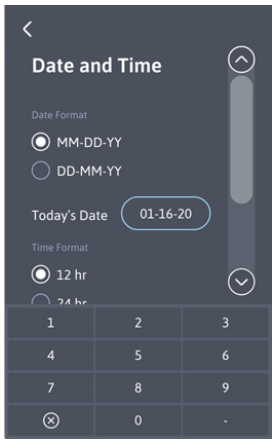


Figure 9

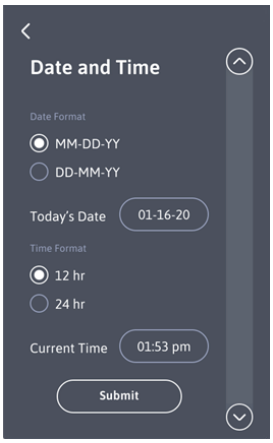


Figure 10

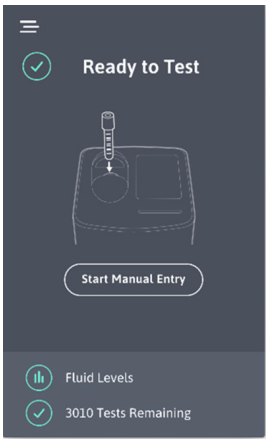


Figure 11

6.2 Basic Operation

Running samples

Test Credits are required for operation. The instrument is loaded with a predetermined quantity of credits for initial set up and use, however additional credits in the form of 'Test Cards' must be purchased. For information on loading additional Test Credits, please refer to section 11: Test Cards.

1. Insert the closed, primary tube, with the barcode facing down, into the loading port of the analyzer, as indicated (Figure 12).
2. Select 'Confirm' on the touch screen to confirm that the sample has been adequately mixed prior to insertion (Figure 13).
3. Optional onboard mixing by miniiSED can be turned on or off based on end user preference. See miniiSED Onboard Mixing Protocol (Document No. 1017-28-007) for instructions on how to activate onboard mixing.

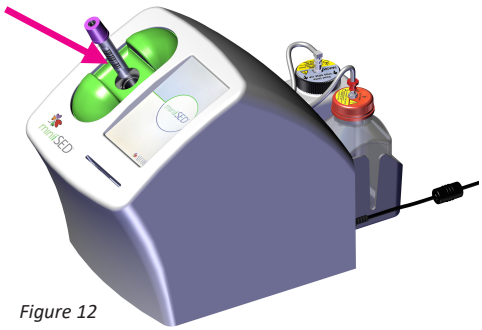


Figure 12

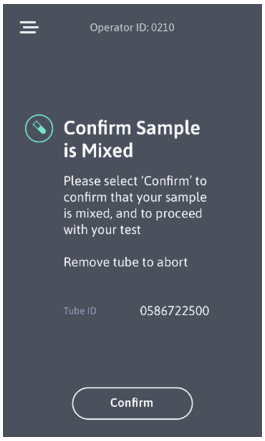


Figure 13

NOTE: If the sample was not properly mixed, remove the tube from the analyzer for external mixing prior to testing.

NOTE: To ensure accurate results patient samples must be well mixed prior to testing. If automated mixing is not available (or enabled) on the analyzer, samples must be mixed manually or by mechanical rocker for a minimum of 3 minutes before testing. Testing should occur immediately after mixing to ensure accuracy of the results.

4. Once sample mixing has been confirmed, the tube is moved into the analyzer and the testing process begins (Figure 14).
5. When testing is complete, the tube is returned to the loading port for retrieval and the test result is displayed on the touch screen (Figure 15).
6. The instrument will return to the home screen once the tube has been removed.

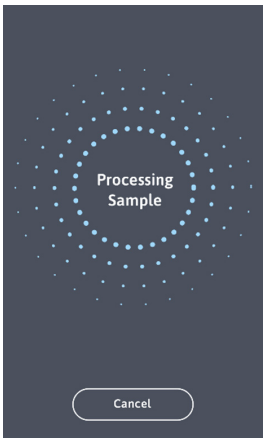


Figure 14

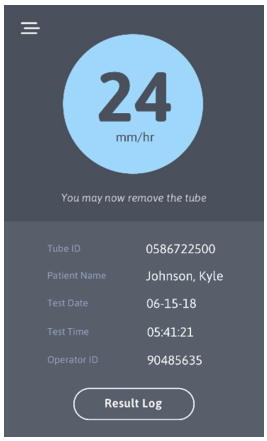


Figure 15

6.3 Touch Screen Menus

The instrument is touch screen controlled and all functions can be done by selecting or inputting data on the following screens:

The Main Menu screen (Figure 17) is accessed by touching this symbol in the upper left-hand corner found on many of the menu screens, see Figure 16, below:

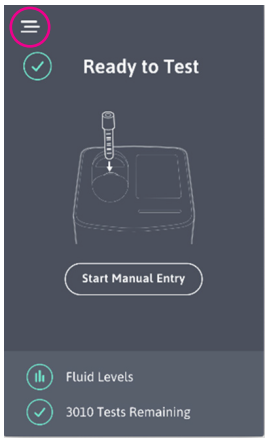


Figure 16

From the Main Menu screen (Figure 17), navigation to the Result Log, Maintenance and Settings menus can occur:

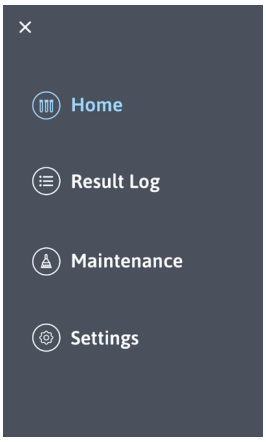


Figure 17

6.3.1 Result Log

The Result Log is organized starting with the most recent test results shown first. Figure 18, displayed icons, listed left to right, top to bottom are:

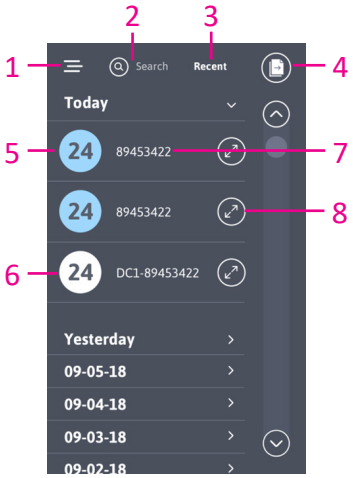


Figure 18

1. Back to main menu
2. Search – Selecting this will allow search by either date, name, patient number, etc.
3. Recent – Is the default page view and orders the result chronologically, with most recent first
4. The “Papers” icon in upper right corner is for exporting the last 7 days of records, either by printing or electronically via USB (Figure 18)
5. The blue “24” represents an individual test result of a patient record
6. The white “24” represents a Test Controls result value/record
7. The 8-digit number is the test or sample number (barcode, manually entered or auto-assigned)
8. The circle with arrows pointed out is an “Expand” command, providing a more detailed look at that test record

Records can be exported 7 days at a time as shown in Figure 18 or individually as shown in Figure 19. In either case, once the “Papers” icon is selected, it will bring up the Export Selection screen (Figure 20):

9. The destination of the files to be Exported can then be selected (Figure 20)
10. Touch the Continue button to complete the Export function

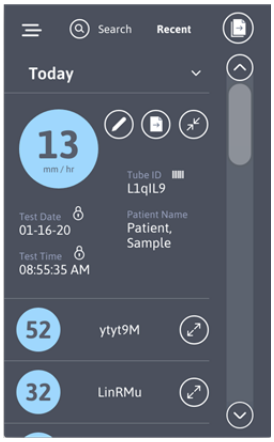


Figure 19

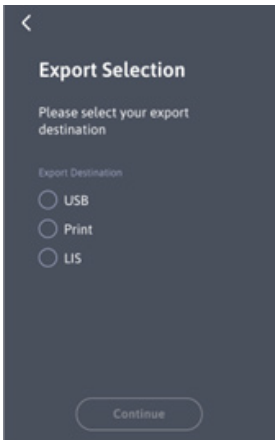


Figure 20

6.3.2 Maintenance Menu

The Maintenance Menu provides a “dashboard” for the user related functions for miniiSED. The circular icons with the green check mark indicate that the listed category is within preset limits. When a miniiSED category is approaching a preset limit, the circular icon will turn yellow indicating attention is needed soon. Should the category limit be exceeded, the icon will turn red and require action to be taken. In Figure 21, displayed icons, top to bottom are:

1. In the “Cleaning Fluid” and “Waste Container” categories, selecting the “Replace” button will reset the counters (Figure 21).
2. In the “Quick Clean” category, selecting the “Run” button will start the washing process.
3. Selecting “Deep Clean” will initiate the Deep Cleaning process.
4. The “Test Credits” category displays the remaining Test Credits. When a new Test Credit Card is available, insertion of the Test Credit Card will guide the user through the Test Credit transfer process.

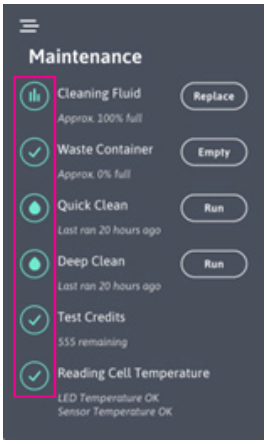


Figure 21

6.3.3 Settings Menu

The Settings sub-menu (Figure 22) provides the user access to functions to customize the operation of miniiSED for their laboratory environment. Using the guided Setup process when the instrument is first turned on will pre-configure some of the typical settings at the time of device installation. There are 2 categories of settings: General and Advanced. The General Settings selection is accessible to the user via the Admin PIN, when activated. Otherwise it is not password protected. Any User can view the Advanced Settings level but changes to these parameters is only allowed once the Advanced level PIN is entered.

Figure 22

6.3.4 General Settings Menu

The General Settings sub-menu (Figure 23) provides the user access to functions to customize the operation of miniiSED for their laboratory environment. Using the guided Setup process will pre-configure some of the typical settings at the time of device installation. Protection of the General Settings can be disabled by selecting the Access option. Use of the Backup and Restore features should be used only with the guidance of ALCOR Scientific Technical Support, as misuse of these features can result in loss of data and settings.

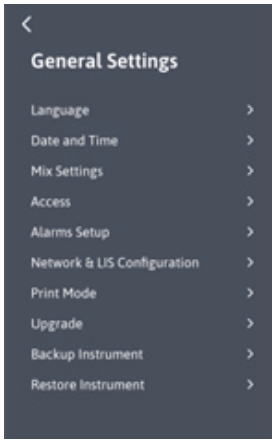


Figure 23

6.3.5 Advanced Settings Menu

The Advanced Settings sub-menu provides the user “Read-only” status of various operational sensors and device settings (Figures 24, 25, and 26). The Advanced Settings level is only accessible to qualified ALCOR Scientific Technicians.

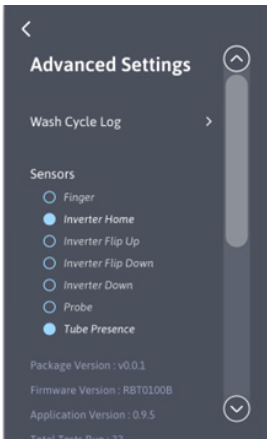


Figure 24

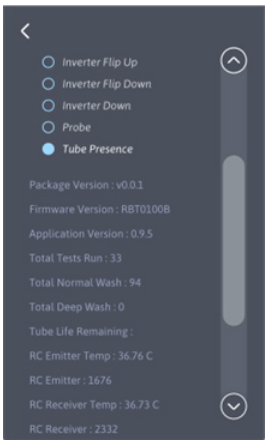


Figure 25

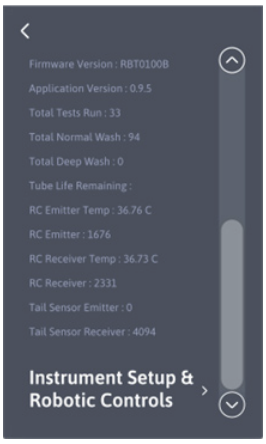
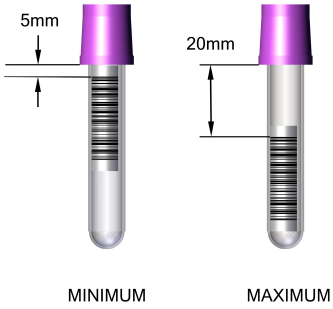


Figure 26

6.4 Patient Identification

Barcoded Tubes: Patient samples are read and identified by the instrument's internal barcode reader automatically as they are loaded into the instrument. All common laboratory barcodes are supported, including Code 39, UPC and Code 93 formats. Note barcode location range:



Instances when patient identification cannot be read by the internal barcode reader or there is no barcode present, miniiSED will provide the user an option to enter the patient data manually or to run the test without entering additional data. If the latter option is selected, miniiSED will assign a unique number to the test sample.

7. Quality Assurance

7.1 Quality Control

The manufacturer recommends running bi-level SEDiTROL ESR Controls at least once per day. SEDiTROL is the only Quality Control material validated for use with miniiSED. Due to the nature of ESR, method-specific Quality Control is recommended.[6] SEDiTROL ESR Controls Levels 1 and 2 are available for purchase (see Consumables - Section 4.2).

SEDiTROL Controls should be run in accordance with the SEDiTROL Instructions for Use (Document No. 315-09-011). After thoroughly mixing (see note below), the operator simply needs to insert a barcoded SEDiTROL tube. The analyzer will recognize SEDiTROl as Quality Control material when the barcode reader scans the tube. Control results must be reviewed to ensure results are in range.

NOTE: It is critical the SEDiTROL tubes are mixed before being run on miniiSED. Onboard mixing will not be sufficient. As per the SEDiTROL Instructions for Use (Document No. 315-09 -011), prior to first use of the SEDiTROL Level 1 and Level 2 Control, place the tubes on a mechanical rocker or rotator for 25 minutes. For subsequent uses, SEDiTROL tubes must be mixed on a mechanical rocker for 5 minutes immediately before use with miniiSED. Ensure that the cells have been thoroughly resuspended before placing the control tubes onto the ALCOR Scientific ESR analyzer.

NOTE: The analyzer will draw an additional 20 µL of sample from the first run to prime the analyzer following a wash cycle. To ensure the volumes for Level 1 and Level 2 remain as consistent as possible, it is recommended to alternate the order controls are run each day.

7.2 Peer Group Comparison

iQAP, ALCOR Scientific's online peer-to-peer quality assurance program, is available to SEDiTROL customers. Contact ALCOR Scientific Technical Support or your authorized representative for more information or to sign up.

7.3 Proficiency Testing (PT)

Quality Assessment is a critical aspect of laboratory quality management and can be conducted in several ways. One of the commonly employed assessment methods is that of external quality assessment, or Proficiency Testing.

Proficiency Testing is an important tool used in the lab to verify accuracy and reliability of its testing methods, alert to areas of testing that are not performing as expected, and to indicate shifts and trends which over time may affect patient results.

There are several manufacturers of Proficiency Testing materials from which to choose.

> **NOTE:** To ensure consistent results, please follow your selected Proficiency Testing manufacturer's instructions for optimal sample handling and processing. Use only approved Proficiency Testing material.

7.4 Calibration

miniiSED instruments are factory calibrated utilizing samples compared to a Reference Instrument that has been correlated to the reference Westergren method. The instrument range is from 1 to 130 mm/hr. During normal operation, parameters affecting calibration are constantly monitored and, if not within expected limits, a warning is given, and further testing prevented.

8. Limitations

- Incorrect sample storage conditions and/or sample age may produce erroneous results. Samples that are too warm or too cold may have falsely elevated or decreased ESR values respectively.
- Sample mixing is automatically performed before analysis with the purpose of homogenizing the sample. Inefficient homogenization or bubbles can affect the results given by the instrument.
- Increased levels of fibrinogen and gamma globulins in the sample may increase ESR values.
- Abnormally shaped RBCs (sickle cells, spherocytosis) may affect RBC aggregation and therefore potentially decrease ESR values.
- Anticoagulants other than EDTA must NOT be used. Excess anticoagulant must also be avoided.
- Lipemia may result in a miniiSED error message because changes in viscosity of the sample can interfere with ESR measurement.
- If hemolysis has occurred to such a degree that aggregation of RBCs has been reduced, it could decrease ESR values.
- The needle used in miniiSED is designed to prevent interfering clots from being aspirated into the analyzer hydraulic circuit and reading cell. If a clot prevents aspiration of the sample, the analyzer will retry the aspiration process 3 times before it gives an "unable to withdraw" error code and aborts the test. Similarly, if the sample volume is too low to be aspirated, the analyzer will attempt to aspirate the sample 3 times before it gives an "unable to withdraw" error code and aborts the test.
- It is broadly accepted that ESR values are elevated in multiple myeloma and other cancers, but it should be noted that studies have reported variability in ESR values with 10% of myeloma patients presenting with normal ESR, concluding that normal ESR values cannot be used to rule out myelomas and additional testing should be performed. In some cases, such as multiple myeloma and other cancers, RBC aggregation can be impacted by the presence of large macromolecules such as abnormal proteins and IgM, and this can lead to hematological testing abnormalities. It is therefore recommended, if the ESR result is inconsistent with the clinical presentation or stage of treatment, to test using additional methodologies.[7]

> **NOTE:** Erythrocyte sedimentation remains an only partially understood phenomenon and is a clinically nonspecific reaction. The ESR results generated by miniiSED should be used in conjunction with other clinical findings. It is highly recommended to perform other tests together with ESR since a normal ESR value is not enough to exclude that a patient is not affected by a pathology.

> **NOTE:** ESR is a transient phenomenon confined to fresh blood. It is not a hematic matrix component at the corpuscular or molecular level. The procedures used to determine ESR cannot be calibrated since the ESR phenomenon is influenced by a variety of factors. For this reason, it is possible to observe instrument performance deviations compared to other ESR procedures when the aforementioned variables are not taken into account.

9. Results

9.1 Expected Values

The reference values found in the table below are averages found in males and females.

ESR Reference Values (mm/hr)[8]	
Males under 50 years old	< 15
Males over 50 years old	< 20
Females under 50 years old	< 20
Females over 50 years old	< 30

NOTE: The ranges provided are for reference only. All laboratories should establish their own reference ranges based on their laboratory protocols.

10. Performance

10.1 Method Comparison

The miniiSED analyzer has been demonstrated to provide results equivalent to the CLSI approved standard methodology for ESR, the Westergren method. Since ESR is based on the physical interactions of RBCs during testing, the Westergren reference method is subject to a number of variables, including sample characteristics, testing environment, and individual operators' techniques. Therefore, Passing Bablok regression analysis is recommended for comparing 2 ESR methods since the reference method is known to be subject to variables.[6]

227 samples were tested on miniiSED and compared with results obtained from the Westergren method. The comparisons demonstrate equivalence to the Westergren method.

Results of Passing-Bablok regression analysis:

Variable X	Westergren
Variable Y	miniiSED
Sample Size	227

Slope	1.0625
Intercept	-0.2500
Correlation Coefficient	0.923

10.2 Precision

Samples spanning a range of ESR values were run on the miniiSED analyzer a total of 10 times to demonstrate precision. As with other laboratory tests, higher CVs are expected when comparing lower numerical values.

	Sample Range 10-20 mm/hr	Sample Range 20-40 mm/hr	Sample Range 40-60 mm/hr	Sample Range 60-105 mm/hr
Repetition 1	16	34	49	84
Repetition 2	15	38	51	86
Repetition 3	16	36	49	86
Repetition 4	16	41	50	85
Repetition 5	16	40	52	88
Repetition 6	17	36	51	84
Repetition 7	16	41	52	85
Repetition 8	17	37	51	85
Repetition 9	17	41	50	89
Repetition 10	17	40	52	86
Mean	16.3	38.4	50.7	85.8
SD	0.67	2.55	1.16	1.62
CV %	4.14	6.63	2.29	1.89

10.3 Sample Stability

Refrigerated Samples
Fresh EDTA-anticoagulated samples spanning the dynamic range of the assay were identified by doing a baseline test on iSED ELITE*. These samples were then stored at 4-8°C and analyzed at multiple time points. Testing was performed November 2024 - April 2025. The 48 hour results were plotted as a function of the baseline results and analyzed by Passing-Bablok regression. Fifty-two samples were tested. The regression statistics of the 48-hour vs. baseline comparison were: slope = 0.94 with a 95% confidence interval of 0.85 to 1.03, intercept = 1.32 with 95% confidence interval of -1.54 to 3.46 and a Spearman correlation coefficient of 0.95. The slope and intercept confidence intervals including 1.00 and 0.00, respectively and a correlation coefficient ≥ 0.90 demonstrates statistically significant identity between baseline and 48 hours when samples are stored at 4-8°C, thus supporting a refrigerated stability claim of 48 hours.

Room Temperature Samples
Fresh EDTA-anticoagulated samples spanning the dynamic range of the assay were identified by doing a baseline test on iSED ELITE*. These samples were then stored at room temperature and analyzed at multiple time points. Testing was performed November 2024 - April 2025. The 28 hour results were plotted as a function of the baseline results and analyzed by Passing-Bablok regression. Fifty-one samples were tested. The regression statistics of the 28 hour vs baseline comparison were: slope = 0.93 with a 95% confidence interval of 0.84 to 1.05, intercept = 1.52 with confidence interval of -2.80 to 3.97 and a Spearman correlation coefficient of 0.90. The slope and intercept confidence intervals including 1.00 and 0.00, respectively and a correlation coefficient ≥ 0.90 demonstrates statistically significant identity between baseline and 28 hours when samples are stored at 18-25°C, thus supporting a room temperature stability claim of 28 hours.

*The iSED family of analyzers, including miniiSED, iSED, iSED ELITE, and iSED PRO, use a common analytical unit for generating ESR results. Since the underlying technology is common and all analyzers are calibrated to a common Reference Unit, sample stability is the same across the analyzers.

11. Test Cards

In order to process and analyze samples, tests, known as ‘credits’, must be downloaded onto the instrument from pre-loaded Test Card.

11.1 Downloading Credits from Test Card

The Home Screen (Figure 27) and the Maintenance Menu (Figure 28) provide the user with the number of Test Credits available. To add additional credits to the instrument the user must insert a Test Card into the Test Card Reader.

Once a Test Card (Figure 29) is inserted, the next screen will show: the number of credits currently on the instrument, the serial number of the inserted Test Card and the number of credits on the Test Card (Figure 30). If the user taps the “Confirm” bubble, all of the available credits will be transferred to the instrument. The total number of credits is then displayed and the user is instructed to discard the Test Card (Figure 31).

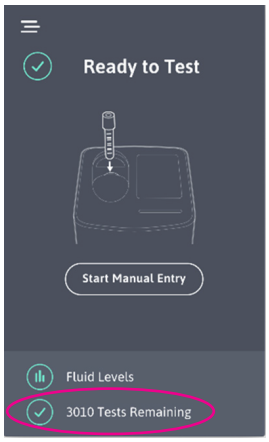


Figure 27

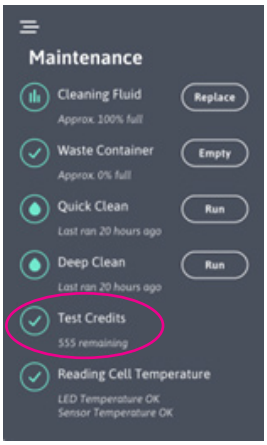


Figure 28

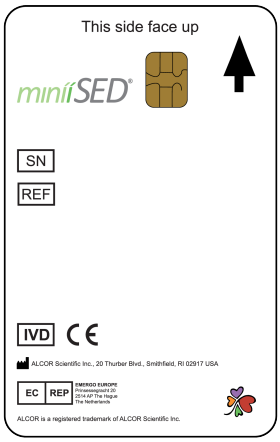


Figure 29

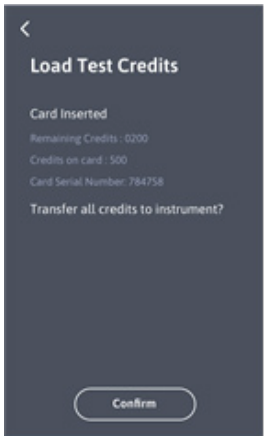


Figure 30

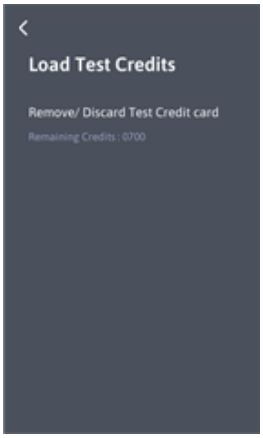


Figure 31

12. ALCOR External Printer

The ALCOR External Printer is an optional accessory for the miniiSED instrument for printing a hard copy of test results. Set up and operational details are noted below.

12.1 Safety Precautions

CAUTION: Do NOT touch the serrated edge used for cutting paper, it is sharp and may cause injury.

CAUTION: Do NOT touch the print head. It may result in burns or inadvertent damage to print head.

CAUTION: Turn off printer immediately if you see smoke, smell a strange odor, or hear an unusual noise.

CAUTION: NEVER ATTEMPT to repair this product yourself. Improper repair work may be dangerous and will invalidate the product warranty.

CAUTION: BE SURE TO USE the specified battery supplied by manufacturer. Installing a wrong battery may destroy your printer and lead to fire.

CAUTION: Prevent foreign objects from falling inside the printer as it may cause damage to the print head and/or the electronic components.

CAUTION: If water or liquid spills onto this equipment, remove the battery immediately and then contact your dealer. Continued usage may lead to fire.

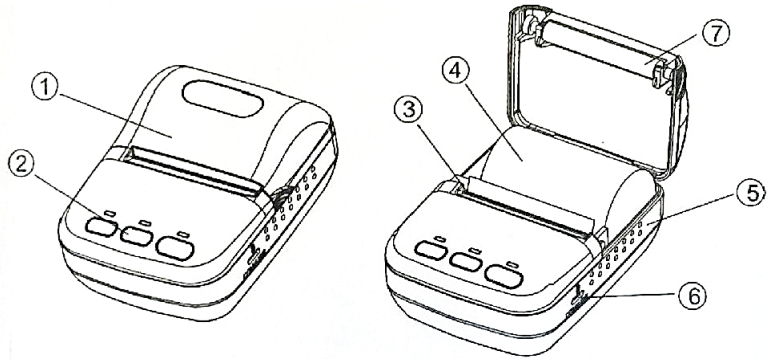
WARNING: DO NOT connect cables in ways other than those mentioned in this manual. Incorrect connections may cause damage to the equipment.

WARNING: DO NOT use in locations subject to high humidity or dust levels. Excessive humidity and dust may cause damage to the thermal head and control board.

WARNING: DO NOT expose this equipment directly in the sun, near fire, or any other heat source, which may cause discoloration of thermal paper.

WARNING: TO ENSURE safety, take out the battery before leaving it unused for an extended period.

12.2 External Printer Part Identification



1	Printer Cover
2	Control Panel
3	Print Head
4	Paper Roll
5	Main Body
6	Interface Connector
7	Rubber Roller, Platen

12.3 Common Operations

- Paper feeding method: After power is on, press and hold the FEED Button, printer feeds paper the desired length; then release and paper feeding will stop.
- Self-test method: Press and hold the FEED button (in the control panel), press the power button, then release the FEED button and self-test receipt will print out.
- The power LED is red when the battery is charging and turns green when fully charged.

12.4 Connection to miniSED

- Please use the data cable provided inside the printer box and connect to the data port on the printer (Figure 32).
- Connect the other end to the USB connection point on the back of miniiSED.

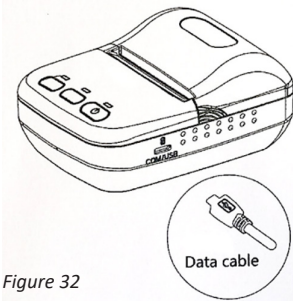


Figure 32

12.5 Control Panel

- Error Light: Indicates if there is a problem.
- MODE Button: Used to change the factory setting.
- Power Light: Indicates the ON or OFF status. If Red the printer is charging. If Green it is fully charged. In either mode the printer will function.
- Power Button – to turn ON: When printer is off, press power button for 1 second at least. After hearing the beep (1 low, 1 high), release it and the printer is on.
- Power Button – to turn OFF: When printer is on, press power button for at least 1 second. After hearing the beep (1 high, 1 low), release it and the printer is turned off.
- Bluetooth Light: Blue tooth is NOT enabled
- FEED Button: Hold down the FEED button, paper feeding begins. Release the FEED button, paper feeding stops.

12.6 Battery Pack Installation

Refer to Figure 33 on the right.

1. Insert the battery in the cavity on printer bottom as demonstrated in Picture 2.
2. Press the battery until it clicks

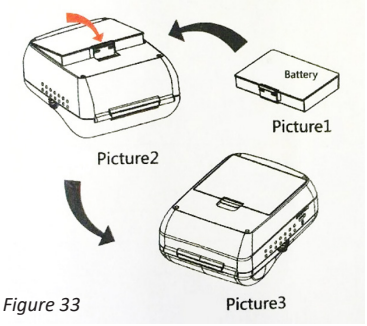


Figure 33

12.7 Loading Paper Sequence

Refer to Figure 34 below.

1. Hold both sides of the Paper Cover and lift to open the access to the paper roll.
2. Drop a new paper roll, with the leading edge curling up, inside the paper trough.
3. Pull out a small amount of paper past the serrated metal tear bar.
4. Close the cover and use the tear bar to cut the excess paper.

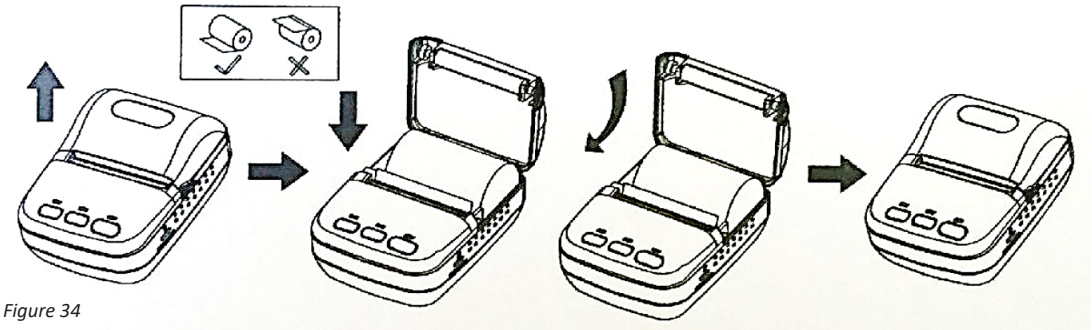


Figure 34

13. Routine Maintenance

13.1 Replacing/Emptying the miniiWASTE Bottle

WARNING: Wear Personal Protective Equipment (PPE) such as protective gloves and safety glasses during this operation.

NOTE: A wash cycle should be run prior to replacing the waste bottle.

WARNING: Dispose liquid waste container contents in a manner consistent with local regulations and laboratory procedures.

1. Locate the miniiWASTE bottle at the rear of the instrument.
2. Disconnect the LUER connector from the waste bottle screw cap.
3. Remove the waste bottle from the back of the instrument and dispose according to your laboratory biologic waste protocol.
4. Replace the waste bottle and **firmly** reconnect the LUER connector on the plastic screw cap.
5. Press Waste Container Empty reset button in the Maintenance Menu to reset (Figure 35).

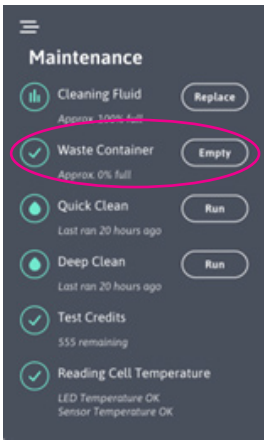


Figure 35

13.2 Replacing miniiWASH Bottle

1. The miniiWASH bottle is located at the rear of the instrument.
2. Disconnect the LUER connector from the miniiWASH bottle screw cap.
3. Remove the empty miniiWASH bottle, unscrew the cap, and replace it with a new miniiWASH bottle.
4. Place the new miniiWASH bottle at the rear of the instrument and **firmly** reconnect the LUER connector on the plastic screw cap.
5. Press Cleaning Fluid Replace reset button in the Maintenance sub-menu to reset (Figure 36).

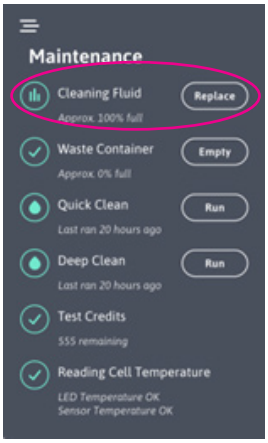


Figure 36

14. Preventative Maintenance

It is always recommended that the instrument be kept free from dusty and particulate environments for best performance.

14.1 Deep Clean Procedure

The analyzer will prompt the user when the Deep Clean is needed. This prompt will be located in the notification area at the bottom of the Home screen. The frequency for Deep Cleaning is monthly or every 1000 samples run, whichever comes first. This procedure will clean the aspiration fluidics pathway from the needle to the reading cell. The deepCLEAN Cleaning Solution is optimized for Deep Cleaning the miniiSED fluidics pathway and can be used to automate this critical process. deepCLEAN comes in pre-filled tubes and eliminates the need to manually prepare tubes of sodium hypochlorite solution.

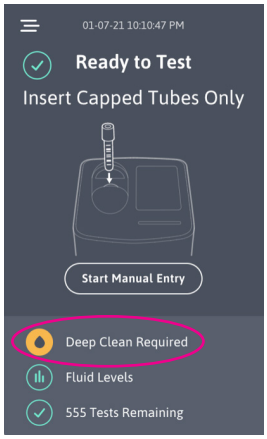


Figure 37

Materials Needed:

- One tube of deepCLEAN Cleaning Solution (see Consumables - Section 4.2 for ordering information)

  OR

- One capped, empty, and unused plain 13 x 75 mm tube (do not use SST tube)
- 6-7% sodium hypochlorite (bleach)

Procedure:

If using deepCLEAN Cleaning Solution:
No preparation is required; each tube is prefilled and ready-to-use. deepCLEAN tubes should be handled in accordance with the deepCLEAN Instructions for Use (Document # 123-09-001). Allow deepCLEAN tubes to come to room temperature before Deep Cleaning process if they were refrigerated.

> **NOTE:** deepCLEAN tubes must remain capped and upright at all times.

If manually preparing cleaning solution:

1. Prepare a solution of 6-7% sodium hypochlorite.
2. Add approximately 3.5 ml of 6-7% hypochlorite to unused, plain 13 x 75 mm tube.
3. Cap tight.

> **NOTE:** Be sure to wear appropriate personal protective equipment when handling sodium hypochlorite.

Initiating the Deep Cleaning Process:

1. Press Deep Clean “Run” button in the Maintenance sub-menu to start a Deep Clean (Figure 38). The analyzer will check for sufficient bottle volumes and prompt to replace if insufficient. If sufficient volume, the analyzer will prompt user to insert the Cleaning Solution.
2. Once prompted by the screen (Figure 39), insert either the deepCLEAN tube or the manually prepared tube of 6-7% sodium hypochlorite solution into the sample loading position to start the automated process.
3. The analyzer will run 2 wash cycles, then automatically perform the Deep Clean (3 minutes) and conclude by automatically running 2 additional wash cycles (Figure 40). During the 3 minute Deep Clean, the device will appear to be idle, while the fluidic system soaks in hypochlorite.
4. The analyzer will present the tube of Cleaning Solution back to the loading port where it should be removed.

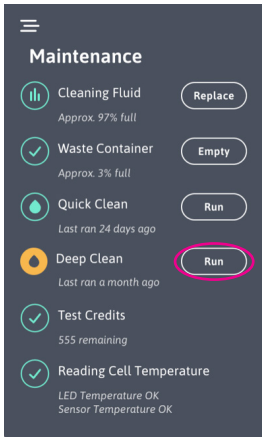


Figure 38

Figure 39

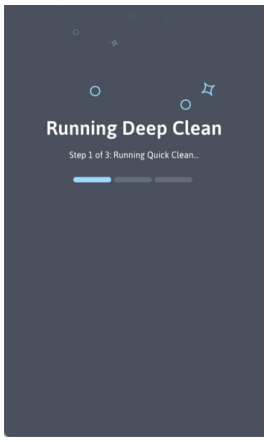


Figure 40

NOTE: The manually prepared tubes of 6-7% sodium hypochlorite, if used instead of deepCLEAN, should be discarded and prepared fresh next time a Deep Clean is required.

NOTE: Do not insert a tube of deepCLEAN without initiating the Deep Clean process from the Maintenance Menu.

14.2 miniiWASH and miniiWASTE Cap Replacement

The manufacturer recommends the onboard miniiWASH and miniiWASTE caps be replaced at least once every 12 months. Contact ALCOR Scientific or your authorized representative to obtain new caps.

15. System Status and Error Messages

The lower portion of the “Home” screen as shown in Figure 41 conveys the maintenance status of the instrument. Icons are green when the system is ready to test; yellow which warns that either fluids or test credits are nearing preset warning limits, or red if immediate action is necessary before testing can resume.

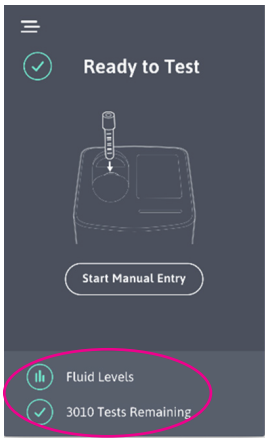


Figure 41

15.1 System Error Messages

If an error is detected during normal operation, the error is shown on the screen, along with information that indicates what needs to be addressed to clear the error. These processing errors supersede the normal processing of samples and prevent use until the error is remedied. The errors and related solution paths are clearly described, enabling the user to affect a correction and resume testing. Examples are shown in Figures 42 and 43 below.

Figure 42

Figure 43

15.2 Displayed Error Messages

For convenience, a list of possible errors and the detailed descriptions can be found in the table below. Should additional assistance be needed contact ALCOR Scientific Technical Support or your authorized representative.

UI Text	Description	Error Code
Inversor Error: Unable to define current sensor status.	State of sensor shows 2 or more sensors active at the same time, impossible to detect position.	inversorErrorSensorUndefined
Inversor Error: Unable to reach Home position.	Home sensor not detected during movement to reach home position.	inversorErrorHomeSens
Inversor Error: Loading port obstructed. Please Free Loading port	Loading aperture is obstructed, finger sensor activated during movement.	inversorErrorLoadingAperture
Inversor Error: Unable to reach Inversor Up position.	Inversor up sensor not detected during movement to reach inversor up position.	inversorErrorInvUpSensor
Inversor Error: Unable to reach Inversor Down position.	Inversor down sensor not detected during movement to reach inversor down position.	inversorErrorInvDownSensor
Inversor Error:Unable to reach Down position.	Down sensor not detected during movement to reach Down position.	inversorErrorDownSensor
Inversor Error: Probe Tube sensor is active. Check Probe on Piercing System.	Inversor probe tube still active when inversor position is not engaging primary tube.	inversorErrorProbeTube
Inversor Error: Unable to recover from unknown position.	During inversor recovery from unknown position, inversor up movement didn't detect any position sensor.	inversorErrorPositionUndefined
ESR_ERR_NOFLOW: Contact Technical Support	Value of optical readings all equal to empty value, no optical detection.	ESR_ERR_NOFLOW
ESR_ERR_NOSPIKE: New Specimen should be drawn	During acquisition sample did not show characteristic drop in optical signal (not human blood).	ESR_ERR_NOSPIKE
ESR_ERR_REVERSE: New Specimen should be drawn	Curve trend is inverted. Sample reaction signal has increased instead of decreased, indicating sample is not human blood.	ESR_ERR_REVERSE
ESR_ERR_NOPOINTS: New Specimen Should be drawn	Minimum point detected too far in the reaction, sample hyper viscous, does not leave room for manipulation of kinetics using standardized number of data points.	ESR_ERR_NOPOINTS

UI Text	Description	Error Code
ESR_ERR_TOODARK: New specimen should be drawn	Optical values detected are too dark, Hematocrit too high, or Emitter changed power level during acquisition without control.	ESR_ERR_TOODARK
ESR_ERR_TOOCLEAR: New specimen should be drawn	Optical values detected are too clear, Hematocrit loo low, or Emitter changed power level during acquisition without control.	ESR_ERR_TOOCLEAR
ESR_ERR_WITHDRAWAL: Contact Technical Support	System Unable to draw correct amount of sample.	ESR_ERR_WITHDRAWAL
ESR_ERR_FLOW_IN: Contact Technical Support	System unable to move the sample inside the reactor.	ESR_ERR_FLOW_IN
ESR_ERR_FLOW_OUT: Contact Technical Support	System unable to move the sample out of the reactor.	ESR_ERR_FLOW_OUT
ESR_ERR_ACQUISITION: Mix sample for additional time and rerun test	Acquisition measure step unable to complete.	ESR_ERR_ACQUISITION
ESR_ERR_TRIGGERDELAY: Remix sample for additional time and rerun test. Otherwise Contact Technical support	Control material did not start the reaction in the expected amount of time.	ESR_ERR_TRIGGERDELAY
ESR_ERR_LOW_CONTROL_HIGH: Remix sample for additional time and rerun test. Otherwise Contact Technical Support	System detects a High value on low control.	ESR_ERR_LOW_CONTROL_HIGH
ESR_ERR_HIGH_CONTROL_LOW: Remix sample for additional time and rerun test. Otherwise Contact Technical Support	System detects a Low value on High control.	ESR_ERR_HIGH_CONTROL_LOW
Measure Error: Another process is running	Measure process asked to start when other blocking process was running.	mErrorOtherProcessRunning
Measure Error: Sample type not set	Sample Type subjected to measure has not been set by Master. System does not know how to process the sample. Is required to set the type of sample that undergoes measure process to allow correct handling. (Patient, Control, or Proficiency).	mErrorSampleTypeNotSet
Measure Error: Reactor Trigger Delay. Remix sample for additional time and run again.	For control material only Reaction for control material did not start during the expected time frame.	mErrorReactorTriggerDelay
Measure Error: Flow In No flow detected when pumping into Reading Cell	Reactor was unable to detect flow of sample stream during laminar flow. After withdrawal sample did not move into reactor.	mErrorFlowIn
Measure Error: Flow Out No flow detected when discarding sample from Reading Cell	Reactor was unable to detect flow of sample stream when discarding. Sample still inside the reactor.	mErrorFlowOut
Mix Error: Unable to reach Inversor Up position.	Error detected during moving the inversor to inversor up sensor, (sensor not reached).	mixErrorMoveInversorUp
Mix Error: Unable to reach Inversor Down position.	Error detected during moving the inversor to inversor down sensor, (sensor not reached).	mixErrorMoveInversorDown
Mix Error: Unable to reach Home position.	Error detected during moving the inversor to inversor home sensor, (sensor not reached).	mixErrorMoveHome
Loading Port Obstructed. Please free Loading Port	Error detected during inversor movement, obstruction on the loading aperture detected.	mixErrorFinger
Withdrawal Error: Unable to position Inversor	Error detected during the movement phases of the process. Inversor unable to reach the required position.	wpErrorMovement

UI Text	Description	Error Code
Withdrawal Error: Unable to calibrate Tail Sensor. Perform Deep Clean. Otherwise contact Technical Support.	The reactor is unable to set the correct value for the reactor tail sensor.	wpErrorTailCalibration
Withdrawal Error: No Sample Tube Detected. Measurement Aborted.	During the piercing phase the primary tube was not detected (probe tube not activated after down sensor reached).	wpErrorNoTube
Withdrawal Error: Unable to withdraw sample. Check for sufficient volume in sample tube.Otherwise contact Technical Support.	No sample detected during liquid extraction from primary tube.	wpErrorNoFlowWithdrawal
Withdrawal Error: Sample has not performed required mixing cycles.	Process start requested when the sample did not complete the required mixing phase.	wpErrorSampleNotInMixSustain
Withdrawal Error: Another process is running preventing withdrawal from executing.	Process start requested when other processes are running: wash process prime process measure process.	wpErrorOtherProcessRunning
Prime Error: No flow detected when pumping FORWARD	No flow detected (transition from empty to full) during movement of sample stream inside the reading cell.	primeErrorNoFlowIn
Prime Error: No flow detected when pumping in REVERSE	No flow detected (transition from full to empty) during movement of sample stream inside the reading cell.	primeErrorNoFlowOut
Barcode Error: If the tube has a barcode, try repositioning it. Select “Run Test” to skip data entry. Remove tube to start manual entry	Unable to read the barcode.	Barcode Error
Quick Clean Error: Error detected during the movement phases of the process. Pump did not start movement	Error detected during the movement phases of the process. Pump did not start movement.	washPumpTimeout
Quick Clean Error: The pump did not move correctly	The pump did not move correctly.	washMovement
Quick Clean Error: The Quick Clean process is unable to set the correct T100 value for the READING CELL	The wash process is unable to set the correct T100 value for the reading cell.	washUnableToSetCellT100
Quick Clean Error: The Quick Clean process is unable to set the correct T100 value for the TAIL SENSOR	The wash process is unable to set the correct T100 value for the tail sensor.	washUnableToSetTailT100
Quick Clean Error: The Quick Clean process is unable to detect a change on optical value for the READING CELL after the miniiWASH fluid has been discarded. Check miniiWASH Bottle is connected and has sufficient fluid available	The wash process is unable to detect a change on optical value for the reading cell after the washing liquid has been discarded.	washUnableToDetectCellEmpty
Quick Clean Error: The Quick Clean process is unable to detect a change on optical value for the TAIL SENSOR after the miniiWASH fluid has been discarded. Verify tubing is secured in the Tail Sensor	The wash process is unable to detect a change on optical value for the tail sensor after the washing liquid has been discarded.	washUnableToDetectTailEmpty
Quick Clean Error: Current for the Reading Cell Emitter is lower than the allowed lower limit Contact Technical Support	Current for the reading cell emitter is lower than the allowed lower limit.	washCellEmitterCurrentToLow

UI Text	Description	Error Code
Quick Clean Error: Current for the Reading Cell Emitter is higher than the allowed higher limit Contact Technical Support	Current For The Reading Cell Emitter Is Higher Than The Allowed Higher Limit.	washCellEmitterCurrentToHigh
Quick Clean Error: Current for the Tail Sensor Emitter is lower than the allowed lower limit Contact Technical Support	Current for the Tail Sensor Emitter is lower than the allowed lower limit.	washTailEmitterCurrentToLow
Quick Clean Error: Current for the Tail Sensor Emitter is higher than the allowed higher limit Contact Technical Support	Current for the Tail Sensor Emitter is higher than the allowed higher limit.	washTailEmitterCurrentToHigh
Quick Clean Error: Wash requested when another process is running	Wash requested when another process is running.	washOtherProcessRunning
Smart Card Error: Card removed. Please try again	Card was removed during an operation.	scErrorCardRemoved
Smart Card Error: Card Type Error. Please try again	Card model/type is not valid.	scErrorCardType
Smart Card Error: Cipher Size Error. Please try again	Card cannot be decrypted due to an invalid memory dimension.	scErrorCipherSize
Smart Card Error: Command Error. Please try again	System has passed an incorrect command to the smart card controller.	scErrorCommand
Smart Card Error: Start Address Error. Please try again	System has requested to read/write to a wrong starting address.	scErrorStartAddress
Smart Card Error: End Address Error. Please try again	System has requested to read/write to a wrong ending address.	scErrorEndAddress
Smart Card Error: Memory Range Error. Please try again	System has requested to read/write a section of memory of the wrong dimension.	scErrorMemoryRange
Smart Card Error: Erasing Error. Please try again	Error encountered during Smart Card error counter erase operation. Smart Card is still valid.	scErrorErasing
Smart Card Error: Non ALCOR Smart Card Error. Please insert a valid card	The inserted Smart Card is not manufactured by ALCOR Scientific.	scErrorNonAlcorSmart
Smart Card Error: Personalization Incorrect. Please try again	The inserted Smart Card does not present the same distributor ID present inside the instrument. Smart card will not be loaded nor will be burned.	scErrorPersonalizationIncorrect
Smart Card Error: Protocol Type Error. Please try again	Inserted Smart Card does not use “Asynchronous” protocol.	scErrorProtocolType
Smart Card Error: PSC Presentation Error. Please try again	Error during presentation of Programmable Security Code, Smart Card cannot be written, procedure is aborted.	scErrorPscPresentation
Smart Card Error: Size Not Okay Error. Please try again	Inserted Smart card contains a denomination that is not allowed.	scErrorSizeNotOk
Smart Card Error: Unable to write EEprom. Please try again	System is unable to store credits into internal memory.	scErrorUnableToWriteEEprom
Smart Card Error: Restore Original Availability Error. Please try again	System is unable to write availability value before smart insertion back to internal memory.	scErrorRestoreOriginalAvailability
Smart Card Error: Unhandled Request Error. Please try again	Value written to request register not handled by the process.	scErrorUnhandledRequest
Smart Card Error: Unable to Clear EEprom. Please try again	During transfer, system unable to clear internal memory availability value.	scErrorUnableToClearEeprom
Smart Card Error: Transfer Content Invalid. Please try again	Content of transfer card is not valid.	scErrorTransferContentInvalid

UI Text	Description	Error Code
Smart Card Error: Card has already been used. Please Insert a valid card	Inserted card is already used. Error Counter already reset.	scErrorCardUsed
Smart Card Error: Card has been cloned. Please insert a valid card	Inserted card has been already downloaded into this unit. Probably this card has been cloned.	scErrorCardCloned
LED Temperature High (or Low)	Reading Cell thermal control shows abnormal temperature. If error does not disappear after 2-3 minutes, contact Technical Support. This error prevents a measurement from starting.	N/A
Sensor Temperature High (or Low)	Reading Cell thermal control shows abnormal temperature. If error does not disappear after 2-3 minutes, contact Technical Support. This error prevents a measurement from starting.	N/A

16. Safety Precautions

16.1 General Considerations

WARNING: It is recommended that blood samples be handled wearing gloves and that all other appropriate precautions be taken when dealing with potentially infectious biological material.

CAUTION: The instrument should be disconnected from power supply before performing any cleaning, maintenance, or exposing internal electrical components and circuits.

NOTE: If used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired and damage or injury could result.

WARNING: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State or the Regulatory Authority in which the user and/or patient is established.

16.2 Biological Waste

Biological hazards can be found in all human and animal body fluids and/or tissues. While using the instrument, it is suggested that your laboratory's Good Laboratory Practices are followed. Please refer to, and follow, all local regulations, department safety guidelines, and bio-safety policies for disposal of bio-hazardous waste.

WARNING: Dispose blood tubes into a biohazard container.

WARNING: Dispose sharps into a biohazard sharps container.

WARNING: All other biohazardous waste should be deposited into a biohazard bag.

WARNING: Biohazard bags will be placed into a Medical Waste Management bin for pick up.

WARNING: Dispose liquid waste container contents in a manner consistent with local regulations and laboratory procedures.

17. Technical Support and Company Contact Information

Technical Support

If you experience any problems while operating the instrument, please contact ALCOR Scientific Technical Support or your local authorized representative. ALCOR Scientific offers Technical Support Monday through Friday 8:30am-5:00pm EST (excluding all USA Federal Holidays). They can be reached by any of the following:

Toll Free: (800) 495.5270 (USA Only) **Fax:** +1 (401) 737.4519

International: +1 (401) 737.3774

Mail: ALCOR Scientific
20 Thurber Blvd
Smithfield, RI 02917
USA

Email: techservice@alcorscientific.com

WARNING: In the event that the instrument must be returned for service, EMPTY ALL FLUID CONTAINERS BEFORE SHIPPING.

WARNING: Remove any liquid waste or on-board sample tubes and decontaminate before returning for service.

Any instrument containing accumulated blood must be cleaned prior to shipment to the manufacturer. This decontamination is required by Federal Law (Title 48 and 49 of the Federal Regulations) in accordance with the Environmental Protected Agency's Regulations for Biohazard Waste Management.

General Contact Information

Phone: (800) 495.5270 (USA Only) /+1 (401) 737.3774
Mail: ALCOR Scientific
20 Thurber Blvd
Smithfield, RI 02917
USA

Fax: +1 (401) 737.4519
General Inquiries: info@alcorscientific.com
Customer Service: customerservice@alcorscientific.com

18. Technical Specifications

Name of Device	miniiSED
Type of Device	Automated analyzer for the determination of erythrocyte sedimentation rate of human whole blood
Principle of Measure	Photometric Rheology
Sample Requirements	Whole blood collected in 13 x 75 mm EDTA capped collection tube / 500 µL minimum volume
	100 µL aspirated volume
Analytical Range	1-130 mm/hr
Time to Result	First result available in 15 seconds once processing is started
Ethernet Port	For manufacturing or LIS Connection
Barcode Scanner	Internal
Printer	Accessory
Operating Environment	10-30˚C, Indoor Use, Pollution Degree – 2
Storage/Transport Environment	-20-60˚C
Humidity	15% - 85% (non-condensing)
Power Supply	Transformer: 100-240 VAC 50/60Hz; Device 24VDC, 2A
Power Consumption	60W
Frequency	50-60 Hz
Over Voltage Category	Category II
Dimensions (L x W x H)	36 x 19 x 24 cm 14 x 7.5 x 9.5 in
Weight	4.5 kgs 10.0 lbs
Operational Altitude**	4000 Meters
Storage Altitude**	4000 Meters
Restrictions	For Professional Use Only

19. Warranty Information

Manufacturer's Warranty

ALCOR Scientific warrants that this product is free from defects in materials and workmanship for a period of one (1) year from the date of original purchase (except as noted below). During the stated one year period, ALCOR Scientific shall, at its sole discretion, repair or replace at no charge to the original end use purchaser or person receiving the product, any product found to be defective due to material or workmanship. In the case of replacement, a new or reconditioned product may be provided at ALCOR Scientific's option.

This warranty is limited to the repair or replacement due to defects in parts or workmanship and shall not include any maintenance and repairs or replacement of parts due to normal wear and tear. Parts required which were not defective shall be replaced at additional costs, and ALCOR Scientific shall not be required to make any repairs or replace any parts which are necessitated by abuse, accident, alteration, misuse, neglect, maintenance by other than ALCOR Scientific or an authorized ALCOR Scientific service agent, or failure to operate the instrument in accordance with instructions. Further, ALCOR Scientific extends no warranty for malfunction or damage to its products resulting from improper or unreasonable use or maintenance; failure to follow operating instructions; connections to improper voltage supply; unauthorized alteration or modification of original condition; damages caused by inadequate packing or shipping procedures; loss of, damage to or corruption of stored data; and any damage due to use of operating supplies other than those manufactured or recommended by ALCOR Scientific.

ALCOR Scientific reserves the right to make changes in design or software of this instrument without obligation to incorporate such changes into previously manufactured instruments.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE.
This warranty is void if the label bearing the serial number has been removed or defaced.

Limitations of Liability

In no event shall ALCOR Scientific be liable for indirect, special or consequential damages, even if ALCOR Scientific has been advised of the possibility of such damages.

Any transport costs and risks are not covered by this warranty. In the event that the instrument shall be returned to ALCOR Scientific for servicing, replacement or for other reasons, it must be shipped and received in original packaging. Otherwise, additional charges may be incurred.

Proof of purchase from an authorized ALCOR Scientific distributor and proof of delivery may be required.

20. References

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CE IVD

EC REP
EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

www.alcorscientific.com

ALCOR Scientific LLC

20 Thurber Boulevard

Smithfield, RI 02917 USA

(T) +1 401.737.3774

WWW.ALCORSCIENTIFIC.COM