iSED® / iSED® ELITE

Automated Erythrocyte Sedimentation Rate Analyzer

OPERATOR'S MANUAL & INSTRUCTIONS FOR USE

For iSED® analyzers with serial numbers above 05000 and all iSED ELITE analyzers

ALCOR SCIENTIFIC

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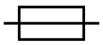
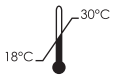
Symbols Reference

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 Operator's Manual includes information and warnings. These need to be observed by the operator in order to ensure safe operation of the instrument. There are four types of messages: Notes, Caution, 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.

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 the iSED/iSED ELITE.

Do not operate iSED/iSED ELITE without sample collection tray.

Empty sample collection tray to prevent overflow of tubes.

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

iSED/iSED ELITE Automated 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 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 the 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-phase proteins. Changes in red cell shape or numbers may also affect ESR.[4]

With the traditional Westergren method of ESR testing (to which iSED/iSED ELITE 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 tube 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. 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 iSED/iSED ELITE 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.[6]

The technical innovation of the iSED/iSED ELITE 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 iSED analyzers with serial numbers above 5000 and iSED ELITE analyzers. 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 collection tube with K3-EDTA or K2 EDTA anticoagulant (lavender top tube) must be used
- Sample tube MUST have a pierceable cap/stopper and only be run on iSED/iSED ELITE 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 requirement is approximately 350 µL (see note below)
- Sample should 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 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: 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.

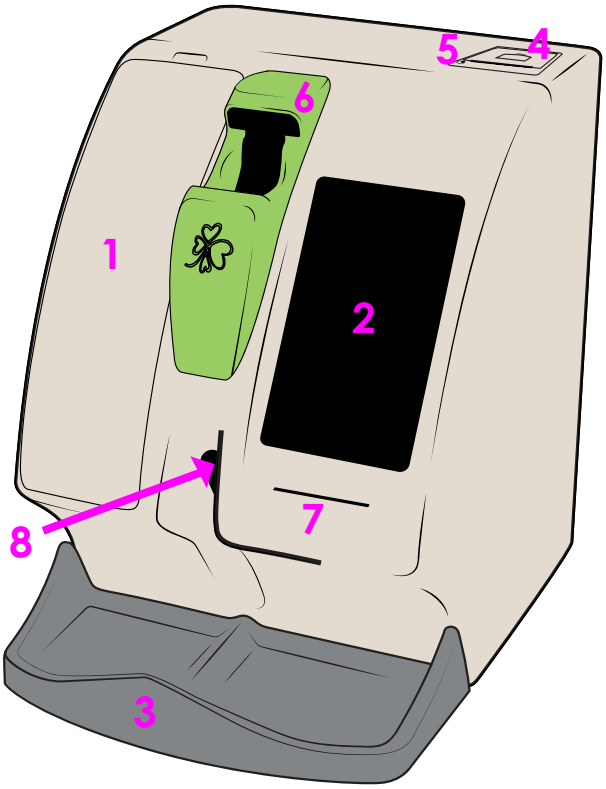
NOTE: Although infrequent, a small amount of sample (<50 µL) may be needed for priming the system in addition to the 100 µL aspirated sample volume.

WARNING: Do not use if the tube stopper is missing. Use only tightly capped samples.

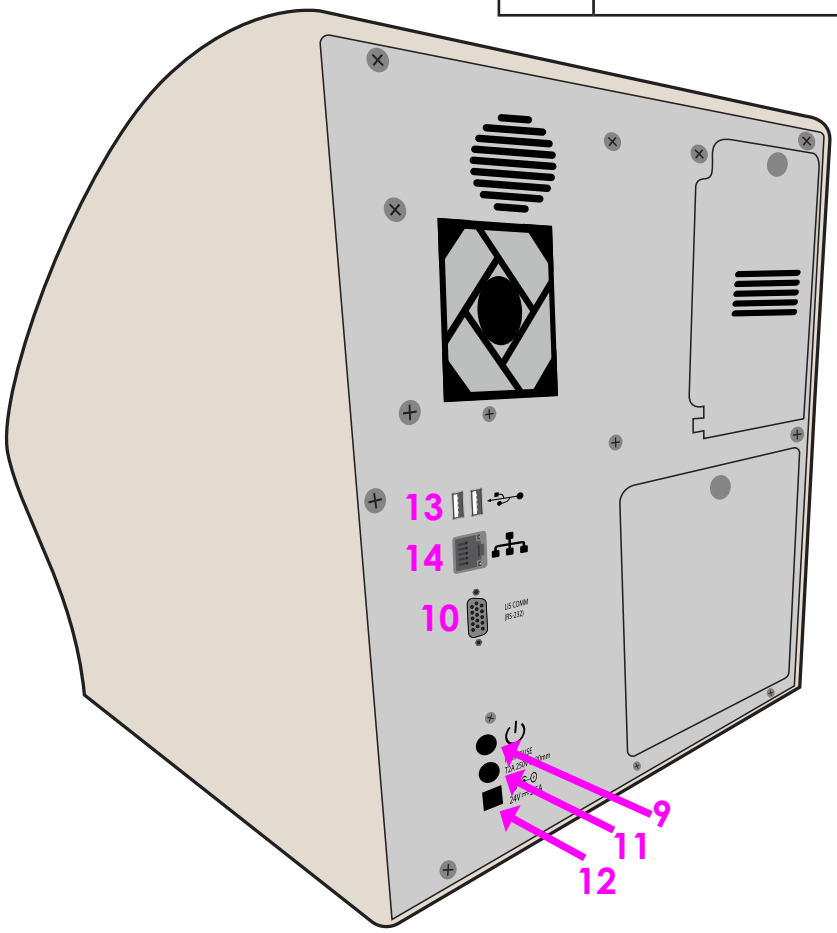
4. Instrument Overview

The iSED/iSED ELITE Erythrocyte Sedimentation Rate Analyzer is a fully automated analyzer that allows for samples to be loaded continuously or random access. Once a sample tube is inserted, the analyzer automatically performs all sample mixing, aspiration, and analysis then returns the sample tube to the sample tray. iSED/iSED ELITE 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 within 20 seconds after appropriate homogenization. Results are reported in units of mm/hr, and iSED/iSED ELITE performance is correlated to the Westergren ESR method.

4.1 Parts Identification



1	iWASH® and iWASTE® Compartment
2	Touch Screen
3	Sample Tube Return Tray
4	Printer
5	Paper Feed Button
6	Sample Loading Port
7	Smart Card Reader
8	Sample Ejection Port
9	On/Off Button
10	RS-232 Connection Port
11	Fuse
12	Power Connection Port (24VDC, 2.5A)
13	USB Ports (2)
14	Ethernet Network Port



4.2 Consumables

Item	Description	Configuration	Reference Number
Test Card	Test Card preloaded with Test Credits	250 test credits	112-00250
		500 test credits	112-00500
		1,000 test credits	112-01000
		2,000 test credits	112-02000
		5,000 test credits	112-05000
		10,000 test credits	112-10000
		20,000 test credits	112-20000
iWASH Fluid	500 mL bottle with screw cap, pre-filled with instrument iWASH	Pack of 4	112-12-001
iWASTE Container	500 mL plastic waste bottle with screw cap	Pack of 4	112-12-005
		Pack of 24	112-12-002
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 sets of 2 tubes	DSC01
		3 x sets of 2 tubes	DSC06
Printer Paper	57 mm x 28 mm OD	Pack of 5	DS-05233

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

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

4.3 Unpacking and Installation

CAUTION: The instrument unit weighs 33 lbs in the box. Use safe lifting techniques and proper 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 any internal components.

All original packaging should be kept in the event the instrument needs to be returned for service or warranty repair. For more information, please refer to the Warranty Information in the Operator's Manual or call ALCOR Scientific Customer Service at +1 401.737.3774.

4.4 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 the shipping carrier.

Figure 1

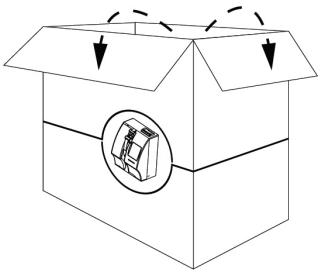


Figure 2

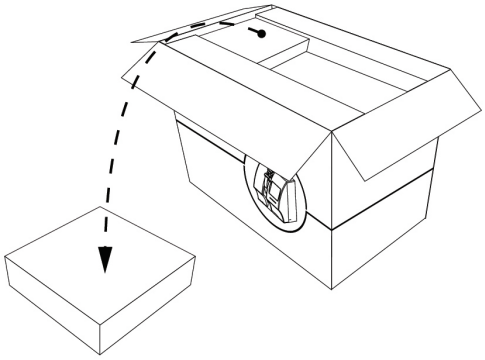


Figure 3

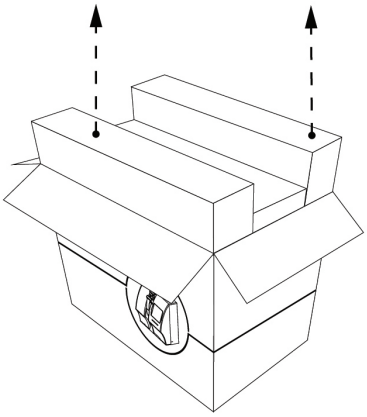
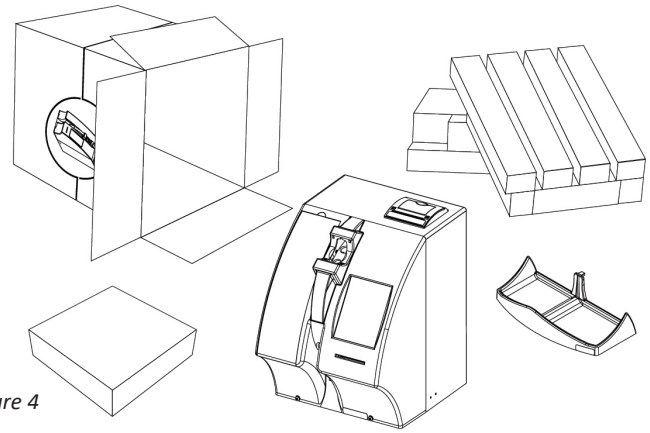


Figure 4



1. Position the box upright and open the top flaps (Figure 1).
2. Remove the Accessory Box and set aside (Figure 2).
3. Keep the box upright. Slowly slide the instrument and surrounding foam out of the box (Figure 3).
4. Remove the Tube Return Tray and set aside (Figure 4).
5. Remove the foam panels from the sides of the instrument (Figure 4).
6. Place the instrument on a secure flat surface and remove the instrument from the protective bag. **Save the box and foam pieces for future use** (Figure 4).

4.5 Contents of the Box

1. iSED/iSED ELITE instrument (1 Each)
2. Power Cord and Power Adapter (1 Each)
3. Sample Collection Tray (1 Each)
4. Pre-filled iWASH Bottle (1 Each)
5. iWASTE Bottle (1 Each)
6. iWASH Filter Cap (1 Each)
7. iWASTE Cap (1 Each)
8. Thermal Paper (1 Each)
9. Spare Fuse (1 Each)
10. Quick Reference Card (1 Each)

4.6 Power Connection

1. Connect the power cord to the power supply.
2. Install and connect both iWASH and iWASTE bottles. See Sections 13.2 and 13.4.
3. Insert the power adapter cord into the power connection port located on the rear panel of the instrument (Figure 5).

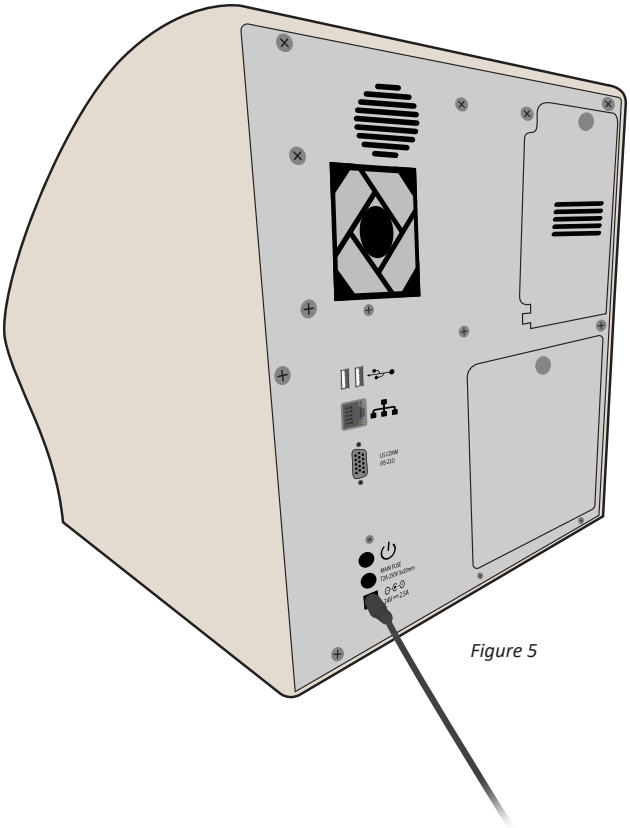


Figure 5

4. Place the instrument in its permanent operating location, and plug the power cord into a standard wall outlet.
5. To power the unit on, press the power button located on the rear of the instrument. The instrument will produce an audible beep, after which the instrument is non-functional while the operating system boots up. This bootup can last up to 1 minute. The device will not accept samples until the temperature of the measurement components has warmed up and stabilized.

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

4.7 RS-232 connection

The analyzer is equipped with a legacy RS232 DB9 male connector for data transfer to LIS systems using the LIS2-A2 Standard. The pin-out of the connector is detailed in Figure 6.

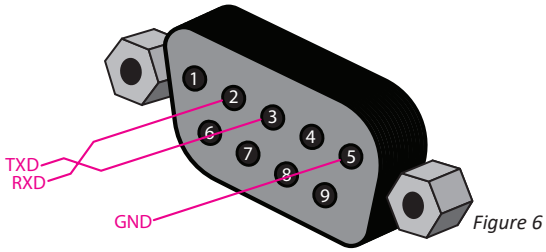


Figure 6

For more information, Document 222-09-006 Communication Protocol is available upon request.

4.8 Ethernet Connection

The analyzer is The analyzer is equipped with an RJ-45 Ethernet connector for Factory use and for connection to TCP/IP-based LIS systems using the LIS2-A2 Standard. For more information, Document 222-09-006 Communication Protocol is available upon request.

4.9 USB Connection

The analyzer is equipped with two USB 2.0 interface connectors to facilitate the export of test results and for updating device software.

5. User Interface

5.1 Initial Setup

5.1.1 Select the language and date/time format

The iSED/iSED ELITE will recognize when it is being powered up for the first time and will guide the user through the initial set up process of selecting a language and the date/time format (Figures 7 and 8). Once Initial Setup is complete, the analyzer is ready for basic operation (Figure 9).

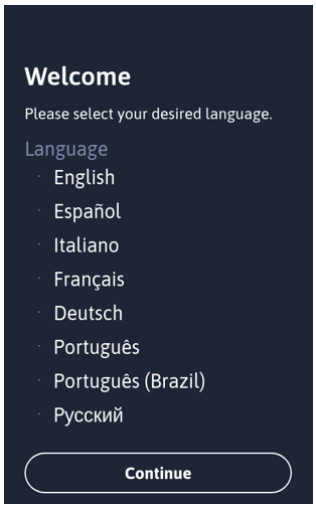


Figure 7

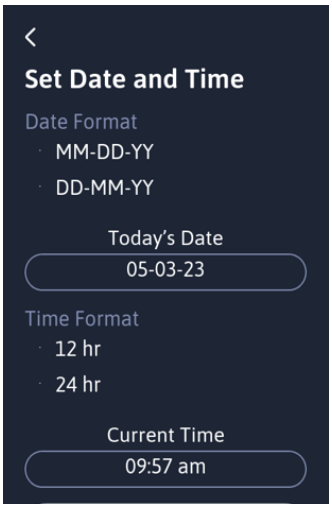


Figure 8

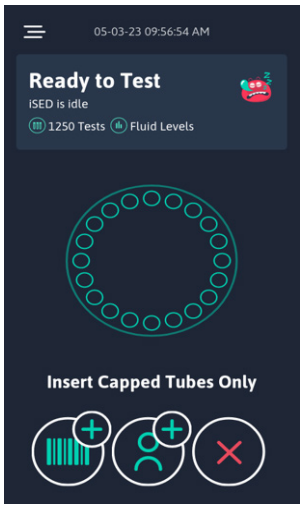


Figure 9

5.2 Touch Screen Menus

The instrument is operated via touchscreen, and all operations can be done by selecting or inputting data on the following screens.

Navigate to the Main Menu screen (Figure 11) by pressing the symbol in the upper left-hand corner found on many of the menu screens (see example in Figure 10). From the Main Menu screen (Figure 11), navigation to the Result Log, Maintenance and Settings menus can occur.

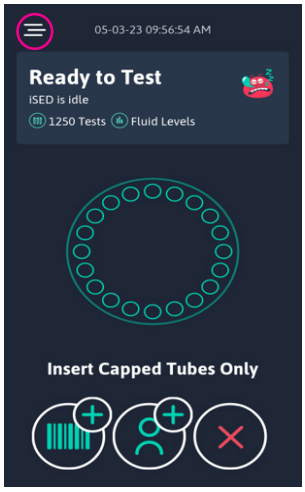


Figure 10

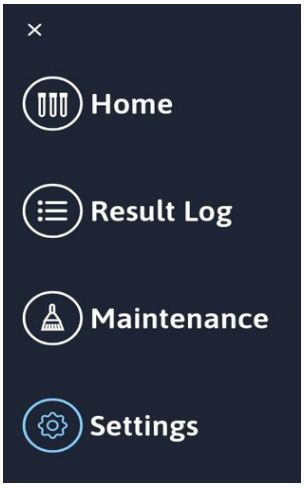


Figure 11

5.2.1 Results Log Menu

The Result Log sub-menu is organized with the most recent test results shown first. Figure 12 icons, listed left to right, top to bottom are:

1. Back to main menu
2. Search: Selecting this will allow search by date, name, patient number, etc.
3. Recent: The default page view; orders the result chronologically with most recent first.
4. This “Papers” icon is for exporting records.
5. The blue circles represent individual test results.
6. The white circle represents a SEDiTROL or proficiency result record.
7. This is the test or sample number.
8. This icon is an expand command, providing a more detailed look at that test record.

Records can be exported as shown in Figure 12 or individually as shown in Figure 13. In either case, once the “Papers” icon is selected, it will bring up the Export Selection screen (Figure 14).

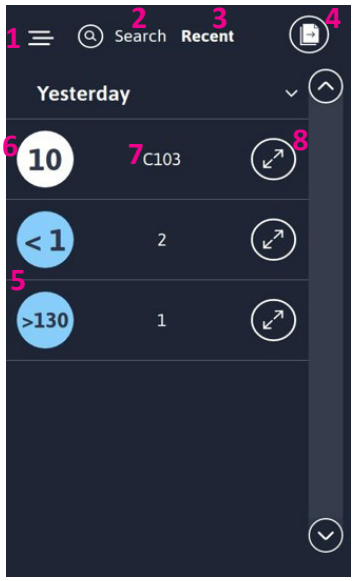


Figure 12

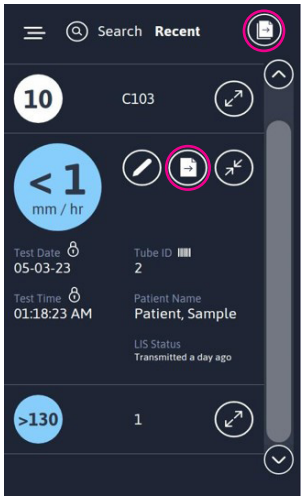


Figure 13

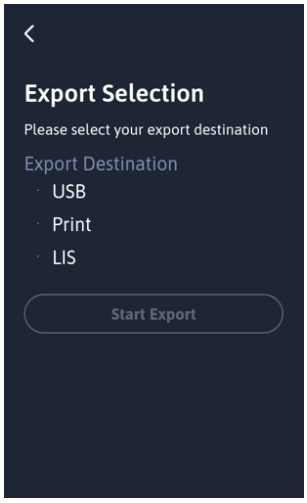


Figure 14

5.2.2 Maintenance Menus

The Maintenance sub-menu provides a “dashboard” for the user-related functions for iSED/iSED ELITE. When green, the circular icons indicate that the listed category is within preset limits. When an iSED/iSED ELITE 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 15, displayed icons, top to bottom are:

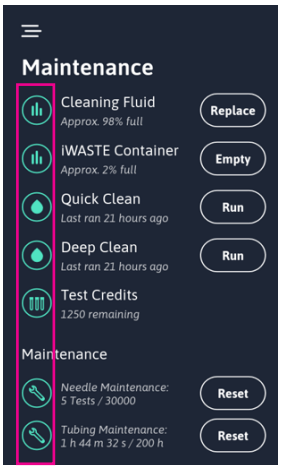


Figure 15

1. **Cleaning Fluid** and **Waste Container:** In the “Cleaning Fluid” and “Waste Container” categories, selecting the “Replace” or “Empty” buttons will reset the counters.
2. **Quick Clean:** In the “Quick Clean” category, selecting the “Run” button will start the cleaning process.
3. **Deep Clean:** In the “Deep Clean” category, selecting the “Run” button will start the deep cleaning process.
4. **Test Credits:** 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.
5. **Reading Cell Temperature:** The “Reading Cell Temperature” category displays the status of the LED and Sensor temperatures. If the LED and Sensor temperature are not up to the correct temperature, the status will display “Not Ready” and samples cannot be processed until the status displays “OK”.

5.2.3 Settings Menu

The Settings sub-menu (Figure 16) provides the user access to functions to customize the operation of the iSED/iSED ELITE 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. If not activated, settings will not be 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.

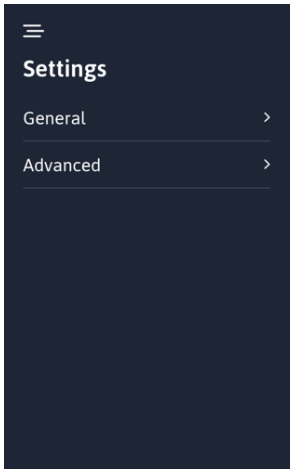


Figure 16

5.2.4 General Settings Menu

The General Settings sub-Menu (Figure 17) provides the user access to functions to customize the operation of the iSED/iSED ELITE 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.

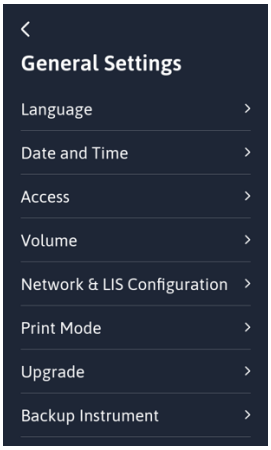


Figure 17

5.2.5 Advanced Settings Menu

The Advanced Settings sub-menu provides the user “Read Only” status of various operational sensors and device settings (Figures 18, 19, and 20). The Advanced Settings level is only accessible to ALCOR Scientific qualified technicians.

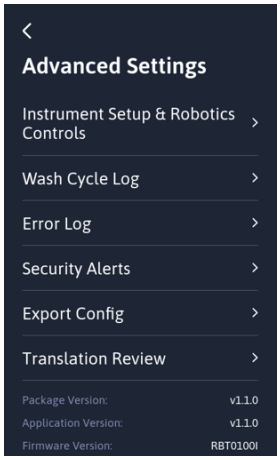


Figure 18

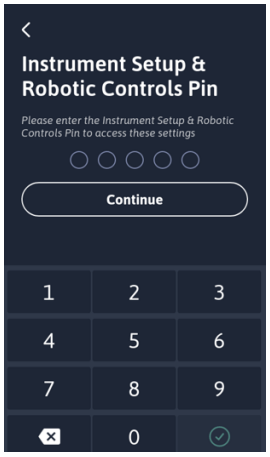


Figure 19

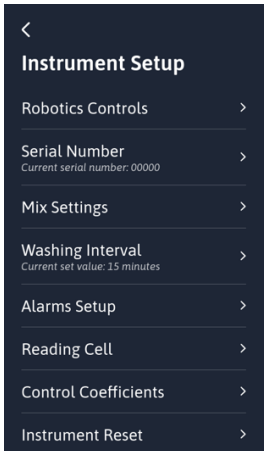
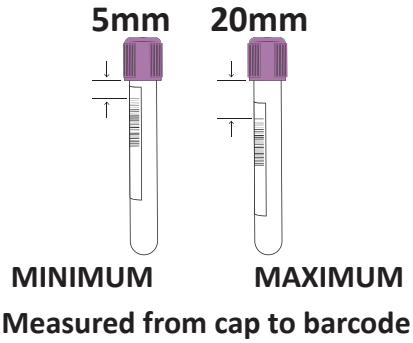


Figure 20

6. Operating Instructions

6.1 Sample Identification

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



For instances when patient identification cannot be read by the internal barcode reader or if there is no barcode present, the operator may enter data manually. **For instructions on manually entering patient data, please refer to Section 6.2.2.**

6.2 Basic Operation

6.2.1 Running Barcoded Samples

All sample mixing, sample aspiration, sample reading, and sample disposal are handled automatically by the instrument. Up to 20 sample tubes may be loaded into the sample wheel at any given time. As each sample is processed (processing happens within 20 seconds after appropriate sample mixing), the sample tube is ejected from the sample wheel and retained in the external sample collection tray. Whenever there is an open position, a sample may be placed in the sample wheel.

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 12.

To run a barcoded sample:

1. Select the barcode icon with the plus sign (Figure 21).

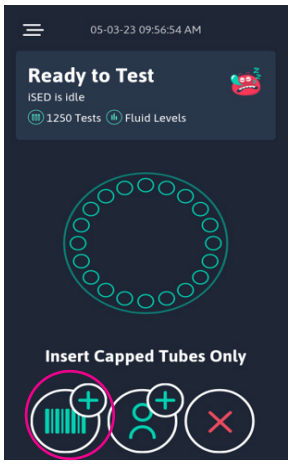


Figure 21

2. Insert the capped pierceable primary tube, with the barcode facing to the right, into the loading port of the analyzer. A red light will illuminate, and a distinctive beep will sound when the barcode is successfully recognized.

3. A position will highlight green on the wheel displayed on the main menu, indicating the sample is on the sample wheel.

4. The sample wheel will move to the next available position to load additional samples. The onscreen information bar will report "waiting for sample" and the instrument will beep quietly for 5 seconds. As the 5 second window draws to a close, beeping will become faster. If no additional samples are loaded, the analyzer mixes the samples for 3 minutes.

NOTE: If the 5 second window is missed, simply select the barcode icon again to restart the sample scheduling process.

5. After a 3 minute mixing cycle, the analyzer starts the testing process.

6. When testing is complete, the tube is ejected from the sample wheel into the collection tray, and the test result is printed via the onboard printer.

6.2.2 Running Non-Barcoded Samples

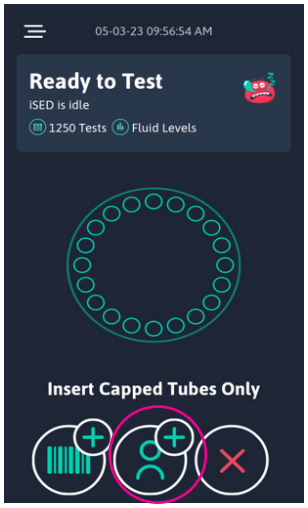


Figure 22

1. Select the “person with the plus sign” icon (Figure 22).

The instrument will prompt the operator to enter sample or patient identification data manually using the alphanumeric keyboard. Sample or Patient Information should be recorded in at least 1 of the following data fields:
-Alphanumerical ID
-Patient’s First Name
-Patient’s Surname

> **NOTE:** If patient information is not entered within 10 seconds from the last pressed key, the instrument will automatically assign an identification number.

2. Insert the capped, pierceable, primary tube into the loading port of the analyzer. A position will highlight green on the wheel displayed on the main menu, indicating the sample is on the wheel.

3. The wheel will move to the next available position to load additional samples. If no additional samples are loaded, the analyzer mixes the samples for 3 minutes.

4. After the 3 minute mixing cycle the analyzer starts the testing process.

5. When testing is complete, the tube is ejected from the sample wheel and the test result is printed on via the onboard printer.

6.2.3 Washing

The instrument uses iWASH Fluid as the cleansing agent during the wash cycle. iSED/iSED ELITE is programmed to perform 1 self-clean (wash) after being idle for 15 minutes following the last sample tested. The process takes approximately one minute and utilizes approximately 4.5 mL of iWASH.

It is recommended that the instrument remain on at all times and ready for use. Should the instrument need to be powered off for any reason, run a wash cycle prior to powering off the unit.

> **NOTE:** The use of any other product for washing could affect the performance of the instrument and void the warranty.

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 on iSED/iSED ELITE. 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 # 315-09-011). 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 and automatically process the material as Quality Control material. Control results must be reviewed to ensure results are within the acceptable range.

> **NOTE:** The order SEDiTROL Level 1 and Level 2 are run in should be alternated each run to ensure consistent volumes between both levels.

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 accurate results, please follow your selected Proficiency Testing manufacturer's instructions for optimal sample handling and processing. Use only approved Proficiency Testing material.

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 an iSED/iSED ELITE 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 iSED/iSED ELITE 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 three 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 three 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 iSED PRO 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. Calibration

iSED/iSED ELITE instruments are factory calibrated using 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.

10. Results

10.1 Expected Values

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

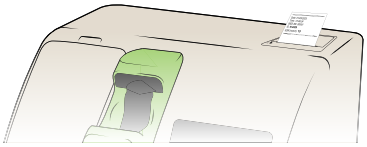
Sedimentation Rate Reference Value (mm/hr)[8]	
Males under 50 years old	< 15
Males over 50 years old	< 20
Females under 50 years old	< 20
Females over 50 years old	< 30

NOTE: The ranges provided are for reference only. All laboratories should follow their laboratory's protocol for establishing their own reference ranges.

10.2 Results Format

Results are shown on screen after analysis and printed by the instrument's internal printer. Data format is as follows:

Date format: Month/Day/Year
Time format: Hour/Minute/Second
Result format: mm/Hour



Example of Results Print Out

==========	
Date: 03/25/2013	Date of measurement
Time: 13:36:24	Timestamp of measurement
iSED Sn: 00001	Instrument serial number
ID: **812409**	Barcoded or Manual sample identification
ESR (mm/h): **15**	Format of ESR result reported
==========	

NOTE: The lower limit of the analytical range is 1; results lower than this will be displayed as "<1".

NOTE: If a sample is entered with Manual identification, then Patient Name (First, Last, or both) will be shown underneath the device serial number.

10.3 Printed Results with Error Message

In the event that the instrument is unable to analyze the sample and report results, the printout will replace the '**ESR (mm/h):**' field with an error message. **For more information on Error Messages, please reference Section 15.**

11. Performance

11.1 Method Comparison

iSED/iSED ELITE ESR 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 two ESR methods since the reference method is known to be subject to variables.[6]

Results of Passing Bablok regression analysis:

Variable X	Westergren
Variable Y	iSED ELITE
Sample Size	200

y= 1.000000 + 1.000000 x	
Systematic Differences	
Intercept A	1.0000
95% CI	-0.4296 to 2.3056
Proportional Differences	
Slope B	1.0000
95% CI	0.9444 to 1.0704
Random Differences	
Residual Standard Deviation (RSD)	9.7999
±1.96 RSD Interval	-19.2078 to 19.2078
Linear Model Validity	
Cusum Test for Linearity	No significant deviation from linearity (P=0.28)

11.2 Precision

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

iSED/iSED ELITE results:

Run #/Range	10--20	20--40	40--60	60--105
Run 1	13	21	48	101
Run 2	13	22	52	102
Run 3	14	22	47	99
Run 4	13	22	46	111
Run 5	12	21	53	100
Run 6	12	22	51	98
Run 7	13	24	51	100
Run 8	11	24	52	104
Run 9	13	24	49	101
Run 10	13	25	52	110
Average	12.7	22.7	50.1	102.6
SD	0.82	1.42	2.42	4.48
% CV	6.48	6.25	4.84	4.36

11.3 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.

11.4 Carryover

Carryover testing was performed to demonstrate the sequence of sample testing does not affect measured values.

iSED/iSED ELITE results:

Sample	Run 1	Run 2	Run 3	Run 4	Average
Sample 1a	70	68	74	67	69.8
Sample 1b	73	71	74	75	73.3
Sample 2a	7	6	7	7	6.8
Sample 2b	5	5	5	5	5.0
% Carryover	3.1	1.6	2.9	3.2	**2.7**

12. Test Credits

In order to process and analyze samples, tests, known as ‘credits’, must be downloaded onto the instrument from a Test Card preloaded with tests of various quantities.

12.1 Downloading Credits from Test Card

The Home screen (Figure 23) and the Maintenance sub-menu (Figure 24) 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 located on the front right corner of the iSED/iSED ELITE with the arrow facing upward and forward (Figure 25).

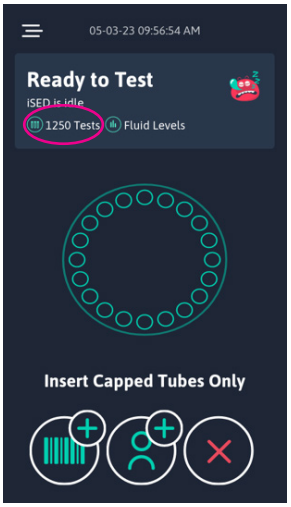


Figure 23

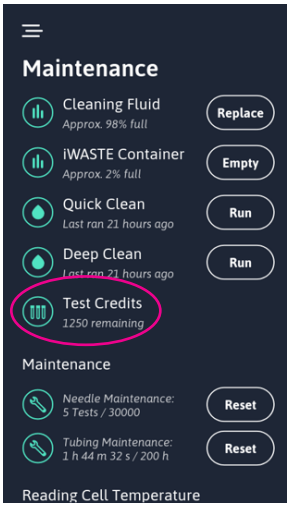


Figure 24

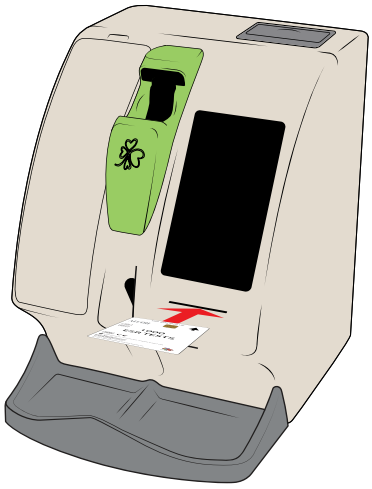


Figure 25

Once a test card 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 26). If the user taps the “Confirm” bubble, all 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 27).

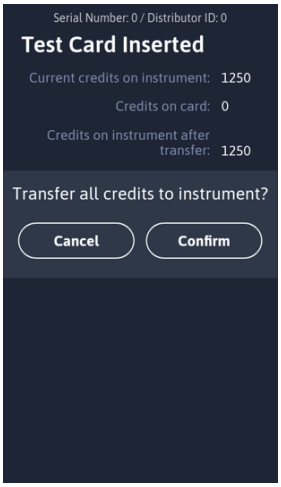


Figure 26

Figure 27

13. Routine Maintenance

13.1 Replacing Printer Paper

A green LED light around the printer paper feed button will flash to indicate it is out of paper. To replace the printer paper in the instrument, the procedure below should be followed:

1. Pull the lever in Figure 28 until the lid is released from its locked position.
2. Open the paper cup lid and remove the remaining paper.
3. Insert thermal paper roll into the printer with the paper unwinding from the bottom of the roll.
4. Reel off a few inches from a new roll of paper. Hold approximately 2 inches of paper outside the printer as you place the new roll into the reservoir.
5. Close the lid by applying equal amounts of pressure on each side ensuring the lid is in the locked position.

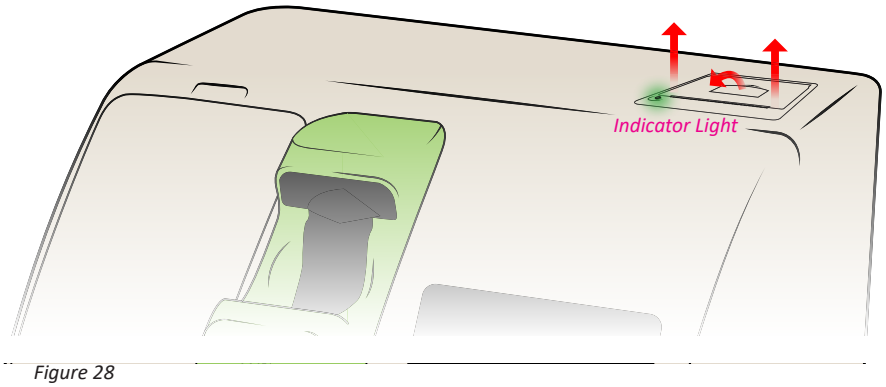
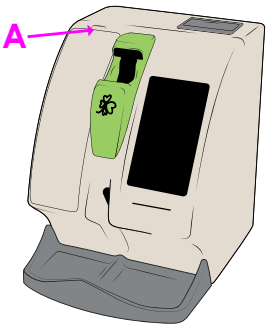


Figure 28

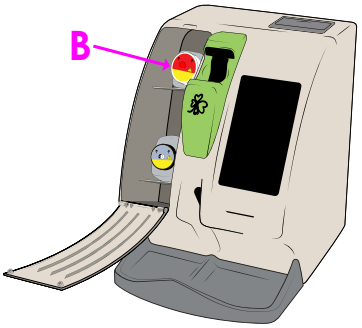
13.2 Replacing/Emptying the iWASTE Bottle

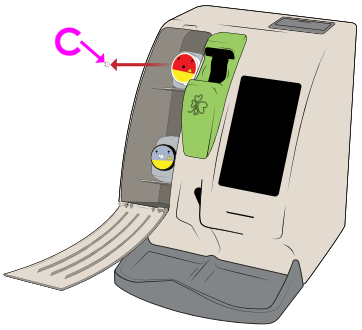


WARNING: Wear Personal Protective Equipment (PPE) such as protective gloves and safety glasses during this operation.

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

1. Open the front door to access the bottle compartment (A).
2. Locate the waste bottle in the upper compartment (B).
3. Disconnect the LUER connector (C) from the waste bottle screw cap.
4. Remove the waste bottle from the instrument and dispose of according to your laboratory biologic waste protocol.
5. Replace the iWASTE bottle in the upper compartment (B), and **firmly** reconnect the LUER connector (C) on the plastic screw cap with the **vent hole positioned at top.**
6. Close the front door (A).
7. Press Waste Container “Empty” button in the Maintenance sub-menu to reset the counter to 0% full (Figure 29).





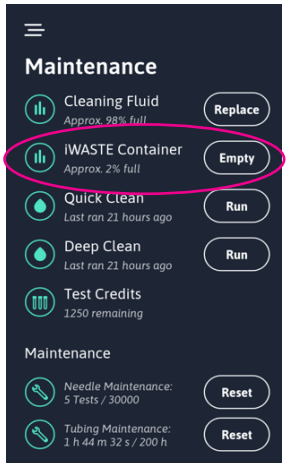


Figure 29

NOTE: Be careful not to kink the line when replacing the bottle.

NOTE: It is recommended that the waste bottle be emptied daily. This procedure can be performed without the waste alarm being triggered.

13.3 iWASTE Bottle Full Indicators and Alarms

In the case of a full iWASTE bottle, a warning message will appear on the screen and be accompanied by an alarm alerting the operator of an error or warning message.

WARNING: This action should be done when this message appears.

Full Waste Bottle

In the event the iWASTE bottle is full, the below error message (Figure 30) will appear on the screen and can be resolved by first replacing or emptying the iWASTE container and then pressing “Empty” to clear the error and continue testing.

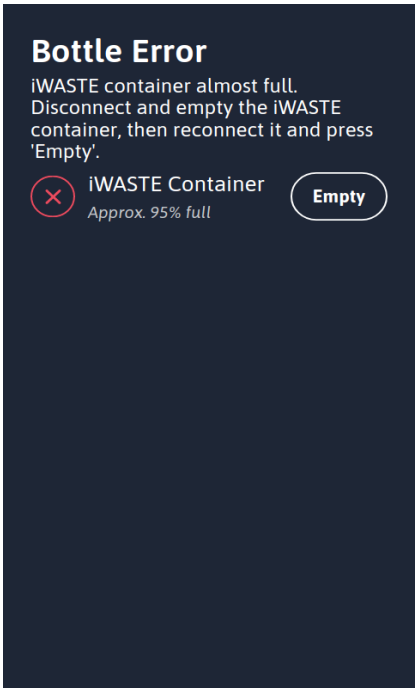
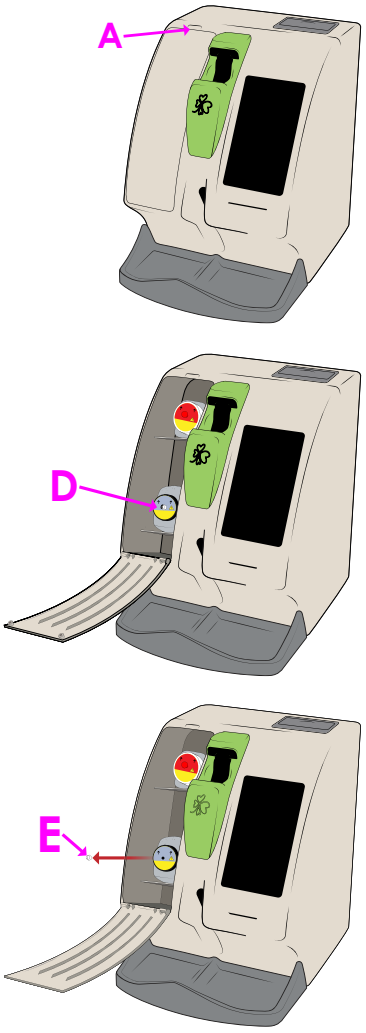


Figure 30

“Empty” button: This option must be selected immediately after the operator replaces the iWASTE bottle. The iWASTE bottle counter will automatically reset once this button has been pressed, and the instrument will continue with the sample loading or washing process. **For instructions on replacing the iWASTE bottle, please refer to Section 13.2.**

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

13.4 Replacing iWASH Bottle



1. Open the front door to access the bottle compartment (A).
2. The iWASH bottle is located in the lower compartment (D).
3. Disconnect the LUER connector (E) from the iWASH bottle screw cap.
4. Remove the empty iWASH bottle, unscrew the cap, and replace it with a new iWASH bottle.
5. Place the new iWASH bottle in the lower compartment and firmly reconnect the LUER connector (E) on the plastic screw cap with the **vent hole positioned at top**.
6. Close the front door (A).
7. Press the Cleaning Fluid “Replace” button in the Maintenance sub-menu to reset counter to 100% full (Figure 31).

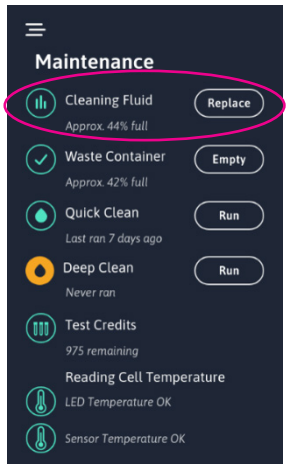


Figure 31

NOTE: Be careful not to kink the line when replacing the bottle.

NOTE: The instrument is programmed to perform 1 self-clean after being idle for 15 minutes following the last sample tested. The process takes approximately 1 minute and utilizes 4.5 mL of iWASH. Once completed, testing can resume as normal.

NOTE: This procedure can be done without the wash alarm being triggered.

13.5 iWASH Bottle Empty Indicators and Alarms

When the iWASH bottle is empty, a message will appear on the screen and be accompanied by an alarm alerting the operator of the error or warning message.

WARNING: This action should be done when this message appears.

Empty iWASH Bottle

In the event the iWASH bottle is empty, the below error message (Figure 32) will appear on the screen and can only be resolved by first replacing the iWASH bottle then selecting “Replace” to clear the error and continue testing.

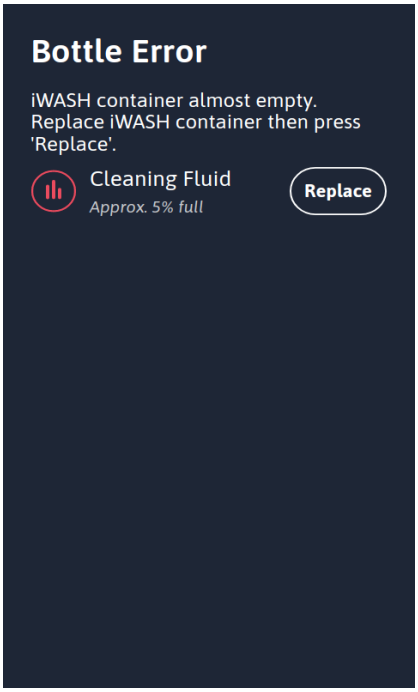


Figure 32

“Replace” button: This option must be selected immediately after the operator replaces the iWASH bottle. The iWASH bottle counter will automatically reset once this button has been pressed, and the instrument will continue with the sample loading or washing processes. **For instructions on replacing the iWASH bottle, please refer to Section 13.4.**

14. Preventative Maintenance

It is recommended that the instrument be kept free from dusty and particulate environments at all times for best performance. If such environments are unavoidable, periodically inspect interior surfaces and rear fan assembly for heavy dust accumulation and clean as needed.

14.1 Exterior Cleaning

- Do not use sterilizing solutions
- Prolonged exposure to alcohol or strong cleaners may damage the instrument housing
- Only use water and mild detergents to wipe the surface of the instrument sample tray

14.2 Deep Cleaning

The analyzer will prompt the user when the Deep Clean is needed. This prompt will be located in the notification area at the top of the Home screen (Figure 33). The frequency for Deep Cleaning is monthly or every 1000 samples run, whichever comes first.
This procedure requires a sodium hypochlorite solution to clean the aspiration pathway from the needle to the reading cell. The deepCLEAN Cleaning Solution is optimized for Deep Cleaning the iSED/iSED ELITE 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.

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)

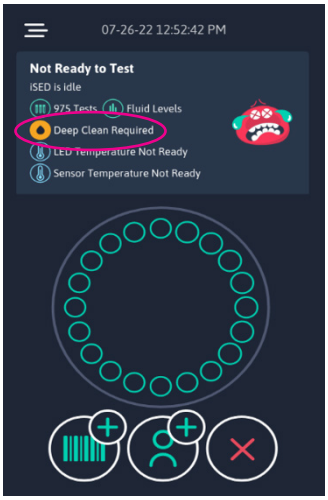


Figure 33

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% sodium hypochlorite solution to an unused, plain 13 x 75 mm tube.
3. Cap tight.

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

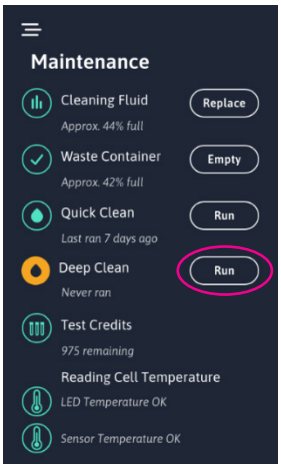


Figure 34

Initiating the Deep Cleaning Process:
1. Press Deep Clean "Run" button in the Maintenance sub-menu to start a Deep Clean (Figure 34). The analyzer will check for sufficient iWASH and iWASTE 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, 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.

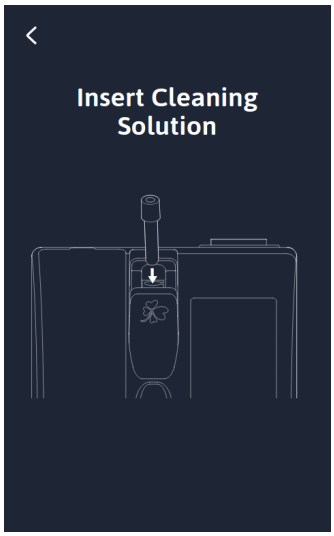


Figure 35

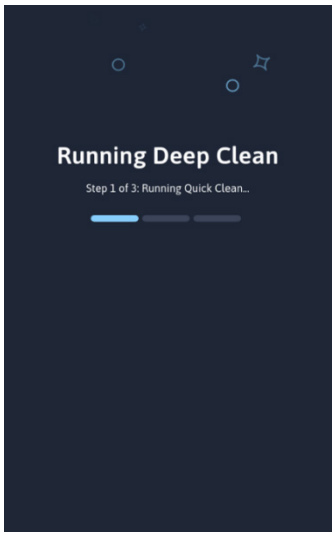


Figure 36

3. The analyzer will automatically run 2 wash cycles, perform the Deep Clean (3 minutes), and conclude by running 2 additional wash cycles (Figure 36). During the 3 minute Deep Clean, the device will appear to be idle while the fluidic system soaks in deepCLEAN Cleaning Solution/sodium hypochlorite.
4. The analyzer will present the tube of Cleaning Solution back to the loading port where it should be removed.

> **NOTE:** The manually prepared tubes of 6-7% sodium hypochlorite, if used instead of deepCLEAN, should be discarded and prepared fresh the 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.

14.3 “Tubing Change is Required” Message

After 200 hours of continuous pump use, iSED/iSED ELITE will generate a message that a ‘Tubing Change is Required’. This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use. Please contact ALCOR Scientific Technical Support or your authorized representative.

14.4. 30,000 Test Aspirations Message

After 30,000 aspirations, iSED/iSED ELITE will generate a message to contact ALCOR Scientific Technical Support. Please contact ALCOR Technical Support or your authorized representative. This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use.

14.5 Replacing the Fuse

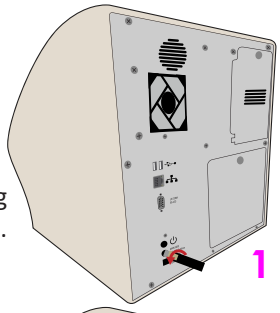
CAUTION: Unplug the instrument from the AC wall outlet before replacing the fuse.

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

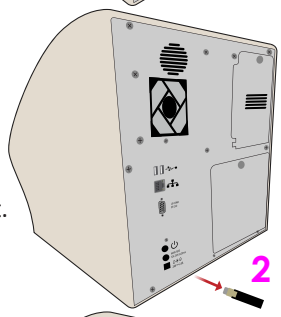
Materials Needed:

- 3/16 inch blade Screwdriver
- Fuse T2A 250V 5x20 mm

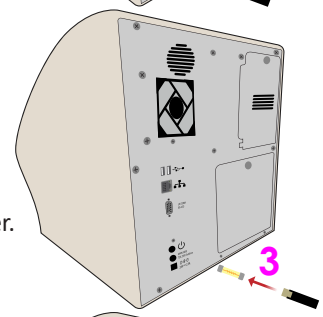
1. Remove fuse holder on the rear of the instrument by gently pushing with the screwdriver and rotating counterclockwise.



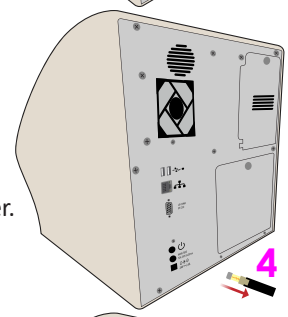
2. Remove the fuse holder from the instrument.



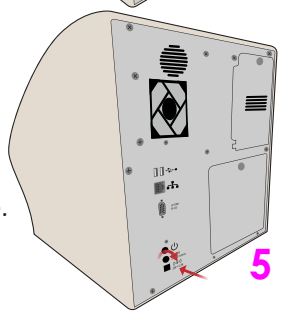
3. Remove the old fuse from the fuse holder.



4. Insert the new fuse of the same type and rating into the fuse holder.



5. Return the fuse holder into the instrument and lock it back into place by turning it clockwise.



14.6. iWASH and iWASTE Cap Replacement

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

14.7. Spare Parts

Spare parts can be purchased by calling ALCOR Scientific Customer Service or your local authorized iSED/iSED ELITE distributor. Please contact ALCOR Scientific Technical Support for help determining what parts are needed.

15. System Status, Error Codes, and Warning Messages

The instrument touchscreen display has a highlighted “window” at the top of the Home screen where all active system messages appear. The Status Window is dedicated to System Status Messages and the number of Test Credits remaining (Figure 37). An animated emoticon, named “SEDRick,” on the right side of the status window provides a quick visual reference to general operating status.

15.1 System Status Messages

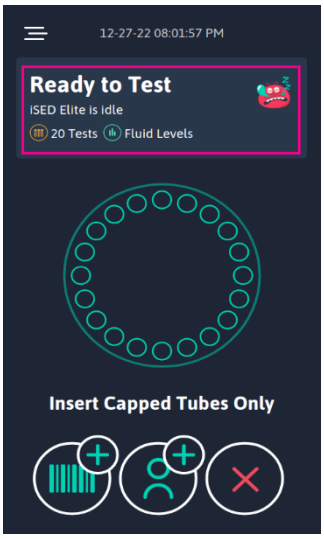


Figure 37

Each of these messages display on the touch screen as the system is processing specimens:

Status	Status Explanation
"Ready to Test	Device is Ready or Not Ready to accept sample tubes. Device is not ready for a number of reasons, such as any blocking errors, Reading Cell Temperature warm up period, or No test credits are available.
number "Tests"	'Quantity' Test credits available Low – Purchase More Tests (Alarm) 0 – No Tests Available
Fluid Levels	**Green** – No errors or warnings in regards to bottle capacity. **Yellow** – iWASTE bottle is nearing full capacity and/or iWASH bottle is nearing empty. **Red** – iWASTE bottle is completely full and/or iWASH bottle is completely empty.

Device Status Text	Status Explanation
"iSED is Idle"	All scheduled testing complete.
"iSED is scanning"	iSED/iSED ELITE is attempting to scan a sample's barcode.
"iSED is positioning rotor at home"	iSED/iSED ELITE is returning the mixing wheel to its Home position.
"iSED is positioning rotor for sample loading"	iSED/iSED ELITE is moving the mixing wheel to the next open position.
"iSED is positioning for ejection"	iSED/iSED ELITE is moving the mixing wheel to position a sample for ejection into the collection tray.
"iSED has loading port blocked"	iSED/iSED ELITE's finger safety sensor is blocked, preventing the mixing wheel from moving.
"iSED is waiting for cuvette"	iSED/iSED ELITE is ready for user to insert a new sample into the loading port (repeating beeps will sound).
"iSED is withdrawing from cuvette"	iSED/iSED ELITE is piercing the sample tube and aspirating sample.

“iSED is mixing”	Sample wheel rotating to mix all samples.
“iSED is ejecting cuvette”	Testing is complete and tube is being ejected from iSED/iSED ELITE instrument.
“iSED is calibrating tail sensor”	iSED/iSED ELITE is preparing the tail sensor for detection of blood from next sample.
“iSED is priming reading cell”	iSED/iSED ELITE is preparing the reading cell for measurement of next sample.
“iSED is positioning sample for withdrawal”	iSED/iSED ELITE is moving the mixing wheel to position the next sample for piercing and aspiration.
“iSED is measuring sample”	Sample is positioned in reading cell and analysis is underway.
“iSED is calculating result”	iSED/iSED ELITE is performing the calculations to provide an ESR measurement.
“iSED is resetting Needle”	iSED/iSED ELITE is recovering from an error by resetting the piercing system position.
“iSED is resetting Ejector”	iSED/iSED ELITE is recovering from an error by resetting the ejector position.
“iSED is washing”	iSED/iSED ELITE is performing a quick clean cycle to remove residual sample and prevent clogging.

Device Error Status Text	**Status Error Explanation**
“iSED has rotor error”	Device is in an error state related to the mixing wheel.
“iSED has needle error”	Device is in an error state related to positioning the piercing system.
“iSED has ejector error”	Device is in an error state related to the sample extractor.
“iSED has withdrawal error”	Device is in an error state related to sample aspiration.

NOTE: Unless the third line starts with “iSED is Warning” or “iSED is in Error”, the operation is normal. Descriptions for iSED/iSED ELITE Warning and Error messages are listed in the following sections.

15.2 System Warning and Error Messages

In the event of a system warning or error, the following alert will appear on the instrument’s screen and be accompanied by the appropriate error message (see examples in Figures 38 and 39):

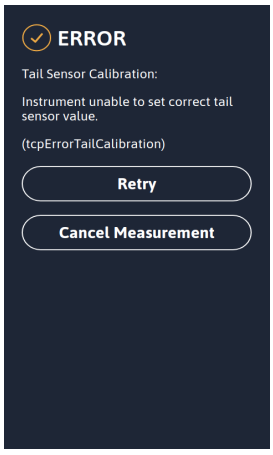


Figure 38

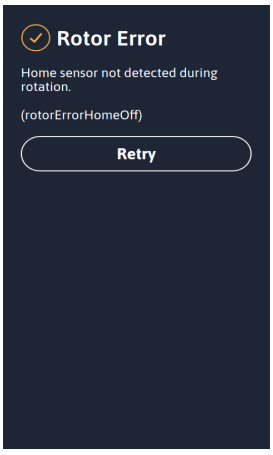


Figure 39

The next table shows examples of the warning or error messages the user may see while operating the instrument and some possible solutions. Contact ALCOR Scientific Technical Support if the error cannot be resolved by any solution provided below:

Error Code	On Screen Text	Troubleshooting
N/A	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	'iWASTE Bottle Full' message displayed and Alarm	Remove and replace iWASTE bottle. See Section 13.5
N/A	'Wash Bottle Empty Message' displayed and Alarm	Remove and replace iWASH bottle. See Section 13.4
N/A	Paper Error/Out (Flashing Green Light)	Replace paper; see section 13.1
rotorErrorFingerDetect	Rotor Error: Loading Port obstruction detected during rotor movement.	Check for obstructions in the loading port. If no obstructions are present, power off device, remove all sample tubes, and power on device again. If the error appears again, contact Technical Support.
rotorErrorHomeOff	Rotor Error: Home Sensor not detected during rotation	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
rotorErrorNeedleOff	Rotor Error: Unable to move rotor. Needle is in error state.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
rotorErrorEjectorOff	Rotor Error: Unable to move rotor. Ejector is in error state.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
rotorErrorPosReq	Rotor Error: Rotor requested to move to invalid position.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
rotorErrorStationUndefined	Rotor Error: Rotor requested to move to undefined station.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
rotorErrorUndefined	Rotor Error: Rotor in undefined state.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.

Error Code	UI Text	Solutions
needleErrorSensorsUndefined	Needle Error: Invalid sensor state. Home and Up Sensor both active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
needleErrorHomeSens	Needle Error: Unable to reach Home position. Please check Piercing System for obstructions.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
needleErrorUpSensor	Needle Error: Unable to reach Up position. Please check Piercing System for obstructions.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
needleErrorProbeTube	Needle Error: Invalid sensor state. Home and Probe sensors both active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
needleErrorNoTube	Needle Error: No Tube detected when tube was expected.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
needleErrorNoMovement	Needle Error: Needle did not move from Home position after requesting it to move up.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorSensorsAllSensorOff	Ejector Error: Invalid Sensor state. All position sensors active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorSensorsHomeLockOff	Ejector Error: Invalid Sensor state. Home and Lock position sensors both active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorSensorsHomeOutOff	Ejector Error: Invalid Sensor state. Home and Out position sensors both active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorSensorLockOutOff	Ejector Error: Invalid Sensor state. Lock and Out position sensors both active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorHomeSens	Ejector Error: Unable to reach Home position. Check for obstructions.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorLockSensor	Ejector Error: Unable to reach Lock position. Check for obstructions.	Ejector Error: Unable to reach Lock position. Check for obstructions.
ejectorErrorOutSensor	Ejector Error: Unable to reach Out position. Check for obstructions.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
ejectorErrorTubeEjection	Ejector Error: Unable to eject tube. Check for obstructions near ejection area.	Remove source of jam. Sensor will reset once tube is removed. If problem persists, contact Technical Support
ejectorErrorPositionUndefined	Ejector Error: Invalid sensor state. No position sensors active.	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
mErrorOtherProcessRunning	Measure Error: Another process is running	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.

Error Code	UI Text	Solutions
mErrorSampleTypeNotSet	Measure Error: Sample type not set	Restart the unit, eject the sample and re-enter the sample. If the error appears again, contact Technical Support.
mErrorReactorTriggerDelay	Measure Error: Reactor Trigger Delay. Remix sample for additional time and run again.	Remix SEDiTROL or Proficiency sample for additional time and run again.
mErrorFlowIn	Measure Error: Flow In. No flow detected when pumping into Reading Cell	Reading cell was unable to detect flow of sample stream during laminar flow. After withdrawal sample did not move into reading cell. Check sufficient sample is in the sample tube and run again. If the error appears again, contact Technical Support.
mErrorFlowOut	Measure Error: Flow Out. No flow detected when discarding sample from Reading Cell	Reading cell was unable to detect flow of sample stream when discarding. Sample still inside the reading cell. Run a Quick Clean and continue with next samples. If error persists, run a Deep Clean and/or contact Technical Support.
wpErrorMovement	Withdrawal Error: Unable to position Inversor	Needle is in error state while attempting to pierce sample. Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.
wpErrorTailCalibration	Withdrawal Error: Unable to calibrate Tail Sensor. Perform Deep Clean. Otherwise contact Technical Support.	The reading cell is unable to set the correct value for the reading cell tail sensor. Perform Deep Clean. If the error appears again, contact Technical Support.
wpErrorNoTube	Withdrawal Error: No Sample Tube Detected. Measurement Aborted.	During the piercing phase, the sample tube was not detected (probe tube not activated after down sensor reached). Check to make sure sample was loaded. Run sample again.
wpErrorSampleNotInMixSustain	Withdrawal Error: Sample has not performed required mixing cycles.	Process start requested when the sample did not complete the required mixing phase. Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.
wpErrorOtherProcessRunning	Withdrawal Error: Another process is running preventing withdrawal from executing.	Process start requested when other processes are running (wash process prime process measure process). Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.

Error Code	UI Text	Solutions
Barcode Error	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. If the tube has a barcode, try repositioning it. Select “Run Test” to skip data entry. Remove tube to start manual entry.
washPumpTimeout	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. Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.
washMovement	Quick Clean Error: The pump did not move correctly	The pump did not move correctly. Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.
washUnableToSetCellT100	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. Check if there is sufficient iWASH fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH bottle was replaced. If iWASH is full, contact Technical Support.
washUnableToSetTailT100	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. Check if there is sufficient iWASH fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH bottle was replaced. If iWASH is full, contact Technical Support.
washUnableToDetectCellEmpty	Quick Clean Error: The Quick Clean process is unable to detect a change on optical value for the READING CELL after the iWASH fluid has been discarded. Check iWASH Bottle is connected and has sufficient fluid available	The wash process is unable to detect a change in optical value for the tail sensor after the washing liquid has been discarded. Check if there is sufficient iWASH fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH bottle was replaced. If iWASH is full, contact Technical Support.
washUnableToDetectTailEmpty	Quick Clean Error: The Quick Clean process is unable to detect a change in optical value for the TAIL SENSOR after the iWASH fluid has been discarded. Verify tubing is secured in the Tail Sensor	The wash process is unable to detect a change in optical value for the tail sensor after the washing liquid has been discarded. Check if there is sufficient iWASH fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH bottle was replaced. If iWASH is full, contact Technical Support.
washCellEmitterCurrentToLow	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. Contact Technical Support.

Error Code	UI Text	Solutions
washCellEmitterCurrentToHigh	Quick Clean Error: Current for the Reading Cell Emitter is higher than the allowed higher limit. Contact Technical Support	Quick Clean Error: Current for the reading cell emitter is higher than the allowed higher limit. Contact Technical Support
washTailEmitterCurrentToLow	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. Contact Technical Support.
washTailEmitterCurrentToHigh	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. Contact Technical Support.
washOtherProcessRunning	Quick Clean Error: Wash requested when another process is running	Wash requested when another process is running. Restart the unit, eject the sample, and re-enter the sample. If the error appears again, contact Technical Support.
scErrorCardRemoved	Smart Card Error: Card removed. Please try again	Card was removed during operation. Try inserting card again.
scErrorCardType	Smart Card Error: Card Type Error. Please try again	Card model/type is not valid. Try inserting card again. If unsuccessful, contact Technical Support.
scErrorCipherSize	Smart Card Error: Cipher Size Error. Please try again	Card cannot be decrypted due to an invalid memory dimension. Restart unit and try again. If error appears again, contact Technical Support.
scErrorCcmand	Smart Card Error: Command Error. Please try again	System has passed an incorrect command to the smart card controller. Restart unit and try again, If error appears again, contact Technical Support.
scErrorStartAddress	Smart Card Error: Start Address Error. Please try again	System has requested to read/write to a wrong starting address. Restart unit and try again, otherwise contact Technical Support.
scErrorEndAddress	Smart Card Error: End Address Error. Please try again	System has requested to read/write to a wrong ending address. Restart unit and try again. If error appears again, contact Technical Support.
scErrorMemoryRange	Smart Card Error: Memory Range Error. Please try again	System has requested to read/write a section of memory of the wrong dimension. Restart unit and try again. If error appears again, contact Technical Support.
scErrorErasing	Smart Card Error: Erasing Error. Please try again	Error encountered during Smart Card error counter erase operation. Smart Card is still valid. Restart unit and try again. If error appears again, contact Technical Support.
scErrorNonAlcorSmart	Smart Card Error: Non ALCOR Smart Card Error. Please insert a valid card	The inserted Smart Card is not manufactured by ALCOR Scientific. Contact Technical Support.

Error Code	UI Text	Solutions
scErrorPersonalizationIncorrect	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. Contact Technical Support.
scErrorProtocolType	Smart Card Error: Protocol Type Error. Please try again	Inserted Smart Card does not use “Asynchronous” protocol. Restart unit and try again. If error appears again, contact Technical Support.
scErrorPscPresentation	Smart Card Error: PSC Presentation Error. Please try again	Error during presentation of Programmable Security Code, Smart Card cannot be written, procedure is aborted. Restart unit and try again. If error appears again, contact Technical Support.
scErrorSizeNotOk	Smart Card Error: Size Not Okay Error. Please try again	Inserted Smart card contains a denomination that is not allowed. Contact Technical Support.
scErrorUnableToWriteEEprom	Smart Card Error: Unable to write EEprom. Please try again	System is unable to store credits into internal memory. Restart unit and try again. If error appears again, contact Technical Support.
scErrorRestoreOriginalAvailability	Smart Card Error: Restore Original Availability Error. Please try again	System is unable to write availability value before smart insertion back to internal memory. Restart unit and try again. If error appears again, contact Technical Support.
scErrorUnhandledRequest	Smart Card Error: Unhandled Request Error. Please try again	Value written to request register not handled by the process. Restart unit and try again. If error appears again, contact Technical Support.
scErrorUnableToClearEeprom	Smart Card Error: Unable to Clear EEprom. Please try again	During transfer, system unable to clear internal memory availability value. Restart unit and try again. If error appears again, contact Technical Support.
scErrorTransferContentInvalid	Smart Card Error: Transfer Content Invalid. Please try again	Content of transfer card is not valid. Restart unit and try again. If error appears again, contact Technical Support.
scErrorCardUsed	Smart Card Error: Card has already been used. Please Insert a valid card	Inserted card has already been used; card should be destroyed. If it is known that card has not been used on any analyzer, contact Technical Support.
scErrorCardCloned	Smart Card Error: Card has been cloned. Please insert a valid card	Inserted card has been already downloaded onto this unit. Card has potentially been cloned. Contact Technical Support.

15.3 Sampling Error Message

In the event of a sampling error, the following messages will be printed:

Error Message (Printed or Logged)	Explanation	Solutions
ESR_ERR_NOFLOW	This error appears when the system is able to withdraw the correct volume from the sample tube but is not able to detect the sample moving in the reading position.	Contact Technical Support.
ESR_ERR_NOSPIKE	Human blood, when flowed into the reading cell, must cause a drop in light transmission. This error indicates the detection of an anomalous sample.	New specimen should be drawn.
ESR_ERR_REVERSE	Usually a hematological sample, after being positioned into the reading cell, starts to form rouleaux (RBC aggregates) which increases light transmission. If the signal detected decreases instead, the error code is provided, indicating a nonstandard condition. It is possible the sample is not of human blood.	New specimen should be drawn.
ESR_ERR_NOPOINTS	This error appears when the reaction takes too much time to develop, or when the drop of the signal of error 3 takes too much time to end. This is an indication of hyperviscosity of the sample or hydraulic malfunctioning.	New specimen should be drawn.
ESR_ERR_TOODARK	Indicates a very high HCT of the sample with a consequential unreliable result. Instead of providing an inaccurate result, the system provides the error message.	New specimen should be drawn.
ESR_ERR_TOOCLEAR	Indicates a very low HCT of the sample with a consequential unreliable result. Instead of providing an inaccurate result, the system provides the error message.	New specimen should be drawn.
ESR_ERR_WITHDRAWAL	System is not able to aspirate the correct volume from the sample tube.	Check for sufficient volume in sample tube. If error appears again, contact Technical Support.
ESR_ERR_FLOW_IN	System unable to move the sample inside the reading cell.	Check for sufficient volume in sample tube. If error appears again, contact Technical Support.
ESR_ERR_FLOW_OUT	System unable to move the sample out of the reading cell.	Contact Technical Support.
ESR_ERR_ACQUISITION	Acquisition measure step unable to be completed.	Contact Technical Support.
ESR_ERR_TRIGGERDELAY	Control material did not start the reaction in the expected amount of time.	Remix sample for additional time and rerun test. If error appears again, contact Technical Support.
ESR_ERR_LOW_CONTROL_HIGH	System detects a high value on a Low control.	Remix sample for additional time and rerun test. If error appears again, contact Technical Support.
ESR_ERR_HIGH_CONTROL_LOW	System detects a low value on a High control.	Remix sample for additional time and rerun test. If error appears again, contact Technical Support.

15.4 Print Out of Sampling Error Message

In the event of a sampling error, the instrument will try to resolve it automatically up to a maximum of three (3) attempts. If after the third attempt, the instrument is unable to resolve the sampling error, an error message will be printed as follows:

==========	
Date: 03/25/2013	Date of analysis
Time: 13:36:24	Time result printed
iSED Sn: 00001	Instrument serial number
ID: **812409**	Barcoded sample identification
Error: ESR_ERR_FLOW_IN	
==========	

15.5 Troubleshooting

The following Troubleshooting Chart aims to help diagnose some simple analyzer problems and offer solutions for resolving them.

Situation	**Possible Causes**	**Solutions**
Instrument will not power ON	Loose power connections	Check all power connections at the rear of instrument, power supply, and wall outlet. Reconnect power cord at all locations. Wait 30 seconds. Plug back in.
	Bad fuse	Remove fuse cap located directly above power connection on rear of instrument. Check fuse and replace if necessary. See Section 13.6.
Sample tube stuck in the wheel	Tube dropped during sample entry	Power OFF the instrument and manually remove the tube(s) from the wheel.
Touch screen not responding	Touch screen is out of calibration or analyzer is frozen	Power cycle the analyzer and check if problem is resolved. If error appears again, contact Technical Support.
Results are running low/high	Lipemic, hemolyzed, or clotted specimen	Verify condition of specimen.
	Pre-analytical sample handling change or system error	Run controls. If results are within range, resume normal operation; if out of range, discontinue testing and contact Technical Support.
Instrument is not scanning patient barcode	Damaged, incompatible, or no barcode label	Validate barcode label.
	Barcode reader misaligned	Contact Technical Support for instruction.

For troubleshooting issues not covered in this manual, please contact ALCOR Scientific Technical Support or an authorized iSED/iSED ELITE Distributor.

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, damage or injury could result.

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 Good Laboratory Practices are followed. Please refer to and follow all local regulations, department safety guidelines, and biosafety policies for disposal of biohazardous 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 should 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.

WARNING: Empty Sample Collection Tray when full to avoid a potential biohazard spill due to broken samples.

17. ALCOR Scientific Contact Information

Technical Support

If you experience any problems while operating the instrument, please contact ALCOR Scientific or your local authorized ALCOR Scientific iSED/iSED ELITE Distributor. ALCOR Scientific offers Technical Support Monday through Friday 8:30 am-5:00 pm EST (excluding all US Federal Holidays). Technical Support can be reached at:

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	iSED serial numbers 05000 and higher and iSED ELITE
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
Sample Throughput	Up to 180/hour
Sample Stability	28 hours room temperature (18-25°C) and 48 hours refrigerated (4-8°C)
Analytical Range	1-130 mm/hr
Time to Result	Within 20 seconds after pre-programmed mixing time
Ethernet Port	For manufacturing or network LIS Connection
Serial Port	Serial RS232 DB9 port for legacy LIS connection
Barcode Scanner	Internal
Printer	Internal
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, 2.5A
Power Consumption	60W
Frequency	50-60 Hz
Over Voltage Category	Category II
Dimensions (L x W x H)	36 x 27 x 35 cm 14.17 x 10.63 x 13.78 in
Weight	12.1 kgs 26.7 lbs
Operational Altitude**	4000 Meters
Storage Altitude**	4000 Meters
Restrictions	For Professional Use Only
**** Rating of 2000 meters for iSED devices serial number 02870 and lower. Rating of 3000 meters for iSED devices with serial number 02871 – 05000. Rating of 4000 meters for iSED devices with serial number 05000 and above and all iSED ELITE devices.**	

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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2. Westergren A. *Studies of the suspension stability of the blood in pulmonary tuberculosis. Acta Med Scand.* 1921; 54: 247–82
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4. International Council for Standardization in Haematology (Expert Panel on Blood Rheology): ICSH recommendations for measurement of erythrocyte sedimentation rate. *J Clin Pathol.* 1993; 46:198-208
5. Thomas RD, Westengard JC, Hay KL, et al. Calibration and validation for erythrocyte sedimentation tests. *Arch Pathol Lab Med.* 1993; 117:719-722.
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7. Keohane EM, Otto CN, Walenga JM. *Rodak's Hematology: Clinical Principles and Applications Sixth Edition.* Elsevier; 2019.
8. Watson J, Round A, Hamilton W. Raised inflammatory markers *BMJ 2012*; 344 :e454 doi:10.1136/bmj.e454

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