



iSED[®] PRO

iSED[®] PRO Fully Automated Erythrocyte Sedimentation Rate Analyzer

OPERATOR'S MANUAL & INSTRUCTIONS FOR USE

Valid for Software Version v1.3.11









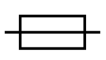


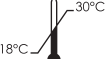







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Document History

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Symbol Reference

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

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

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

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

Notes

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

Cautions



CAUTION: Electrical caution! Unplug before handling.



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

Warnings



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



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 iSED PRO.



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.

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1. Intended Use

iSED PRO 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 of ESR

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 Fåhræus (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 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 due to 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 PRO 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 PRO 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 PRO 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

This document is the Instructions For Use for operators of all models of iSED PRO. 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. Read these Instructions for Use carefully prior to operating the analyzer and retain 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 PRO when tightly capped
- Sample volume for testing is approximately 500 µL whole blood (only 100 µL of sample volume is aspirated)
- If using false bottom/pediatric tubes, sample volume is approximately 350 µL (see note below)
- Sample should free of clots and not grossly hemolyzed or lipemic upon visual inspection (DO NOT mix vigorously!)
- Sample should be tested within 28 hours from venipuncture when stored at room temperature (18-25°C) and within 48 hours if stored refrigerated (4-8°C)
- If sample has been refrigerated, sample must be brought to room temperature for at least 15 minutes before testing

NOTE: 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 (approximately 50 µL) may be needed for priming the system in addition to the 100 µL aspirated sample volume.



WARNING: Do not load a sample if the tube stopper/cap is loose or missing. Use only tightly capped samples.

3.3 Sample Rack Requirements

Samples MUST be loaded onto the iSED PRO analyzer via a hematology rack. The iSED PRO analyzer is designed to be used with common hematology racks; there are no custom iSED PRO racks required. Samples cannot be processed if not contained in a hematology rack. Hematology racks do not need to be full in order to be loaded onto the analyzer, and every sample does not require an ESR test in order for the rack to be processed.

See iSED PRO Models (Section 4) for information on hematology rack compatibility. See Sample Rack Preparation (Section 7.2.2) for how to prepare and load hematology racks onto iSED PRO.

4. iSED PRO Models

iSED PRO is available in different configurations that accept specific third-party hematology system sample racks.

Device Name	Reference Number	Hematology System Rack Compatibility	Onboard Rack Capacity
iSED PRO Series S	112-00120-SYS	Sysmex XN Series, Mindray BC Series, Horiba Yumizen Series	12 Racks
iSED PRO Series B	112-00120-BCD	Beckman Coulter DxH Series, Cassette Type A	22 Racks (in 11 Rack Carriers)

5. Instrument Overview

The iSED PRO ESR analyzer is a fully automated ESR analyzer compatible with common hematology system racks. Racks can be loaded random access or continuously, and the analyzer can connect to the local LIS via a bi-directional interface to determine which samples require an ESR test. A robotic arm removes the sample tube from the hematology rack, scans the barcode, and places the tube on the analyzer's Mixing Wheel for mixing if an ESR test is indicated. After 3 minutes of mixing, the sample is analyzed, an ESR result is generated, and the sample is returned to its position in the hematology rack.

iSED PRO 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 maintained at 37°C (±1) 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. The measurement cycle to generate an ESR result is approximately 13.1 seconds after appropriate homogenization. Results are reported in units of mm/hr, and iSED PRO performance is correlated to the Westergren ESR method.

5.1 Parts Identification

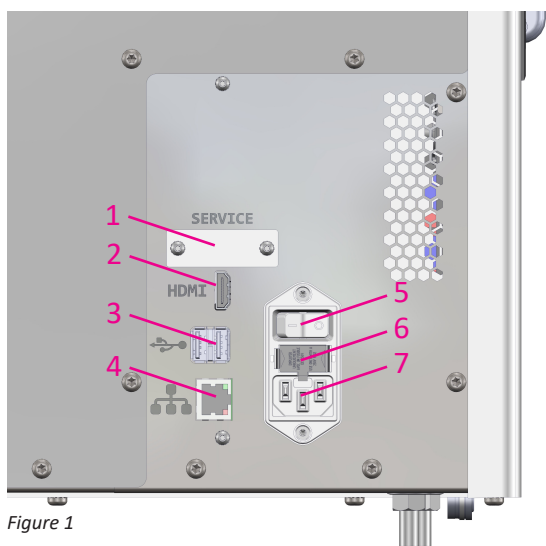


Figure 1

1	Service Port (authorized technicians only)
2	HDMI (currently unsupported)
3	USB Ports (2)
4	Ethernet Network Port
5	Main Power Switch
6	Fuses
7	AC Power Connection Port

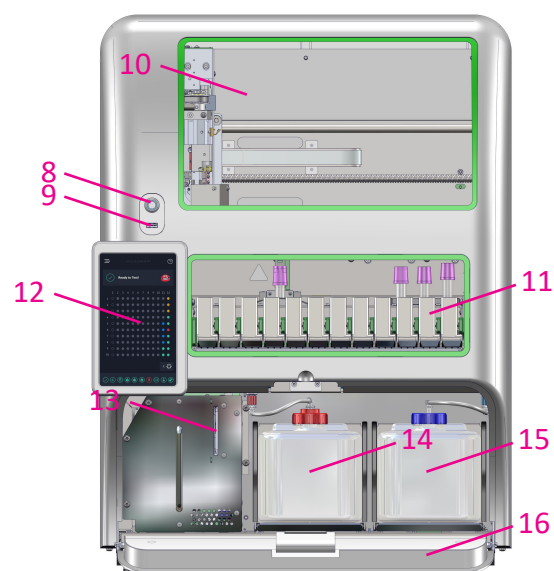


Figure 2

8	Power Button
9	USB Port (1)
10	View Port
11	Rack Loading Area
12	Touch Screen
13	Test Card Reader
14	iWASTE® PRO Bottle Compartment (shown with iWASTE PRO Waste Container)
15	iWASH® PRO Bottle Compartment (shown with iWASH PRO Wash Fluid)
16	Bottle Compartment Door

5.2 Consumables

Item	Description	Configuration	Reference Number
iSED PRO Test Card	Test Card preloaded with Test Credits	4,000 Test Credits	120-04000
		7,500 Test Credits	120-07500
		12,500 Test Credits	120-12500
		25,000 Test Credits	120-25000
		50,000 Test Credits	120-50000
iWASH PRO Wash Fluid	Bottle with screw-cap pre-filled with iWASH PRO Wash Fluid (Can be repurposed into a waste container when empty)	1 x 1.8 L	112-12-006
iWASTE PRO Waste Container	Waste bottle with screw cap	1 x 1.8 L	112-12-009
deepCLEAN® PRO Cleaning Solution	Sodium hypochlorite solution for the Deep Cleaning procedure	3 x 3.0 mL	112-12-022
SEDiTROL® Quality Control, Levels 1 & 2	Human red cell-based, bi-level, external controls for the iSED family of analyzers	1 x set of 2 tubes	DSC01
		3 x sets of 2 tubes	DSC06
Beckman Coulter Rack Carrier	2 position carrier for loading Beckman Coulter racks	1 each	112-12-010
High Capacity Thermal Printer	External thermal printer	1 each	112-12-011
Thermal Printer Paper	Printer paper for High Capacity Thermal Printer	5 pack	112-12-012

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

NOTE: The use of any other consumables could affect the performance of the instrument and will void the warranty.

5.3 Unpacking and Installation

Unpacking and installation must be performed by a trained authorized representative.

Initial iSED PRO Box Contents:

- iSED PRO instrument (1 Each)
- Power Cord (1 Each)
 - Only use approved IEC 320 C13 detachable AC power cable, 10A rating minimum
- iWASH PRO Wash Fluid (1 Each)
- iWASTE PRO Waste Container (1 Each)
- iWASH PRO Filter Cap (1 Each)
- iWASTE PRO Cap (1 Each)
- Quick Reference Guide (1 Each)
- **iSED PRO Series B only:** 11 Beckman Coulter Rack Carriers

5.4 Power Connection

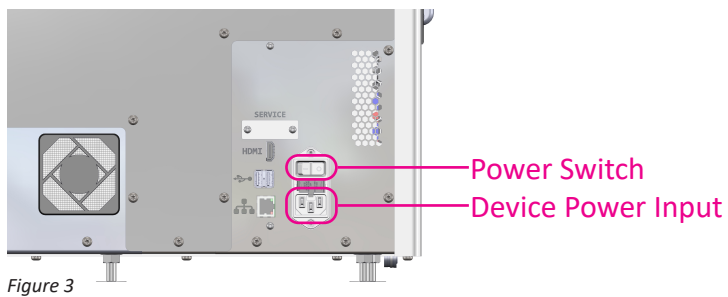


Figure 3

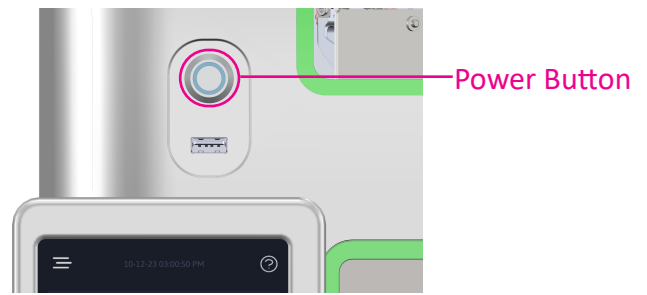


Figure 4

- Place the instrument in its permanent operating location located near a standard wall power outlet. Allow for access to power switch and appliance inlet.
- Ensure the switch at the AC power entry is set to OFF (“O”) position.
- Connect the AC Power Cord to the device power input at the rear of the device (Figure 3).
- Connect the AC Power Cord to the wall outlet.
- To power on the unit, set the AC power switch at the rear of the device to the ON (“I”) position (Figure 1). Press the glowing Power Button (Figure 4) located above the Touch Screen on the front of the device. 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; the Touch Screen will indicate when the analyzer is ready for use.



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.

5.5 Ethernet Connection

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, the iSED PRO LIS Communication Protocol (Document # 120-09-006) is available upon request from ALCOR Scientific Technical Support or your authorized representative.

5.6 USB Connection

The analyzer is equipped with 3 USB 2.0 interface connectors to facilitate the export of test results and update device software. Two ports are located at the rear of the device, and 1 is located above the Touch Screen at the front of the device (Figures 5, 6).

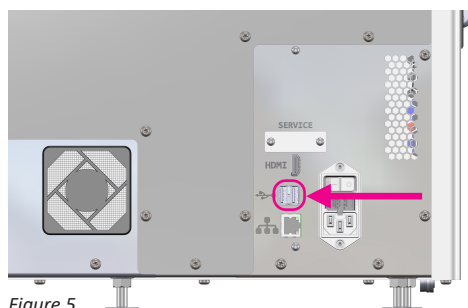


Figure 5

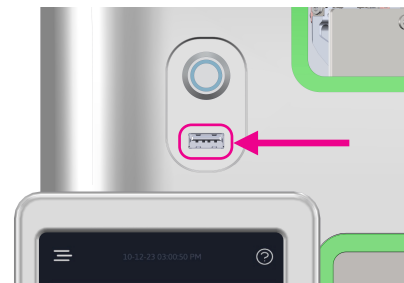


Figure 6

6. User Interface/Touch Screen

The Touch Screen contains an interactive User Interface that is used for the majority of the device interactions.

6.1 Initial Setup

iSED PRO will recognize when it is being powered on for the first time and will guide the user through the initial set up process of selecting a date/time format and language, loading consumables, and scheduling QC that best suit your laboratory's testing workflow (Figures 7-11). These settings can be changed at any time after initial setup via the device's General Settings.

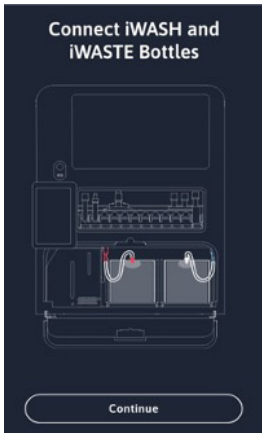


Figure 7

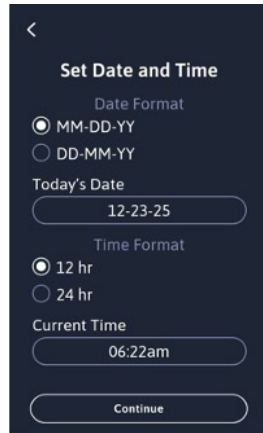


Figure 8

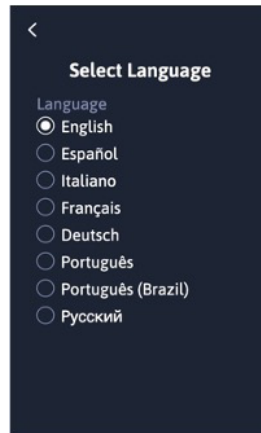


Figure 9

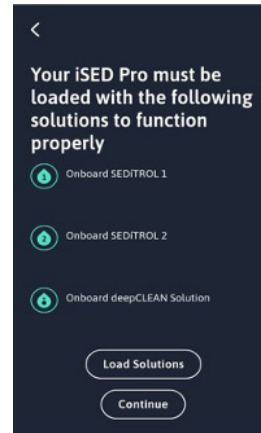


Figure 10

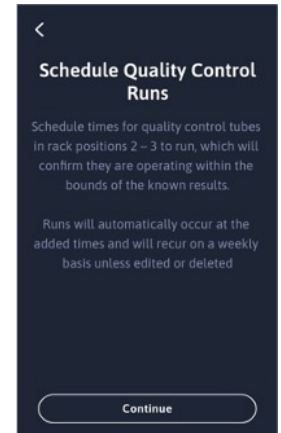


Figure 11

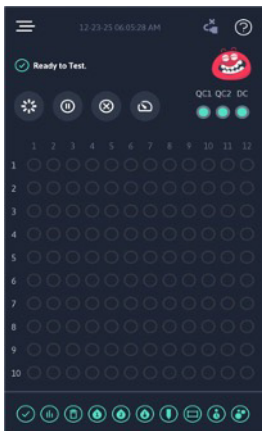


Figure 12

Once Initial Setup is complete, the analyzer is ready for basic operation, and the Home Screen in Figure 12 will be visible.

6.2 Menu Navigation

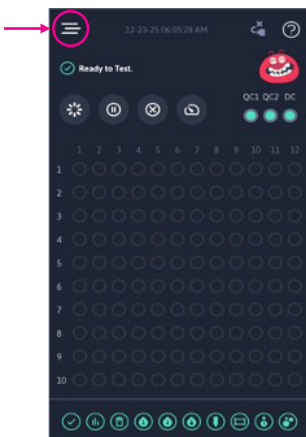


Figure 13

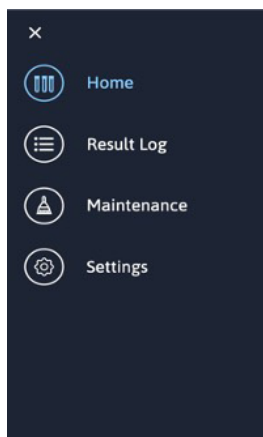


Figure 14

The instrument is operated via the Touch Screen, and all routine operations can be done by selecting or inputting data in the screens.

Navigate to the Main Menu screen by pressing the symbol in the upper left-hand corner found on many of the menu screens (Figure 13). From the Main Menu screen, navigation to the Home Screen, Result Log, Maintenance Menu, and Settings Menu can occur (Figure 14).

6.2.1 Home Screen

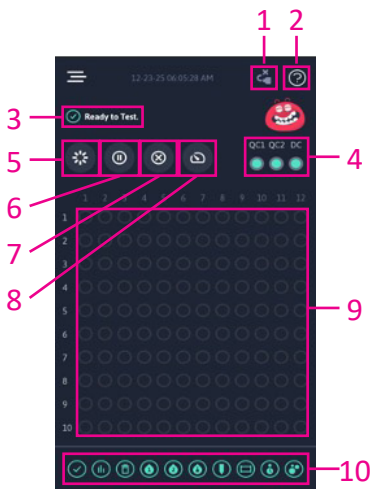


Figure 15

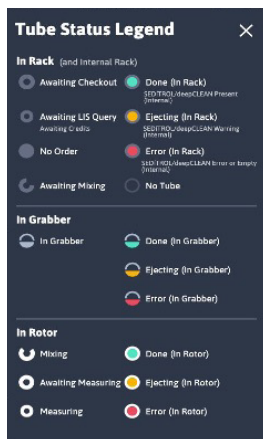


Figure 16

The Home Screen is the primary screen that will be displayed during routine use of the analyzer (Figure 15).

- LIS Connection:** Denotes the LIS connection status – green indicates the analyzer is connected to the LIS.
- Sample Legend:** Color legend for onboard sample status (Figure 16).
- Status Banner:** Displays important information about the status of the analyzer.
- Onboard Consumable Levels:** These 3 circles indicate levels of SEDIROL 1 and 2 and deepCLEAN PRO. The circles will turn from green to yellow then red when the onboard vials run out of uses. A circle will also appear red when there is an error associated with the onboard consumable.
- Mixing Wheel:** Used to view the samples currently queued and loaded in the Mixing Wheel.
- Pause:** Used to pause testing – see Section 7.2.5 for more information.
- Eject:** Used to eject racks currently onboard ISED PRO.
- STAT:** Used to mark a rack as STAT priority for testing – see Section 7.2.4 for more information.
- Sample Status:** Each circle represents a sample position. Touching any of the circles will display information about the sample in that specific position. The circles are color coded to show sample status, and the Sample Legend (Figure 16) is viewable by tapping the question mark icon (2) at the top right corner of the Home Screen.
- Maintenance Menu:** Tapping the icon bar at the bottom of the screen will bring up the Maintenance Menu which further details system status.

6.2.2 Results Log

The Results Log is organized with the most recent test results shown first (Figure 17).

- Search Function:** Operator can search for specific sample ID
- This icon opens the Filter screen which allows the operator to filter results based on sample type, barcode scan, LIS query, and LIS result transmission (Figure 18)
- This icon is used to export multiple results
- White Circle: Represents a SEDIROL Control or Proficiency Test result
- Red Circle: Represents a scanning or processing error
- Green Circle: Represents an individual test result
- The arrows can be used to expand the individual test result for more detail (Figure 19)



Figure 17

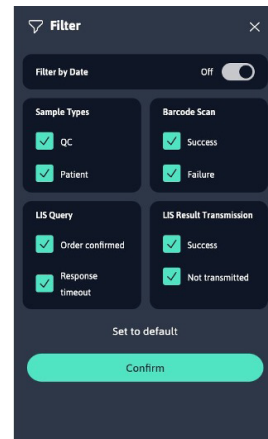


Figure 18

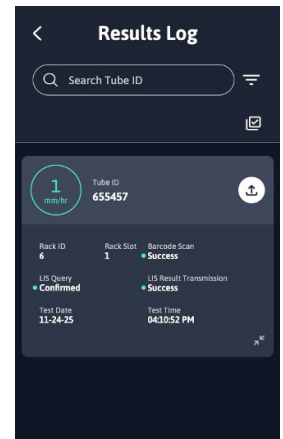


Figure 19

See Section 11.2 for details on exporting results.

6.2.3 Maintenance Menu

The Maintenance Menu provides a “dashboard” for the user-related functions for iSED PRO. When green, the circular icons indicate that the listed category is within preset limits. When an iSED PRO category is approaching a preset limit, the circular icon will turn yellow, indicating that attention is needed soon. Should the category limit be exceeded, the icon will turn red and require action to be taken. In Figure 20, displayed icons top to bottom are:

Test Credits: The “Test Credits” category displays the remaining Test Credits. When a new iSED PRO Test Card is inserted, the device will guide the user through the Test Credit transfer process.

Quick Clean: Selecting the “Run” button will start the washing process.

iWASH Container and iWASTE Container: In the “iWASH Container” and “iWASTE Container” categories, selecting the “Replace” or “Empty” buttons will initiate screen-guided instructions to replace the iWASH PRO or iWASTE PRO container and reset the counter.

Onboard SEDI^TROL Level 1, Onboard SEDI^TROL Level 2, and Onboard deepCLEAN Solution: SEDI^TROL Level 1, SEDI^TROL Level 2, and deepCLEAN PRO Cleaning Solution are stored onboard iSED PRO in the Onboard Consumables Holder. These categories provide approximate remaining usage of each of the SEDI^TROL Quality Controls and deepCLEAN PRO. Pressing replace will start the screen-guided process to replace each or all of these tubes at the user’s request. See Onboard Consumables Holder Loading Procedure (Section 9.1) for more information. Pressing any of the “Run” buttons will queue an off-schedule run of Quality Control measurement for the selected QC level or the Deep Cleaning process.

Needle Maintenance and Pump Tubing Run Time: These categories keep track of preventive maintenance needs. Pressing the “Replace” buttons will assume corresponding maintenance was performed and will reset the maintenance counter. See Preventive Maintenance (Section 16) for more information.

6.2.4 Settings Menu

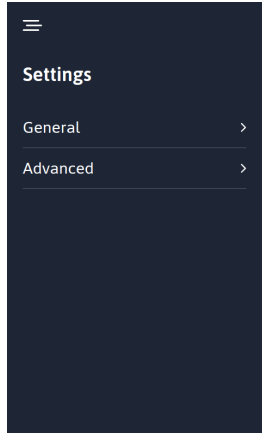


Figure 21

The Settings Menu (Figure 21) provides the user access to functions to customize the operation of iSED PRO for their laboratory environment and workflow. Using the guided setup process when the instrument is first turned on will preconfigure some of the typical settings at the time of device installation. There are 2 categories of settings: General and Advanced. The General Settings can be password protected via an “Admin Pin” if desired. If the Admin Pin is not activated, settings will not be password protected. Advanced Settings can only be changed when the Advanced Level Pin is entered.

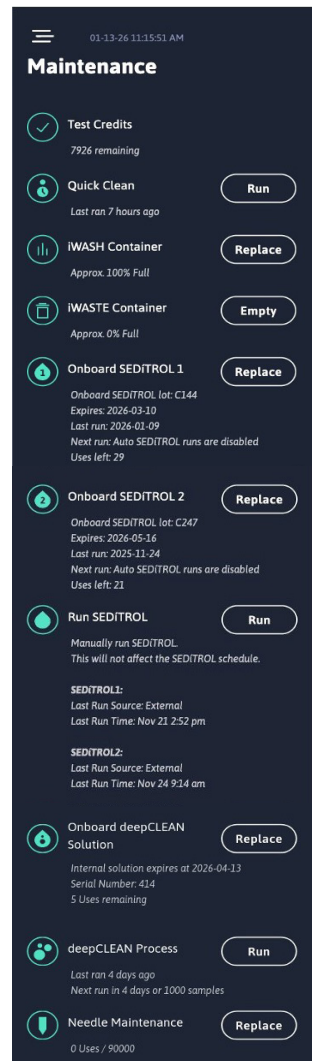


Figure 20

6.2.5 General Settings

The General Settings sub-menu (Figure 22) provides the user access to functions to customize the operation of iSED PRO for their laboratory environment and workflow. Protection of the General Settings can be disabled by selecting the Access option.

NOTE: 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.

6.2.6 Advanced Settings

The Advanced Settings sub-menu provides the user “read only” status of various operational sensors and device settings (Figure 23). The Advanced Settings level is only accessible to ALCOR Scientific qualified technicians (Figure 24).

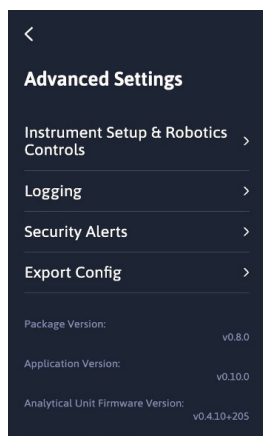


Figure 23

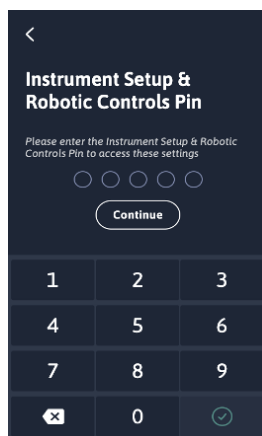


Figure 24

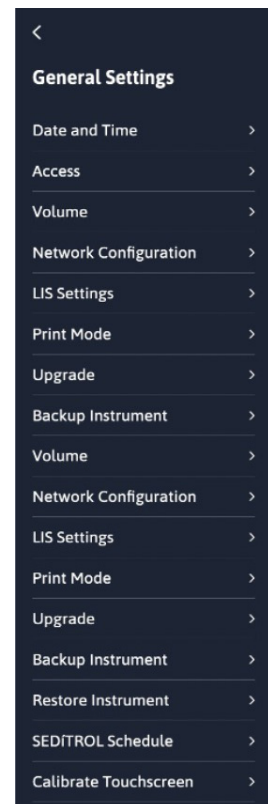
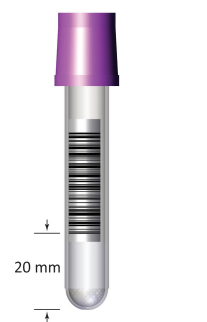


Figure 22

7. Operating Instructions

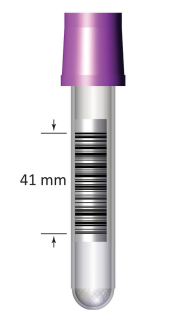
7.1 Sample Identification

Barcoded Tubes: Samples in barcoded tubes are read and identified automatically by the instrument’s internal barcode reader. Once samples are loaded onto the analyzer, a robotic arm picks up each sample tube in order to scan the barcode and place the sample tube into the Mixing Wheel if an ESR test is necessary. iSED PRO complies with CLSI AUTO02-A2 standard for barcode symbology and location.⁷ Common laboratory barcodes are supported, including Code 128, Code 39, UPC, and Code 93 formats. Barcodes do NOT need to be oriented a specific way when samples are placed into the hematology rack, but the vertical barcode location range should be noted in Figure 25.



Distance to first bar, measured from bottom of the tube to barcode

Figure 25



Maximum barcode length

Non-Barcoded Tubes: For instances when sample identification cannot be read by the internal barcode reader or if there is no barcode present, the instrument will process samples according to the selected workflow mode. See Workflow Modes (Section 7.3) for details.

7.2 Basic Operation

7.2.1 Terminology

Rack Lane: This is a position on the analyzer that accepts hematology racks (11 or 12 lanes depending on the iSED PRO model).

Rack Position: The individual sample tube's specific position within the hematology rack (for Beckman Coulter racks, the position in the Rack Carrier is noted instead).

Tube Slot: The individual sample tube's position on the iSED PRO internal Mixing Wheel prior to measurement.

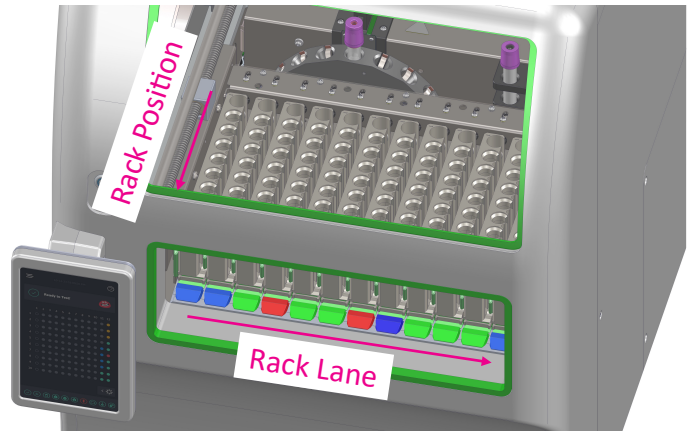


Figure 26

7.2.2 Sample Rack Preparation

iSED PRO accepts racks with any number of tubes properly loaded into the rack. The analyzer does not require pre-alignment of the tubes' barcode labels prior to loading aside from the vertical positioning specified in Section 7.1. **All sample tubes must be tightly capped with pierceable caps** (refer to Sample Requirements – Section 3.2 for more information). Racks can be loaded into any green lane (see Basic Workflow – Section 7.2.3).

For Sysmex, Mindray, and Horiba hematology racks: Rack must be loaded with sample position 1 in the front (see Figure 27).

For Beckman Coulter hematology racks: Racks must be placed in the Rack Carrier before being loaded onto iSED PRO. **Do not attempt to load a Beckman Coulter rack on iSED PRO if not contained in a Rack Carrier.** Two Beckman Coulter hematology racks fit into one Rack Carrier. See Figure 28 for how to position racks in the Rack Carrier. The Rack Carrier can be loaded onto iSED PRO holding 1 or 2 Beckman Coulter Racks. If the Rack Carrier only contains 1 rack, the rack must be in the forward rack position (Rack Carrier positions 1-5, farther away from handle).

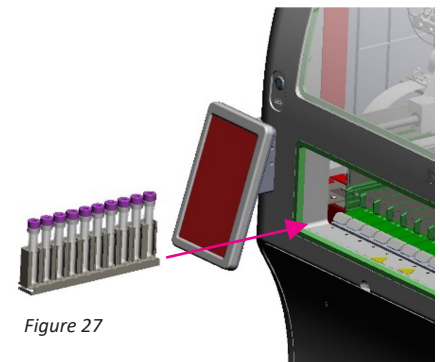


Figure 27

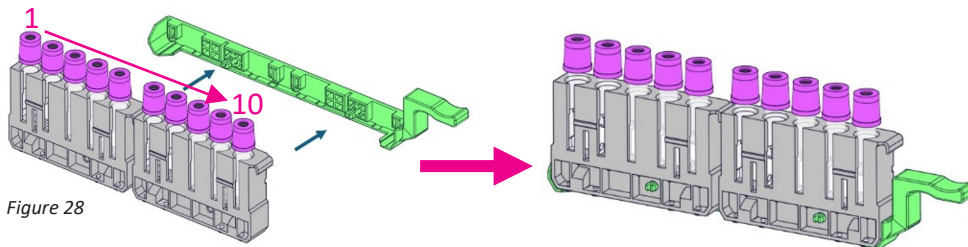


Figure 28

The Rack Carrier is loaded onto iSED PRO with the sample position 1 in the front and the handle in the back (see Figures 29-30).

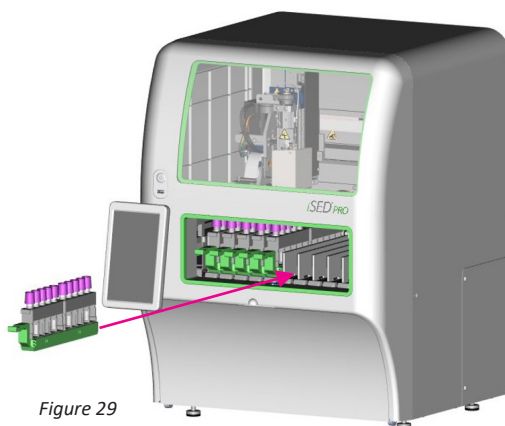


Figure 29

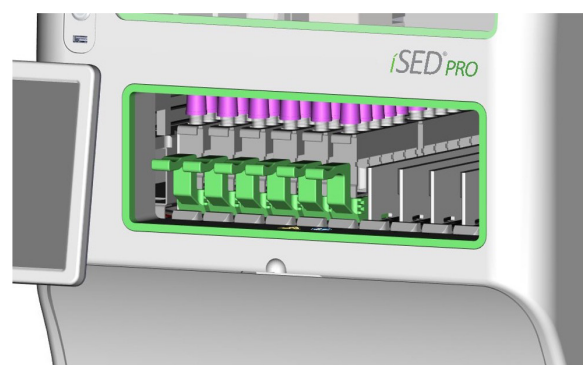


Figure 30

7.2.3 Basic Workflow

iSED PRO operates via the insertion of hematology racks into any unoccupied Rack Lane located through the front Rack Port opening. Rack Lane status is indicated by a status light at the front of the lane:

- Green:** Lane is unoccupied and ready to accept a new rack.
- Blue:** Lane is occupied. The rack that is inserted is queued for processing.
- Flashing Blue:** Lane is occupied and the inserted rack is currently being processed.
- Red:** This lane has an error and cannot be used at the moment.

To start processing a sample rack, insert the rack into an available Rack Lane indicated by a green status light. Slide the rack completely into the lane until a click latch locks the rack in place. When the rack is locked into place, the lane status light changes from green to blue. At this point, the operator can walk away while the analyzer processes the rack. iSED PRO will begin to build out a work queue by picking up each tube and scanning the barcode ID, handling the sample according to the laboratory-chosen workflow mode. Refer to Workflow Modes (Section 7.3) for details. If no tube is present in a Rack Position, iSED PRO will skip to the next rack position.

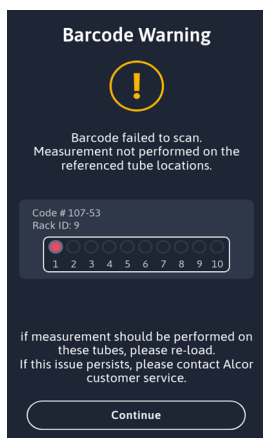


Figure 31

If a sample is marked for ESR measurement (as determined by Workflow Mode), the sample is queued for removal from the rack and will be measured. All sample mixing, aspiration, analysis, and waste disposal are automatically handled by the instrument. Each sample is analyzed within seconds after appropriate sample mixing. Upon measurement completion, iSED PRO will return the sample tube back to its original Rack Position. When all queued samples on the rack are complete and the rack is finished processing, the device will release the rack and change the indicator light back to green to indicate the rack can be removed and another rack can be inserted into the previously occupied Rack Lane.

Depending on the Workflow Mode (see Workflow Modes - Section 7.3), if a sample barcode fails to scan, the analyzer holds the affected rack, flashes the corresponding lane red, and displays the warning in Figure 31. This error does not interrupt ongoing processing, but the operator must press “Continue” to release the rack and fix the barcode issue.

Test Credits are required for operation. Credits in the form of iSED PRO Test Cards must be purchased (see Consumables - Section 5.2). For information on loading Test Credits, please refer to Section 14.

7.2.4 STAT Testing

iSED PRO allows STAT testing prioritization for whole racks of samples. To initiate a STAT test, press the STAT button on the Home Screen (Figure 32) to display the prioritization screen in Figure 33.

While this screen is present, the analyzer will treat the next rack inserted as STAT priority. iSED PRO will stop processing new samples in non-STAT lanes and begin picking up samples from the STAT rack. Non-STAT samples already placed in the Mixing Wheel will continue to be measured as normal. Any non-STAT tubes that were previously scanned and queued for measurement, but not yet moved to the Mixing Wheel, will be pushed down the priority queue to ensure samples on the STAT rack are tested first.

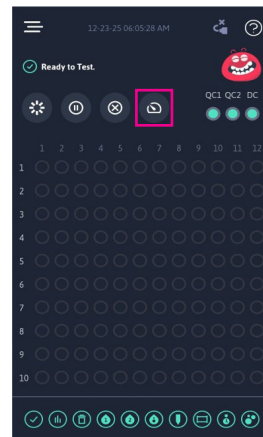


Figure 32

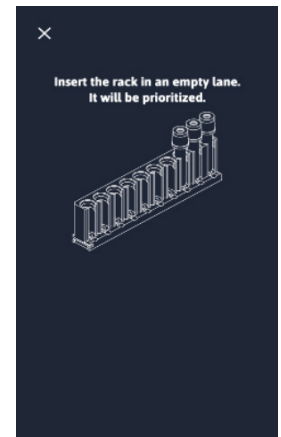


Figure 33

NOTE: If the STAT button is erroneously pressed, the user may cancel STAT prioritization mode by hitting the X button in the upper left corner of Figure 33.

NOTE: When a new rack is marked STAT priority, it will be prioritized over any other racks previously marked STAT priority even if those racks are still processing.

7.2.5 Pause Feature

The Pause button (Figure 34) may be pressed at any time during operation to pause the analyzer. When paused, no sample measurement, loading, or mixing will occur. The system will retain its current measurement queue. iSED PRO indicates that it is in a paused state by changing the pause button to a yellow “play” button and indicating “System Paused” in the Status Banner (Figure 35).

When the yellow Play button is pressed, the system will resume functionality from where it left off in the measurement queue.

NOTE: iSED PRO will automatically pause if system errors are encountered during testing. When in a paused state, menu navigation and non-sample related functionality is still allowed.

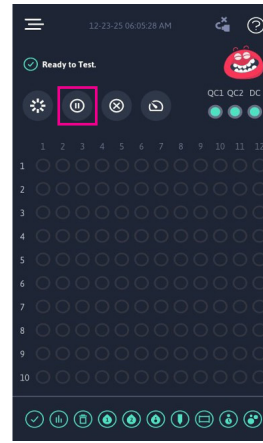


Figure 34

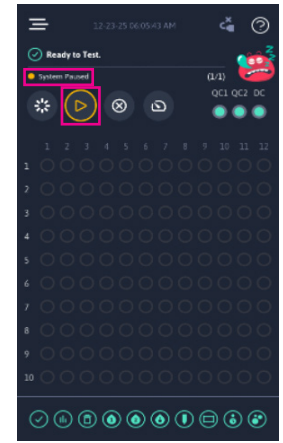


Figure 35

7.2.6 Washing

The instrument uses iWASH PRO Wash Fluid as the cleansing agent during the wash cycle. The instrument is programmed to perform 1 enhanced self-clean (wash) on startup or after being idle for 15 minutes following the last sample tested. The process takes approximately 70 seconds and utilizes approximately 9 mL of iWASH PRO.

The instrument also performs a non-idle self-clean every 200 samples run. This cleaning cycle takes approximately 60 seconds and utilizes approximately 4 mL of iWASH PRO.

It is recommended that the instrument remain powered 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.

7.3 Workflow Modes

This section describes the workflow modes that can be chosen by the lab administrator. These modes can be changed from the General Settings sub-menu. All modes will store all sample, SEDIROL, and Proficiency Test results in the Results Log for future review.

7.3.1 Bidirectional LIS Mode (Recommended)

The primary intended workflow mode for iSED PRO utilizes bidirectional LIS communication (Figure 36) to determine whether a specimen requires ESR measurement by querying the LIS for an ESR order. In this default mode, LIS connection is required. See iSED PRO Communication Protocol (Document # 120-09-006) for details on setting up an LIS connection.

In this mode, iSED PRO will scan the sample's barcode ID and query the LIS server to determine if ESR is required. If no ESR test is required, iSED PRO will return the sample tube back to its original Rack Position. If an ESR test is required, iSED PRO will move the sample to the Mixing Wheel and measure the sample.

Information from samples that were not run due to a negative query response from the LIS server while in bidirectional LIS Mode, including the specimen ID, time stamp, and specimen location (Rack Lane and Rack Position) are recorded.

Samples that could not be scanned due to barcode quality or lack of a barcode ID will not be run by the iSED PRO in Bidirectional LIS Mode .

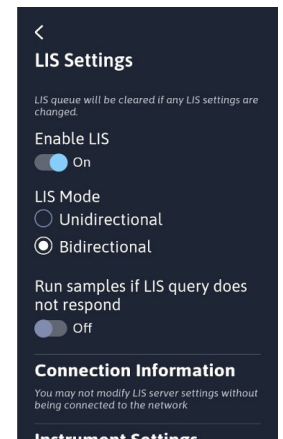


Figure 36

7.3.2 Unidirectional LIS Mode

In this mode, iSED PRO will perform an ESR test on every sample without querying the LIS for an order. ESR results will be sent to the LIS Server. This mode assumes all samples loaded onto the analyzer require ESR testing.

Within Unidirectional Mode, there is a setting for handling samples with no barcode or with a barcode that is not readable by the instrument. If enabled with this setting, called “Run samples on barcode failure” (Figure 37), the instrument will auto-assign an ID for unscannable or non-barcoded samples. A Result Log entry will be made with the time stamp and specimen location (Rack Lane and Rack Position) and marked as an “unknown” sample ID.

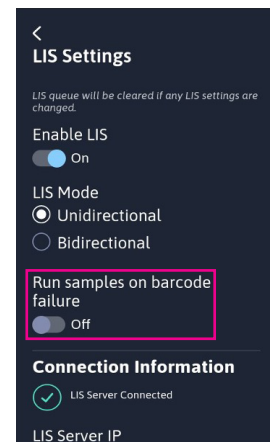


Figure 37

7.3.3 LIS Disabled Mode

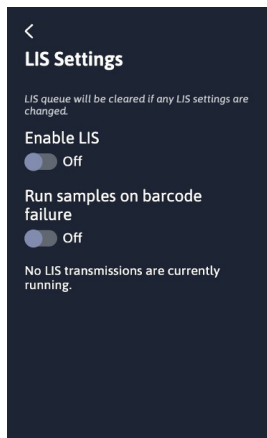


Figure 38

When the LIS is disabled in settings (Figure 38), iSED will pick up, scan, and measure all samples on each rack. For unscannable or non-barcoded samples, the instrument will automatically measure the sample and auto-assign an ID. iSED PRO will not send results to the LIS Server. ESR results will be stored on the internal memory of the analyzer and can be reviewed via the Results Log on the Touch Screen.

In all modes, results can be exported via USB port or printed (see USB Export and Print - Section 11.2.2).

NOTE: The setting that allows non-barcoded samples to be processed is not available in Bidirectional LIS Mode.

NOTE: Unnecessary ESR testing should be avoided.

8. Quality Control

8.1 External Controls

The manufacturer recommends running bi-level SEDIROL ESR Controls at least once per day. SEDIROL is the only Quality Control material validated for use on iSED PRO. Due to the nature of ESR, method-specific Quality Control is recommended.⁶ SEDIROL ESR Controls Levels 1 and 2 are available for purchase (see Consumables - Section 5.2). SEDIROL Controls should be run in accordance with the SEDIROL Instructions for Use (Document # 315-09-011). **Control results must be reviewed to ensure results are in range.**

8.1.1 QC Scheduler

SEDIROL Levels 1 and 2 tubes are stored onboard iSED PRO in the Onboard Consumables Holder within the device. The Quality Control frequency/schedule can be set based on laboratory needs. iSED PRO will automatically follow the schedule and queue **both** SEDIROL levels to be measured. The QC schedule will be set at initial setup and can be changed later via the General Settings sub-menu shown in Figure 39.

NOTE: iSED PRO will alternate which SEDIROL Level 1 and Level 2 is run first to prevent uneven sample volume consumption between the control tubes due to sample priming.

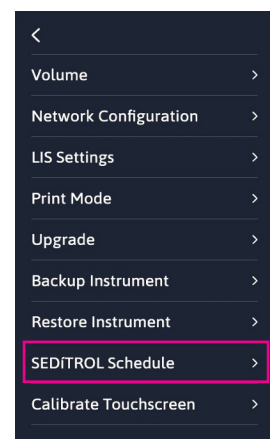


Figure 39

8.1.2 Replacing Onboard SEDIROL

The analyzer will notify users to replace SEDIROL Controls when 1 of 2 things occurs:

1. QC material was measured for the first time 60 days ago. This is the open vial stability for SEDIROL.
2. The usage counter reaches 0 uses. There is enough sample volume for approximately 28-30 uses in each of the 4.0 mL SEDIROL vials.

The user will confirm the on-screen notification and begin the Onboard Consumables Holder Loading Procedure; see Section 14 for details.

For SEDIROL tubes, the open vial stability timer will begin once the tube has been used/pierced by the analyzer for the first time.

8.2 Peer Group Comparison

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

8.3 Proficiency Testing

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 (PT).

Proficiency Testing is an important tool used in the lab to verify accuracy and reliability of 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.

9. 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 PRO 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 PRO is designed to prevent interfering clots from being aspirated into the analyzer hydraulic circuit and reading cell. If a clot prevents aspiration of the sample, the analyzer will retry the aspiration process 3 times before it gives an "unable to withdraw" error code and aborts the test. Similarly, if the sample volume is too low to be aspirated, iSED PRO will attempt to aspirate the sample 3 times before it gives an "unable to withdraw" error code and aborts the test.
- It is broadly accepted that ESR values are elevated in multiple myeloma and other cancers, but it should be noted that studies have reported variability in ESR values with 10% of myeloma patients presenting with normal ESR, concluding that normal ESR values cannot be used to rule out myelomas and additional testing should be performed. In some cases, such as multiple myeloma and other cancers, RBC aggregation can be impacted by the presence of large macromolecules such as abnormal proteins and IgM, and this can lead to hematological testing abnormalities. It is therefore recommended, if the ESR result is inconsistent with the clinical presentation or stage of treatment, to test using additional methodologies.⁸

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.

10. Calibration

The iSED PRO analyzers are factory calibrated using samples compared to a Reference Instrument that has been correlated to the Westergren method. The instrument's analytical 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.

11. Results

11.1 Expected Values

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

ESR Reference Values (mm/hr) ⁹	
Males under 50 years old	< 15
Males over 50 years old	< 20
Females under 50 years old	< 20
Females over 50 years old	< 30

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

11.2 Exporting Results

11.2.1 LIS Transmission

Results will be sent to the LIS server depending on the enable workflow mode (see Workflow Modes – Section 7.3). When the LIS is enabled, results will automatically be sent to the LIS. For more information on LIS data format and protocol, please refer to the iSED PRO Communication Protocol (Document # 120-09-006). Results can also be exported from the Result Log – see section 11.2.2 for how to reach the Export Screen.

11.2.2 USB Export or Print

Results can be exported individually (Figure 40) or in groups (Figure 41). In either case, once the icons are selected, they will bring up the Export Selection screens (Figures 42, 43). Make selection and select “Export”.

NOTE: Records of all samples will be displayed in the Results Log. For samples with barcodes that could not be scanned or no barcodes, the workflow mode will determine how the sample is handled (see Workflow Modes – Section 7.3).

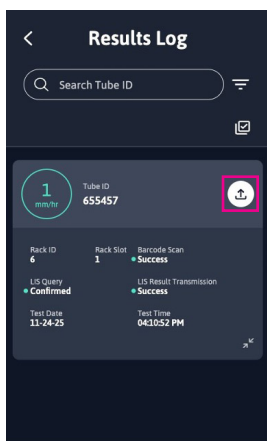


Figure 40

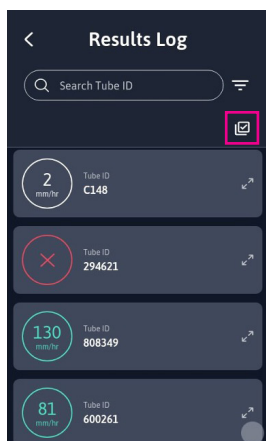


Figure 41

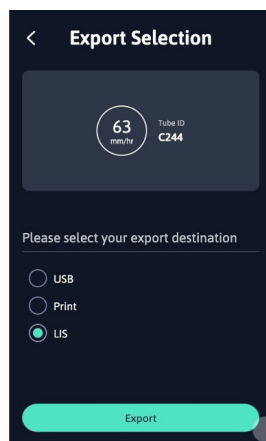


Figure 42

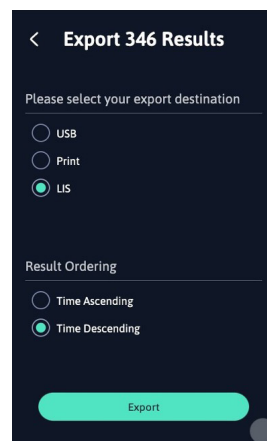


Figure 43

12. Performance

12.1 Method Comparison

The iSED PRO ESR analyzer has been demonstrated to provide results equivalent to the Westergren method.

Since ESR is based on the physical interactions of RBCs during testing, the Westergren reference method is subject to a number of variables, including sample characteristics, testing environment, and individual operators' techniques. Therefore, Passing-Bablok regression analysis is recommended for comparing 2 ESR methods since the reference method is known to be subject to variables.^{4,6}

Results of Passing-Bablok Regression Analysis

Variable X	Westergren
Variable Y	iSED PRO
Sample Size	200
Regression Equation	$y=1.03x + 1.58$
Slope 95% Confidence Interval	1.000 to 1.093
Intercept 95% Confidence Interval	-0.058 to 2.000
Cusum Test for Linearity	No significant deviation from linearity (P=0.57)

12.2 Precision

NOTE: As with other laboratory tests, higher CVs are expected when comparing lower numerical values.

12.2.1 Intrarun Precision

Ten replicates of a sample from each quartile of the analytical range were tested, and the process was repeated in 4 separate runs.

	Quartile 1 (0-30 mm/hr)				Quartile 2 (31-60 mm/hr)			
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 1	Sample 2	Sample 3	Sample 4
Mean (mm/hr)	9.8	16.4	27.6	27.7	36.7	46.3	55.7	53.5
SD (mm/hr)	1.2	0.7	0.7	1.3	0.7	1.5	1.6	2.0
CV	12.5%	4.3%	2.5%	4.5%	1.8%	3.2%	2.9%	3.8%
Average CV	6.0%				2.9%			
	Quartile 3 (61-90 mm/hr)				Quartile 4 (>90 mm/hr)			
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 1	Sample 2	Sample 3	Sample 4
Mean (mm/hr)	75.2	86.6	78.7	72.6	109.5	100.4	91.0	104.8
SD (mm/hr)	1.5	1.3	2.1	2.5	2.6	2.6	2.9	3.5
CV	2.0%	1.6%	2.6%	3.5%	2.4%	2.6%	3.2%	3.3%
Average CV	2.4%				2.9%			

12.2.2 Interrun Precision

SEDiTROL Quality Controls (Levels 1 and 2) were run 3 times a day over a period of 5 consecutive days. Stabilized quality control material was used to minimize the effect of sample age on results.

	Run 1		Run 2		Run 3		Overall %CV
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2	
Average (mm/hr)	10.8	68.0	10.8	67.4	10.2	68.2	
SD	0.8	0.7	0.4	0.5	1.1	0.8	
%CV	7.7	1.0	4.1	0.8	10.7	1.2	4.3%

12.3 Sample Stability

Refrigerated Samples

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

Room Temperature Samples

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

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

12.4 Carryover

Carryover testing was performed to demonstrate the sequence of sample testing does not affect measured values. High target value and low target value samples were selected for each run, and each sample was run in triplicate. Samples with high ESR values were run ahead of the samples with lower ESR values, and % carryover was calculated for each run.

	Run A	Run B	Run C	Overall
Carryover	1.96%	3.53%	0.00%	1.83%

13. Test Credits

In order to process and analyze samples, “credits” must be downloaded onto the instrument from iSED PRO Test Cards preloaded with various quantities of Test Credits.

The Maintenance Menu (Figure 44) provides the user with the number of test credits available. A notification will appear in the Status Banner when credits are below 1000. If credits run out during processing, the instrument will alert the user with a full page error allowing the user to abort the measurement process and eject the tube(s) that are unable to be measured.

To add additional credits to the instrument, the user must insert an iSED PRO Test Card into the Test Card Reader located inside the Bottle Compartment on the front right corner of the iSED PRO with the arrow facing forward and to the left (Figure 45).

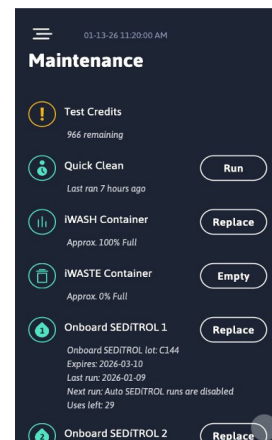


Figure 44

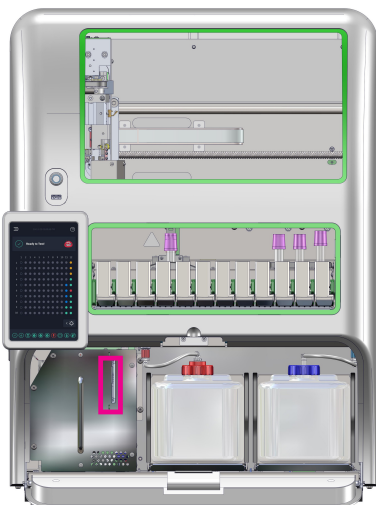


Figure 45

Once a Test Card is inserted, the screen (Figure 46) will show the number of credits currently on the instrument, the serial number of the Test Card, and the number of credits on the Test Card. If the user processes “Confirm”, all the available Test Credits will be transferred to iSED PRO. The total number of credits is then displayed, and the user is instructed to remove the test card (Figure 47).

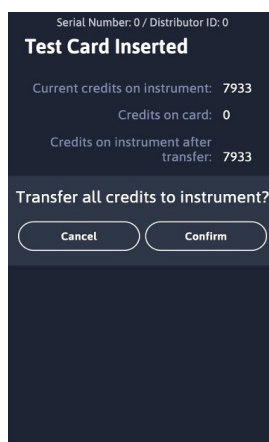


Figure 46

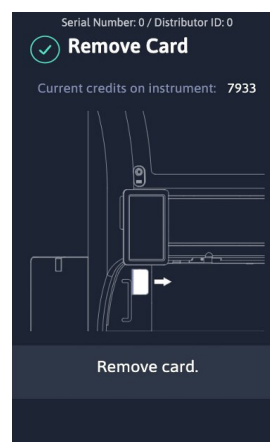


Figure 47

NOTE: iSED PRO Test Cards cannot be reused.

14. Onboard Consumable Holder Loading Procedure

iSED PRO has an Onboard Consumable Holder for storing SEDIROL Levels 1 and 2 and deepCLEAN PRO onboard iSED PRO. This procedure is for unloading expired or empty SEDIROL and deepCLEAN PRO tubes from the Onboard Consumable Holder and replacing them with new tubes. The user will be notified when it is time to replace any or all consumable tubes. The process can be initiated via the Maintenance Menu by pressing any of the “Replace” buttons next to Control Fluid Level 1, Control Fluid Level 2, and Deep Cleaning Fluid (Figure 48).

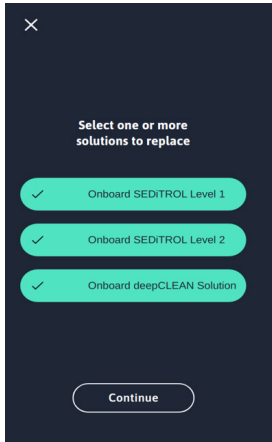


Figure 49

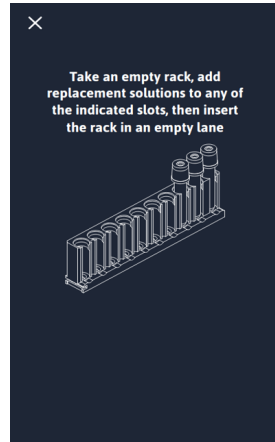


Figure 50

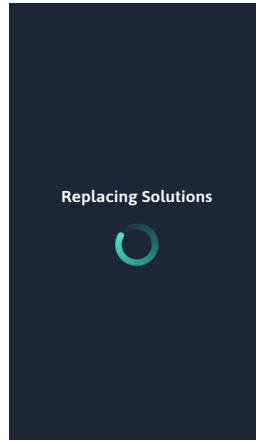


Figure 51

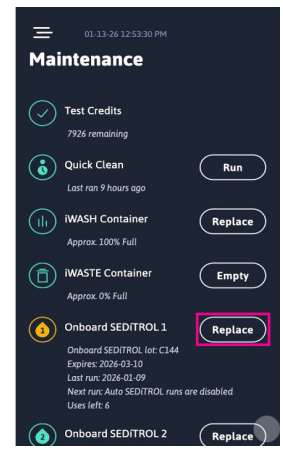


Figure 48

Follow the onscreen instructions (Figures 49-51) exactly to prepare a hematology rack containing a maximum of 1 of each replacement tube. Once a rack with replacement tubes is loaded, iSED PRO will unload the expired or used tubes from the Onboard Consumables Holder and return them to the hematology rack. The new tubes will be picked up and scanned to verify the material and ensure correct placement in the Onboard Consumables Holder (Figure 52).

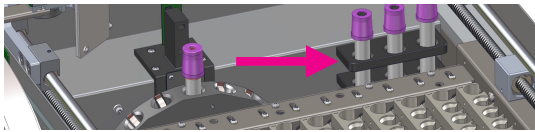


Figure 52

NOTE: NEVER attempt to load the Onboard Consumables Holder manually. iSED PRO will not recognize consumables that were loaded manually.

15. Routine Maintenance

15.1 iWASTE PRO Maintenance

15.1.1 iWASTE PRO Full Indicators and Alarms

In the event the iWASTE PRO Waste Container is full, a warning message will appear on the screen and be accompanied by an alarm. An error message will also appear in the Home Screen's Status Banner (Figure 53) and can be resolved by first replacing or emptying the iWASTE PRO container (following the procedure in Section 15.1.2) and then pressing “Empty” to clear the error and continue testing. The iWASTE PRO bottle counter will automatically reset once this button has been pressed, and the instrument will continue with the sample loading or washing process.

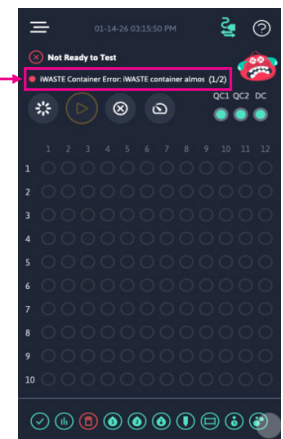


Figure 53

15.1.2 Replacing/Emptying the iWASTE PRO Waste Container



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

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



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

1. Open the front door to access the Bottle Compartment (Figure 54).

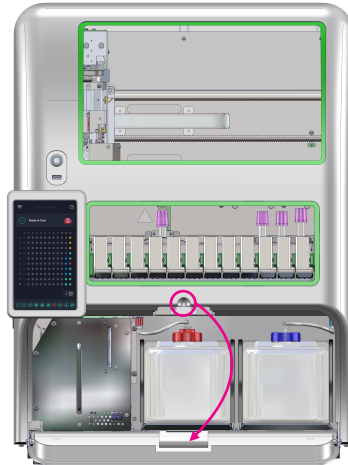


Figure 54

2. Locate the iWASTE PRO container in the left bottle tray (Figure 55).

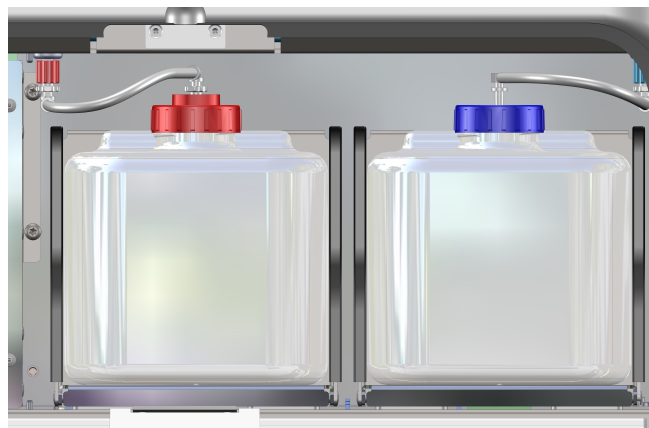


Figure 55

3. Pull out the iWASTE PRO container slightly to provide access to the cap and tubing connections.

4. Disconnect the LUER connector from the waste bottle screw cap (Figure 56).

NOTE: DO NOT dispose of the empty container's cap.

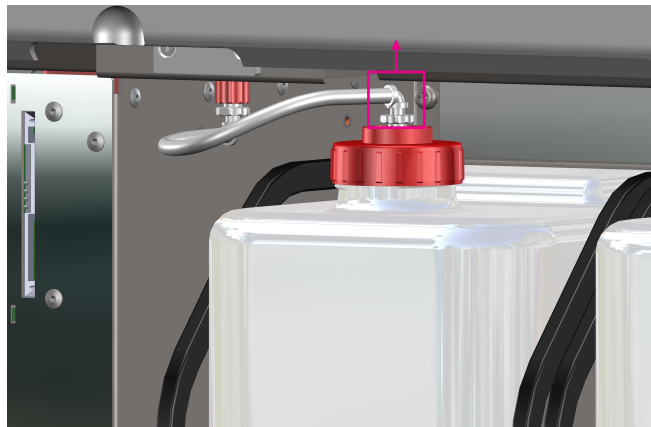


Figure 56

5. Remove the iWASTE PRO container from the instrument and dispose of the waste according to your laboratory's biological waste protocol.
6. Replace the iWASTE PRO container and firmly reconnect the LUER connector on the plastic screw cap. If using a new container, be sure the use the screw cap from the waste container being replaced.
7. Close the Bottle Compartment Door (Figure 57).

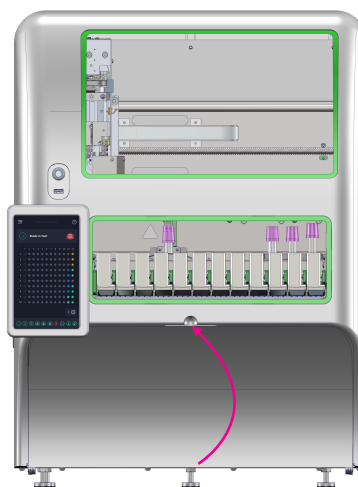


Figure 57

8. From the Maintenance Menu, press the iWASTE Container "Empty" button to reset the counter to 0% full (Figure 58).

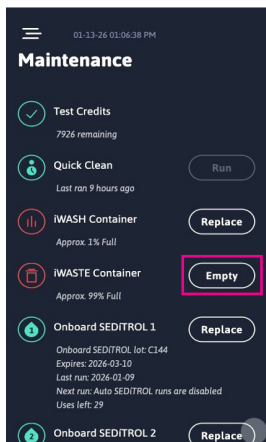


Figure 58

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

NOTE: It is recommended that the waste container be checked daily for fill volume and emptied/replaced as needed.

NOTE: This procedure can be done without the waste alarm being active.

NOTE: An empty iWASH PRO container can be repurposed as a waste container. Be sure to label the container appropriately according to your laboratory's requirements for biohazardous materials.

15.2 iWASH PRO Maintenance

15.2.1 iWASH PRO Empty Indicators and Alarms

When the iWASH PRO Wash Fluid container is empty, a message will appear on the screen and be accompanied by an alarm. An error message will also appear in the Home Screen's Status Banner (Figure 59) and can be resolved by first replacing the iWASH PRO container (following the procedure in Section 15.2.2) then selecting "Replace" next to iWASH Container to clear the error and continue testing. The iWASH PRO counter will automatically reset once this button has been pressed, and the instrument will continue with the sample loading or washing process.

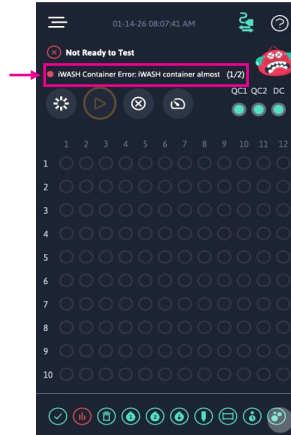


Figure 59

15.2.2 Replacing the iWASH PRO Wash Fluid

1. Open the front door to access the Bottle Compartment (Figure 60).

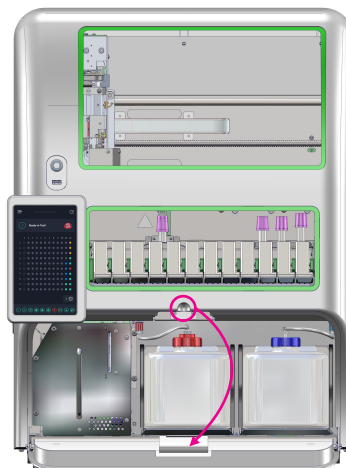


Figure 60

2. The iWASH PRO container is located in the bottle tray on the right (Figure 61).

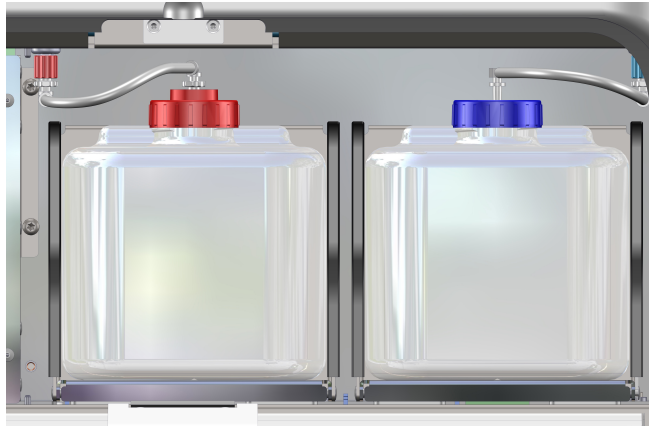


Figure 61

3. Pull out the iWASH PRO container slightly to provide access to the cap and tubing connections.
4. Disconnect the LUER connector from the iWASH PRO screw cap (Figure 62).

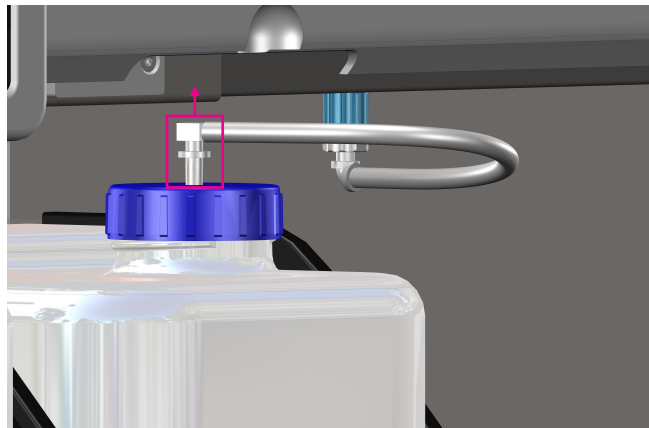


Figure 62

5. Remove the empty iWASH PRO container, unscrew the cap, and replace it with a new iWASH PRO bottle.

NOTE: DO NOT dispose of the empty container's cap.

6. Place the new iWASH PRO Wash Fluid container in the compartment, replace the current container's cap with the vented screw cap (used on the previous bottle), and firmly reconnect the LUER connector on the plastic screw cap with the vent hole positioned at the top.

7. Close the Bottle Compartment Door (Figure 63).

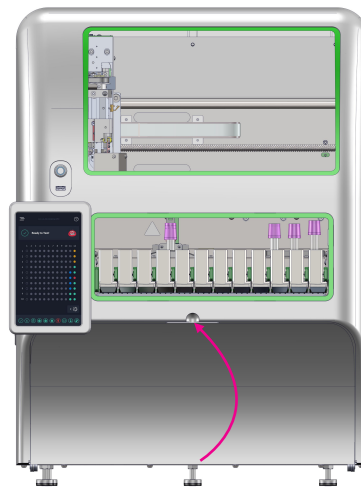


Figure 63

8. From the Maintenance Menu, press the iWASH Container “Replace” button to reset counter to 100% full (Figure 64).

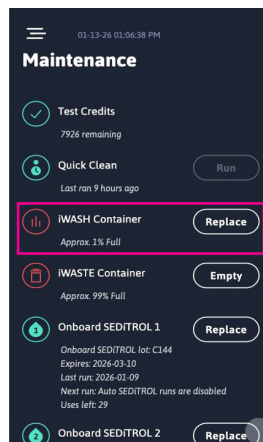


Figure 64

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

NOTE: The instrument is programmed to perform self-cleaning 1 time after being idle for 15 minutes following the last sample tested. The process takes approximately 70 seconds and utilizes 9 mL of iWASH PRO. A non-idle wash also occurs every 200 samples; this wash takes approximately 1 minute and uses 4 mL of iWASH PRO. Once completed, testing can resume as normal.

NOTE: This procedure can be performed without the iWASH PRO alarm being active.

NOTE: The empty iWASH PRO container can be repurposed as the waste container for iSED PRO. Be sure to label appropriately according to your laboratory’s requirements for biohazardous material if reusing as a waste container.

16. 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.

16.1 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 iSED PRO cover and view port
- DO NOT use any liquid cleaners on interior of the device or Rack Lanes

16.2 Deep Cleaning

The analyzer will automatically perform a Deep Clean of the aspiration pathway from the needle to the reading cell once per week or every 1000 samples, whichever comes first. Deep Cleaning can also be performed as needed for troubleshooting purposes. Deep Cleaning removes accumulated blood residuals from the fluidics path and is important for proper functioning of the iSED PRO analyzer. The Deep Clean process requires a deepCLEAN PRO tube to be preloaded into the Onboard Consumables Holder. iSED PRO can only perform the Deep Clean procedure with the deepCLEAN PRO Cleaning Solution which contains sodium hypochlorite. The use of any other product could affect the performance of the instrument and void the warranty. See Consumables (Section 5.2) for deepCLEAN PRO ordering information.

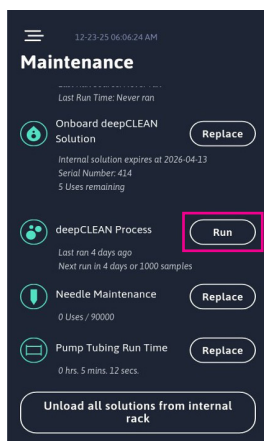


Figure 65

When the Deep Clean process is initiated from the Maintenance Menu (Figure 65), iSED PRO will automatically run 2 wash cycles then perform the Deep Clean procedure (which takes approximately 3 minutes) by picking up the deepCLEAN PRO tube and aspirating the sodium hypochlorite cleaning solution. During the 3 minute Deep Clean, the device will appear to be idle while the fluidic system soaks in sodium hypochlorite solution. Once the Deep Clean is completed, the analyzer will perform 2 additional washes to purge the system of sodium hypochlorite and return the deepCLEAN PRO tube back to the Onboard Consumables Holder for re-use.

See the deepCLEAN PRO Instructions for Use (Document # 123-09-002) for specific details on deepCLEAN PRO.

16.2.1 Replacing deepCLEAN PRO

Each tube of deepCLEAN PRO can be used up to 4 times. The analyzer will notify the user when the onboard deepCLEAN PRO tube needs to be replaced. The replacement notification will be located on the Home Screen (Figure 66).

The user will then begin the Onboard Consumables Holder Loading Procedure. Refer to Onboard Consumables Holder Loading Procedure (Section 14) for details on how to load deepCLEAN PRO.

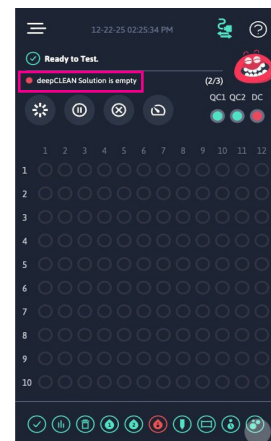


Figure 66

16.3 Pump Tubing Message

After 200 hours of continuous use, iSED PRO will generate a notification on the Home Screen: “Pump Tubing runtime exceeded. Please contact ALCOR support.” Please contact ALCOR Scientific Technical Support or your authorized representative as pump tubing must be replaced. This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use. It is important to replace the tubing as required so that analyzer performance is not impacted.

16.4 Needle Maintenance Message

After 90,000 aspirations, iSED PRO will generate a notification on the Home Screen: “Maximum number of needle pierces exceeded. Please contact ALCOR support.” Please contact ALCOR Scientific Technical Support or your authorized representative as the needle system must be replaced. This message only serves as a warning that maintenance should be performed and does not prevent the analyzer from operational use. It is important to replace the needle system as required so that analyzer performance is not impacted.

16.5 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.

NOTE: Replace only if fuse has blown. See Troubleshooting (Section 17.3).

Materials needed:

- 2.5mm blade screwdriver
- 2x Fuse T5A 250V 5x20mm



1. Use the blade screwdriver to release latch on both sides of fuse holder, as shown.
2. When released, pull out fuse holder from instrument.
3. Remove both fuse cartridges from the fuse holder.
4. Insert the new fuses 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 pressing until the latches click into place.

16.6 iWASH PRO and iWASTE PRO Cap Replacement

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

16.7 Spare Parts

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

17. System Status, Error Codes, and Warning Messages

The iSED PRO Touch Screen has a Status Banner at the top of the Home Screen where all active system messages appear (Figure 67). An animated emoticon, named “SEDRick,” on the right side of the status banner provides a quick visual reference to general operating status.

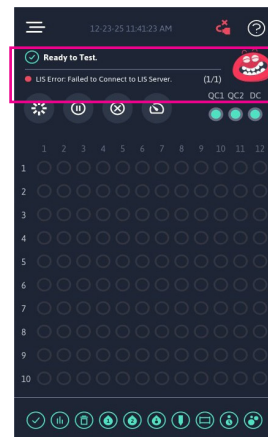


Figure 67

17.1 System Warning and Error Messages

Each of the messages display on the Touch Screen as iSED PRO is processing specimens:

Status	Status Explanation
“Ready to Test” / “Not Ready to Test”	Device is ready or not ready to accept sample tubes. Device could be not ready for a number of reasons, such as any blocking errors, reading cell temperature warm up period, or no Test Credits are available.

Message	
No remaining Test Credits	Add test credits using a valid iSED PRO Test Card. Measurement is suspended until test credits have been added to the instrument.
Test Credits running low	Remaining test credits are below the alarm threshold. Add test credits using a valid iSED PRO Test Card.
iWASH is empty	Replace iWASH PRO and click “Replace” on the Maintenance Menu when complete. Measurement and wash processes are suspended until iWASH PRO has been replaced.
iWASH is low	Remaining iWASH PRO fluid is below the alarm threshold and will soon be empty.
iWASTE container is full	Dispose / replace iWASTE PRO bottle and click “Replace” on the Maintenance Menu when complete. Measurement and wash processes are suspended until iWASTE PRO has been replaced.
iWASTE container is almost full	iWASTE PRO fill is above the alarm threshold and will soon be full.
SEDiTROL Level 1 is empty	SEDiTROL Level 1 (Quality Control Fluid) is empty. Load a new on-board SEDiTROL Level 1 tube via the Maintenance Menu, described by the Onboard Consumable Holder Loading Procedure.
SEDiTROL Level 1 is low	SEDiTROL Level 1 (Quality Control Fluid) will soon be depleted.
SEDiTROL Level 2 is empty	SEDiTROL Level 2 (Quality Control Fluid) is empty. Load a new on-board SEDiTROL Level 2 tube via the Maintenance Menu, described by the Onboard Consumable Holder Loading Procedure.
SEDiTROL Level 2 is low	SEDiTROL Level 2 (Quality Control Fluid) will soon be depleted.
deepCLEAN Solution is empty	deepCLEAN PRO solution is empty. Load a new on-board deepCLEAN PRO tube via the maintenance page, described by the Onboard Consumable Holder Loading Procedure.
deepCLEAN Solution is low	deepCLEAN PRO will soon be depleted.
Maximum number of needle pierces exceed. Please contact ALCOR support.	Needle pierces have exceeded recommended use life. The assembly should be replaced to ensure continued proper function. Please contact ALCOR Scientific Technical Support.
Needle system will need maintenance soon. Please contact ALCOR support.	Needle pierces are approaching recommended use life.
Pump Tubing runtime exceeded. Please contact ALCOR support.	The pump tubeset has exceeded recommended use life. The assembly should be replaced to ensure continued proper function. Please contact ALCOR Scientific Technical Support.

Pump Tubing Run Time approaching threshold. Please contact ALCOR support.	Pump tubing approaching recommended use life.
Quick Clean required. Measurement has been suspended.	Quick clean must be performed to ensure proper operation of measurement. Please manually run the quick clean process via the Maintenance Menu.
Quick Clean needed	Quick clean must be performed to ensure proper operation of measurement. Please manually run the quick clean process via the Maintenance Menu.
deepCLEAN needed	deepCLEAN PRO should be run. If a deepCLEAN PRO tube is not present in the internal rack, please either load a new deepCLEAN PRO tube into the internal rack or run a deepCLEAN PRO tube manually by loading via an external rack.
LIS Disconnected	LIS is not currently connected. Depending on your LIS settings, measurement may or may not be suspended. Please contact your local IT department to ensure proper functionality.

Certain iSED PRO errors result in a blocking condition where continued robotic movement or measurement is not possible or not safe for the instrument. In these instances, the iSED PRO will pause measurement functionality and show a full-page error on the display until the user selects “Retry” or “Continue” – see Figure 68 for an example. Although non-measurement functionality is allowed when in this paused state (such as result export), sample measurement and robotic movement are not allowed until the error is cleared.

If “Retry” is selected, the condition that generated the failure will be retried. While the retry attempt is in process, the selection buttons on this page will become gray and will not accept user inputs (see Figure 69). If the retry attempt succeeds, the error will be cleared. If it fails, the error workflow will restart with “Retry” and “Continue” selectable.

1. If “Continue” is selected, iSED PRO will remain in a paused state and the Home Screen will show “Not Ready to Test” in the Status Banner” (Figure 70).

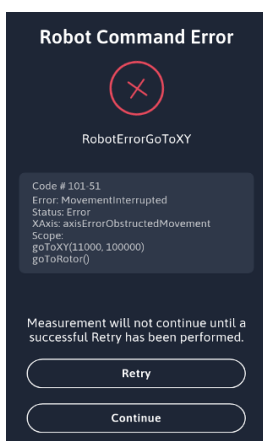


Figure 68

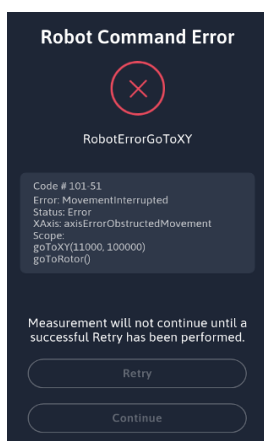


Figure 69

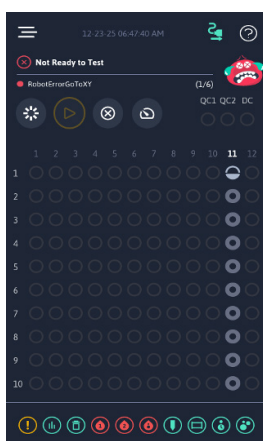


Figure 70

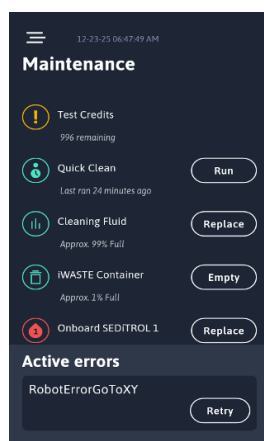


Figure 71

2. To attempt to clear the error from the Home Screen before or after troubleshooting, navigate to the Maintenance Menu. At the bottom of the page will be an active error list with all blocking errors (Figure 71). Selecting one will open the full page error window once more, allowing selection of “Retry” or “Continue” (Figure 68).

The next table shows the error codes, titles, and descriptions for errors the user may see while operating the instrument and troubleshooting solutions. Contact ALCOR Scientific Technical Support or your authorized representative if the error cannot be resolved by any solutions provided below:

Code	Title	Description	Troubleshooting
100-1	Robot Post Error	POSTErrorProcessBusy	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-2	Robot Post Error	POSTErrorBarcodeFailed	Inspect the barcode cable connection. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-3	Robot Post Error	POSTErrorXAxisFailed	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-4	Robot Post Error	POSTErrorYAxisFailed	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-5	Robot Post Error	POSTErrorZAxisFailed	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-6	Robot Post Error	POSTErrorGAxisFailed	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
100-7	Robot Post Error	POSTErrorTimeout	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-1	Robot Command Error	RobotErrorTimeout	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-3	Robot Command Error	RobotErrorMovementInterrupted	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
101-4	Robot Command Error	RobotErrorAxisNotIdle	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-5	Robot Command Error	RobotErrorXyOutOfRange Please record this error and contact customer service. Instrument restart required.	Restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
101-6	Robot Command Error	RobotErrorGripperOutOfRange	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-7	Robot Command Error	RobotErrorZOutOfRange	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-8	Robot Command Error	RobotErrorZIsDown	XY Movement was prevented because the Z axis is too low. Please check for obstructions on the Z axis. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-9	Robot Command Error	RobotErrorCalibrationNotDone	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-10	Robot Command Error	RobotErrorCommandInProgress	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
101-11	Robot Command Error	RobotErrorXAxisTimeout	<p>Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.</p> <p>If obstructions are present, turn off the device, remove obstructions, and retry.</p>
101-12	Robot Command Error	RobotErrorYAxisTimeout	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
101-13	Robot Command Error	RobotErrorZAxisTimeout	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
101-14	Robot Command Error	RobotErrorGAxisTimeout	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
101-51	Robot Command Error	RobotErrorGoToXY	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
101-52	Robot Command Error	RobotErrorPickUp	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.

Code	Title	Description	Troubleshooting
101-53	Robot Command Error	Tube could not be placed at location. Eject all racks.	Check for obstructions preventing the robot from reaching its intended location. If no obstructions are present, retry through the UI. If the issue persists, attempt to eject all racks from the home screen. If the instrument is unable to recover, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support. If obstructions are present, turn off the device, remove obstructions, and retry.
102-4	Rotor Error	RotorErrorHomeOff Home sensor not detected during rotation.	Check for obstructions preventing the rotor from rotating. If no obstructions are present, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-6	Rotor Error	RotorErrorNeedleOff Unable to move rotor. Needle is in error state.	Check the needle assembly to ensure it is in the down / home position. Inspect the needle assembly flex cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-9	Rotor Error	RotorErrorPosReq Rotor requested to move to invalid position.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-10	Rotor Error	RotorErrorStationUndefined Rotor requested to move to undefined station.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-12	Rotor Error	RotorErrorUndefined Rotor in undefined state.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-51	Rotor Error	RotorErrorMoveTo Unable to reach the commanded rotor position.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-52	Rotor Error	RotorErrorMix Unable to mix rotor.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
102-53	Rotor Error	RotorErrorReset Unable to reset rotor.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103-0	Needle Error	NeedleErrorUndefined Needle in undefined state.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103--1	Needle Error	NeedleErrorDisconnect Needle is disconnected.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103-2	Needle Error	NeedleErrorSensorsUndefinedInvalid sensor state.Home and Up sensors both active.	Check the needle assembly for obstructions. Inspect the needle assembly cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103-3	Needle Error	Unable to reach Home position. Please check Piercing System for obstructions.	Check the needle assembly for obstructions. Inspect the needle assembly flex cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103-4	Needle Error	Unable to reach Up position. Please check Piercing System for obstructions.	Check the needle assembly for obstructions. Inspect the needle assembly flex cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
103-5	Needle Error	Invalid sensor state. Home and Probe sensors both active.	Check the needle assembly to ensure it is in the down / home position. Inspect the needle assembly flex cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
103-8	Needle Error	Needle did not move from Home position after requesting it to move up.	Check the needle assembly to ensure it is in the down / home position. Inspect the needle assembly flex cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-0	Pump Error	PumpErrorUndefined	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-1	Pump Error	PumpErrorNone	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105--1	Pump Error	PumpErrorDisconnect	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-2	Pump Error	PumpErrorOtherProcessesRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-3	Pump Error	PumpErrorPrimaryParameters	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-4	Pump Error	PumpErrorWashPumpParameters	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-5	Pump Error	PumpErrorTimeout	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-6	Pump Error	PumpErrorMovement	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-7	Pump Error	PumpErrorWashRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-8	Pump Error	PumpErrorPrimeRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-9	Pump Error	PumpErrorMeasureRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-10	Pump Error	PumpErrorWithdrawalRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-11	Pump Error	PumpErrorDeepCleanRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-12	Pump Error	PumpErrorTailCalibrationRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
105-51	Pump Error	PumpErrorClearDeadMaterial	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
106-0	Withdrawal Error	WpErrorUndefined	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-1	Withdrawal Error	WpErrorDisconnect	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-2	Withdrawal Error	WpErrorMovementNeedle is in error state while attempting to pierce sample.	Check the needle assembly for obstructions. Inspect the needle assembly cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-3	Withdrawal Error	WpErrorTailCalibration Unable to Calibrate Tail Sensor. Perform deepCLEAN, otherwise contact Technical Support.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-4	Withdrawal Error	WpErrorNoTube No sample tube detected. Measurement aborted.	During the piercing phase, the primary tube was not detected (probe tube not activated after down sensor reached). Check to make sure sample was loaded. Run sample again. If issue persists, please contact ALCOR Scientific Technical Support.
106-5	Withdrawal Error	WpErrorNoFlowWithdrawal Unable to withdraw Sample. Check for sufficient volume in sample tube, otherwise contact Technical Support.	The system was unable to withdraw the correct volume from the sample tube or was unable to detect sample moving to the reading position. Confirm that there is adequate sample in the test tube. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-6	Withdrawal Error	WpErrorSampleNotInMixSustain 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 ALCOR Scientific Technical Support.
106-7	Withdrawal Error	WpErrorNoCredits No test credits on instrument. Please insert a test card and add credits to the instrument.	Add Test Credits to the instrument.
106-8	Withdrawal Error	WpErrorOtherProcessRunning Withdrawal requested while another process is running.	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 ALCOR Scientific Technical Support.
106-9	Withdrawal Error	WpErrorUnableToStartTailCalibration Unable to start tail sensor calibration. Pump not responding.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-10	Withdrawal Error	WpErrorRotorRunning Rotor was moving when withdrawal started.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-11	Withdrawal Error	WpErrorNeedle Needle is in error state.	Check the needle assembly for obstructions. Inspect the needle assembly cable to ensure it is properly engaged. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-12	Withdrawal Error	WpErrorWashRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-13	Withdrawal Error	WpErrorPrimeRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-14	Withdrawal Error	WpErrorMeasureRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-15	Withdrawal Error	WpErrorDeepCleanRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
106-16	Withdrawal Error	WpErrorTailCalibrationRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-51	Withdrawal Error	WpErrorQC	Unable to withdraw QC sample. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
106-52	Withdrawal Error	WpErrorExceededMaxAttempts Too many tubes failed withdraw	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
107-4	Barcode Error	BarcodeErrorInternal	Inspect the barcode cable connection. If no issues are observed, retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
107-51	Barcode Error	Barcode scan failed on {failedReads} consecutive tubes.	Inspect the barcode cable connection. Ensure that the red LED is illuminating on barcode read attempts. Power cycle the device. If the error still persists, contact ALCOR Scientific Technical Support.
107-52	Barcode Error	Barcode scan failed on {failedReads} consecutive tubes.	Inspect the barcode cable connection. Ensure that the red LED is illuminating on barcode read attempts. Power cycle the device. If the error still persists, contact ALCOR Scientific Technical Support.
108-0	Wash Error	WashUndefined	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-1	Wash Error	WashNone	Replace iWASH PRO.
108--1	Wash Error	WashDisconnect	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-2	Wash Error	WashPumpTimeout	Error detected during the movement phases of the wash process. Pump did not start movement. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-3	Wash Error	WashMovement	Error detected during the movement phases of the wash process. Pump did not move correctly. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-4	Wash Error	WashUnableToSetCellT100	The wash process is unable to set the correct T100 value for the reading cell. Check if there is sufficient iWASH PRO fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH PRO bottle was replaced. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.
108-5	Wash Error	WashUnableToSetTailT100	The wash process is unable to set the correct T100 value for the tail sensor. Check if there is sufficient iWASH PRO fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH PRO bottle was replaced. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.
108-6	Wash Error	WashUnableToDetectCellEmpty	The wash process is unable to detect a change on optical value for the reading cell after the washing liquid has been discarded. Check if there is sufficient iWASH PRO fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH PRO bottle was replaced. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.
108-7	Wash Error	WashUnableToDetectTailEmpty	The wash process is unable to detect a change on optical value for the tail sensor after the washing liquid has been discarded. Check if there is sufficient iWASH PRO fluid in the bottle. This can occur when the fluid level counter was not reset after the iWASH PRO bottle was replaced. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.

Code	Title	Description	Troubleshooting
108-8	Wash Error	WashCellEmitterCurrentToLow	Current for the reading cell emitter is lower than the allowed lower limit. Contact ALCOR Scientific Technical Support.
108-9	Wash Error	WashCellEmitterCurrentToHigh	Current for the reading cell emitter is higher than the allowed higher limit. Contact ALCOR Scientific Technical Support.
108-10	Wash Error	WashTailEmitterCurrentToLow	Current for the Tail Sensor Emitter is lower than the allowed lower limit. Contact ALCOR Scientific Technical Support.
108-100	Wash Error	WashExceededMaxAttempts Quick Clean failed. Please check your fluid levels and tubing connections.	The wash process failed after a number of auto-retry attempts. Check if there is sufficient iWASH PRO fluid in the bottle. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.
108-101	Wash Error	WashErrorBottleClean iWASH container almost empty. Replace iWASH container then press 'Replace'.	Check is the waste bottle is near full. If so, empty the waste bottle and reset the counter on the Maintenance Menu.
108-102	Wash Error	WashErrorBottleClean iWASH container almost empty. Replace iWASH container then press 'Replace'.	Check if the wash bottle is near empty. If so, refill and reset the counter on the Maintenance Menu.
108-11	Wash Error	WashTailEmitterCurrentToHigh	Current for the Tail Sensor Emitter is higher than the allowed higher limit. Contact ALCOR Scientific Technical Support.
108-12	Wash Error	WashOtherProcessRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-13	Wash Error	WashWithdrawalRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-14	Wash Error	WashMeasureRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-15	Wash Error	WashPrimeRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-16	Wash Error	WashDeepCleanRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
108-17	Wash Error	WashTailCalibrationRunning	Wash requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-0	Deep Clean Error	DeepWashErrorUndefined	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-1	Deep Clean Error	DeepWashErrorDisconnect	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-2	Deep Clean Error	DeepWashErrorPumpTimeout	Error detected during the movement phases of the Deep Clean process. Pump did not start movement. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-3	Deep Clean Error	DeepWashErrorMovement	Error detected during the movement phases of the Deep Clean process. Pump did not start movement. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-4	Deep Clean Error	DeepWashErrorNoTube	The deepCLEAN PRO tube was not detected in the expected rotor location upon withdraw. Restart the instrument and attempt to re-run deepCLEAN PRO either manually or via schedule. If the error persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
110-5	Deep Clean Error	DeepWashErrorOtherProcessRunning	Deep Clean requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-6	Deep Clean Error	DeepWashErrorCellNotWashed	Wash failed during the Deep Clean process. Check if there is sufficient iWASH PRO fluid in the bottle. If iWASH PRO is full, contact ALCOR Scientific Technical Support. Otherwise, replace iWASH PRO fluid and retry.
110-11	Deep Clean Error	DeepWashErrorWithdrawalRunning	deepCLEAN PRO requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-12	Deep Clean Error	DeepWashErrorMeasureRunning	deepCLEAN PRO requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-13	Deep Clean Error	DeepWashErrorPrimeRunning	deepCLEAN PRO requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-14	Deep Clean Error	DeepWashErrorWashRunning	deepCLEAN PRO requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
110-15	Deep Clean Error	DeepWashErrorTailSensorCalibrationRunning	deepCLEAN PRO requested when another process is running. Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-0	Measure Error	MeasureErrorUndefined	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112--1	Measure Error	MeasureErrorDisconnect	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-2	Measure Error	MeasureErrorOtherProcessRunning Measurement requested while another process is running.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-3	Measure Error	MeasureErrorSampleTypeNotSet Sample type not set.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-4	Measure Error	MeasureErrorReactorTriggerDelay Reactor trigger delay. Remix sample for additional time and run again.	Remix SEDITROL or Proficiency sample for additional time and run again. If the error still persists, contact ALCOR Scientific Technical Support.
112-5	Measure Error	MeasureErrorFlowIn Flow in. No flow detected when pumping into Reading Cell.	Reactor was unable to detect flow of sample stream during laminar flow. After withdrawal sample did not move into reactor. Check sufficient sample is in the sample tube and run again, otherwise contact ALCOR Scientific Technical Support.
112-6	Measure Error	MeasureErrorFlowOut Flow Out. No flow detected when discarding sample from Reading Cell.	Reactor was unable to detect flow of sample stream when discarding. Sample still inside the reactor. Run a Quick Clean and continue with next samples. If error persists, run a Deep Clean and/or contact ALCOR Scientific Technical Support.
112-7	Measure Error	MeasureErrorFlowBackup Flow backup.	Reactor was unable to detect flow of sample stream when discarding. Sample still inside the reactor. Run a Quick Clean and continue with next samples. If error persists, run a Deep Clean and/or contact ALCOR Scientific Technical Support.
112-8	Measure Error	MeasureErrorDiscardAvailability Failed to update instrument test credits.	Instrument is unable to properly update credits. Please contact ALCOR Scientific Technical Support.
112-9	Measure Error	MeasureErrorAvailability No test credits on instrument. Please insert a test card and add credits to the instrument.	Add credits to the instrument.
112-11	Measure Error	MeasureErrorSampleType Invalid sample type.	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
112-12	Measure Error	MeasureErrorWithdrawalRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-13	Measure Error	MeasureErrorWashRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-14	Measure Error	MeasureErrorDeepCleanRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-15	Measure Error	DeepWashErrorMeasureRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-16	Measure Error	MeasureErrorTailCalibrationRunning	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
112-100	Measure Error	MeasureErrorExceededMaxAttempts Too many tubes failed measurement	Retry through the UI. If the error persists, power cycle the device and attempt to run samples again. If the error still persists, contact ALCOR Scientific Technical Support.
113-0	Smart Card Error	ScErrorInvalid Card is invalid. Please try again.	Card model/type is not valid. Try inserting card again. If unsuccessful, contact ALCOR Scientific Technical Support.
113-2	Smart Card Error	ScErrorCardRemoved Card removed. Please try again.	Card was removed during an operation. Try inserting card again.
113-3	Smart Card Error	ScErrorCardType Card type error. Please try again.	The inserted Smart Card does not comply with SLE4442. Please try again. If the issue persists, contact ALCOR Scientific Technical Support.
113-4	Smart Card Error	ScErrorCipherSize Cipher size error. Please try again.	Card cannot be decrypted due to an invalid memory dimension. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-5	Smart Card Error	ScErrorCommand Command error. Please try again.	System has passed an incorrect command to the smart card controller. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-6	Smart Card Error	ScErrorStartAddressStart address error. Please try again.	System has requested to read/write to a wrong starting address. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-7	Smart Card Error	ScErrorEndAddress End address error. Please try again.	System has requested to read/write to a wrong ending address. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-8	Smart Card Error	ScErrorMemoryRange 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, otherwise contact ALCOR Scientific Technical Support.
113-9	Smart Card Error	ScErrorErasing Erasing error. Please try again.	Error encountered during Smart Card error counter erase operation. Smart Card is still valid. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-10	Smart Card Error	ScErrorNonAlcorSmart Non Alcor Smart Card Error. Please insert a valid card.	The inserted Smart Card is not manufactured by ALCOR Scientific. Please contact ALCOR Scientific Technical Support.
113-11	Smart Card Error	ScErrorPersonalizationIncorrect Personalization incorrect. Please try again.	The inserted Smart Card does not present the same distributor ID stored on the instrument. Smart card will not be loaded. Please contact ALCOR Scientific Technical Support.
113-12	Smart Card Error	ScErrorProtocolType Protocol type error. Please try again.	Inserted Smart Card does not use "Asynchronous" protocol. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-13	Smart Card Error	ScErrorPscPresentationPSC 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, otherwise contact ALCOR Scientific Technical Support.
113-14	Smart Card Error	ScErrorSizeNotOk Size not okay error. Please try again.	Inserted Smart card contains a denomination that is not allowed. Contact ALCOR Scientific Technical Support.

Code	Title	Description	Troubleshooting
113-15	Smart Card Error	ScErrorUnableToWriteEeprom Unable to write EEPROM. Please try again. If issue persists, please contact customer service.	System is unable to store credits into internal memory. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-16	Smart Card Error	ScErrorRestoreOriginalAvailability 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, otherwise contact ALCOR Scientific Technical Support.
113-17	Smart Card Error	ScErrorUnhandledRequest Unhandled request error. Please try again.	Value written to request register not handled by the process. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-18	Smart Card Error	ScErrorUnableToClearEeprom Unable to clear EEPROM. Please try again. If issue persists, please contact customer service.	During transfer, system unable to clear internal memory availability value. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-19	Smart Card Error	ScErrorTransferContentInvalid Transfer content invalid. Please try again.	Content of transfer card is not valid. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-20	Smart Card Error	ScErrorCardUsed 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 ALCOR Scientific analyzer, contact ALCOR Scientific Technical Support.
113-21	Smart Card Error	ScErrorUnableToLogCard	System is unable to store credits into internal memory. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-22	Smart Card Error	ScErrorUnableToRestoreLogCard	System is unable to store credits into internal memory. Restart unit and try again, otherwise contact ALCOR Scientific Technical Support.
113-23	Smart Card Error	ScErrorCardCloned Card has been cloned. Please insert a valid card.	Inserted card has been already downloaded into this unit. This card may have been cloned. Please contact ALCOR Scientific Technical Support.
113-24	Smart Card Error	ScErrorIncorrectDeviceID Card is for another device. Please insert a valid card.	The inserted card does not match the iSED PRO Device ID. Please contact ALCOR Scientific Technical Support.
113-51	Reading Cell Error	ReadingCellTempOutOfRange Reading Cell Temperature Out of Range	Reading Cell thermal control shows an abnormal temperature reading, which will prevent measurement from starting. If this error persist for more than 3 minutes, contact ALCOR Scientific Technical Support.
201-1	Rack Error	RackErrorEjection	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
201--1	Rack Error	RackErrorDisconnect	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
201-2	Rack Error	RackErrorLoading	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
201-3	Rack Error	RackErrorInvalidProcessingRequest	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
201-4	Rack Error	RackErrorProcessingError	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
201-5	Rack Error	RackErrorUndefined	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
300-51	LIS Error	LisNotConnected Failed to Connect to LIS Server. Without an LIS connection, the instrument is unable to check if a test has been requested or automatically transmit results.	Check with local IT to ensure proper LIS settings for bidirectional communication between the iSED PRO and the LIS. If the iSED PRO is intended to be run in unidirectional mode or without a LIS, please select the appropriate configuration under General Settings.

Code	Title	Description	Troubleshooting
400-1	QC Schedule Error	QCNotRun Unable to run scheduled QC samples.	Check the internal rack to ensure that SEDIROL tubes are loaded. Check the maintenance page to ensure that loaded SEDIROL tubes have remaining uses. If both of these conditions are true, restart the instrument and attempt to re-run. If the issue persists, contact ALCOR Scientific Technical Support. If no SEDIROL tubes are present, load new SEDIROL tubes onto the device via the load process.
400-2	QC Schedule Error	QCAreadyRunning QC run requested but already running.	This alert is for informational purposes only and is non-blocking. If this occurred due to an automated scheduling conflict, please review your scheduling configuration.
90-51	Board Error	BoardStartFailed	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.
90-52	Board Error	BoardInitFailed	Retry through the UI. If the error persists, restart the unit. If the error still persists, contact ALCOR Scientific Technical Support.

17.2 Sampling Error Codes

In the event of a sampling or measurement related error, the following messages will be shown in the Result Log:

Error Code	Explanation	Solution
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 ALCOR Scientific Technical Support.
ESR_ERR_NOSPIKE	Human blood, when stopped into the reading cell, must present 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 (aggregates) with the increase of the detected signal. If the signal detected decreases instead, the error code is provided, indicating a non-standard 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 hyper-viscosity 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	This error appears when the system is not able to aspirate the correct volume from the sample tube.	Check for sufficient volume in sample tube, otherwise contact ALCOR Scientific Technical Support.
ESR_ERR_FLOW_IN	System unable to move the sample inside the reactor.	Check for sufficient volume in sample tube, otherwise contact ALCOR Scientific Technical Support.
ESR_ERR_FLOW_OUT	System unable to move the sample out of the reactor.	Contact ALCOR Scientific Technical Support.
ESR_ERR_ACQUISITION	Acquisition measure step unable to complete.	Contact ALCOR Scientific 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. Otherwise Contact ALCOR Scientific Technical Support.
ESR_ERR_LOW_CONTROL_HIGH	System detects a High value on a Low control.	Remix sample for additional time and rerun test. Otherwise Contact ALCOR Scientific Technical Support.
ESR_ERR_HIGH_CONTROL_LOW	System detects a Low value on a High control.	Remix sample for additional time and rerun test. Otherwise Contact ALCOR Scientific Technical Support.

17.3 Troubleshooting

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

Situation	Possible Causes	Solutions
Analyzer 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 16.5.
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 ALCOR Scientific Technical Support or your authorized representative.
Results are running low/high	Lipemic, hemolyzed, or clotted specimen	Verify condition of specimen.
	Pre-analytical sample handling change or system error	Run SEDiTROL Controls. If results are within range, resume normal operation; if out of range, discontinue testing and contact ALCOR Scientific Technical Support or your authorized representative.
Analyzer is not scanning barcodes	Barcode is damaged or incompatible or tube has no barcode label	Validate barcode label.
	Barcode reader misaligned	Contact ALCOR Scientific Technical Support or your authorized representative.

For troubleshooting issues not covered in these Instructions for Use, please contact ALCOR Scientific Technical Support or an authorized representative.

18. Safety Precautions

18.1 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 the power supply before performing any cleaning, preventive maintenance other than Deep Cleaning, or exposing internal electrical components and circuits.

NOTE: If iSED PRO is used in a manner not specified by the manufacturer, damage or injury could result.



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

18.2 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, 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 of liquid waste container contents in a manner consistent with local regulations and laboratory procedures.



WARNING: Monitor iWASTE PRO Waste Container to ensure there are no leaks or spills within the analyzer.

19. ALCOR Scientific Contact Information

Technical Support

If you experience any problems while operating the instrument, please contact ALCOR Scientific Technical Support or your local authorized ALCOR Scientific iSED PRO representative. 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 onboard 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 Protection Agency's Regulations for Biohazard Waste Management.

General Contact Information

Phone: (800) 495.5270 (USA Only) /+1 (401) 737.3774

Fax: +1 (401) 737.4519

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

General Inquiries: info@alcorscientific.com

Customer Service: customerservice@alcorscientific.com

20. Technical Specifications

Name of Device	iSED PRO
Type of Device	Automated analyzer for the determination of ESR 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 test volume
	100 µL aspirated volume
Sample Stability	Up to 28 hours when stored at room temperature or 48 hours when stored refrigerated
Analytical Range	1 – 130 mm/hr
Time to First Result	Within 20 seconds after pre-programmed sample mixing
Throughput	Up to 275 samples per hour
Capacity	iSED PRO Series S: 120 samples / iSED PRO Series B: 110 samples
Ethernet Port	RJ45, 10/100/1000 Mbps
Connectivity	LIS - Bidirectional and unidirectional protocol; LAN TCP/IP
Barcode Scanner	Internal
Printer	Optional External
Operating Environment	10 to 30°C, indoor use, pollution degree – 2
Storage/Transport Environment	-20 to 60°C
Humidity	15% to 85% (non-condensing)
Power Supply	100-240 VAC
Power Consumption	500W
Frequency	50/60 Hz
Over Voltage Category	Category II
Dimensions (L x W x H)	495 x 553 x 670 mm (20 x 22 x 27 in)
Package Dimensions (L x W x H)	940 x 718 x 889mm (37 x 28.25 x 35 in)
Weight	38 Kg
Package Weight	68 Kg
Operational Altitude	4000 Meters
Storage Altitude	4000 Meters
Restrictions	For Professional Use Only

21. 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 (1) 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.

22. References

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