



# iSED<sup>®</sup> PRO

## QUICK REFERENCE GUIDE

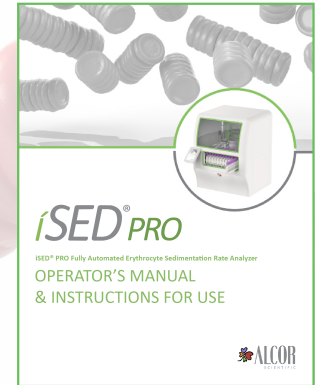
Valid for Software Version v1.3.11

## Table of Contents

Intended Use . . . . .	2
Sample Requirements . . . . .	2
Sample Rack Preparation . . . . .	3
Sample Processing . . . . .	4
Running External Controls . . . . .	4
Home Screen . . . . .	5
Results Log . . . . .	5
Replacing iWASH® PRO . . . . .	6
Emptying iWASTE® PRO . . . . .	7
Replacing Onboard Consumables . . . . .	8
Deep Cleaning . . . . .	8
Consumables . . . . .	9
Contact Information . . . . .	10



Scan for  
Instructions  
for Use



## 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.

## 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 requirement is smaller – contact ALCOR® Scientific Technical Support for tube compatibility details
- Sample should not be clotted or grossly lipemic or hemolyzed upon visual inspection (DO NOT mix vigorously!)
- Sample should be tested within 28 hours from venipuncture when stored at room temperature (18-25°C) or 48 hours when refrigerated (4-8°C)
- If sample has been refrigerated, sample must be brought to room temperature for at least 15 minutes before testing



### Rack Requirements

**iSED PRO Series S** is compatible with Sysmex XN Hematology Rack System, Mindray BC Series, and Horiba Yumizen Series.

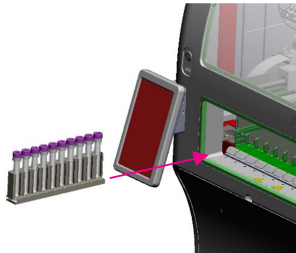
**iSED PRO Series B** is compatible with Beckman Coulter DxH Series, Cassette Type A racks.

Samples MUST be loaded onto the iSED PRO analyzer via a hematology rack. Beckman Coulter racks must be placed in a Rack Carrier.

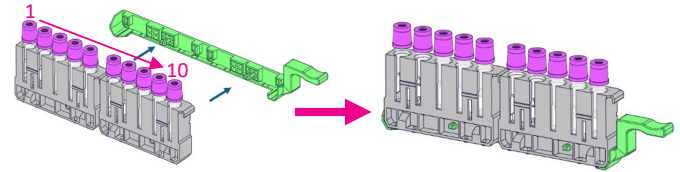
## Sample Rack Preparation

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. **All sample tubes must be tightly capped with pierceable caps.** Racks can be loaded into any green lane.

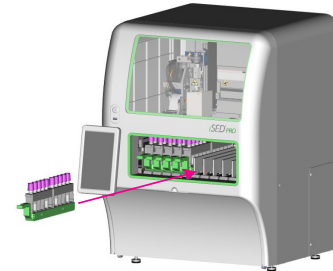
**For Sysmex, Mindray, and Horiba hematology racks:** Rack must be loaded with sample position 1 in the front as seen below.



**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. The image below shows 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).



The Rack Carrier is loaded onto iSED PRO with the sample position 1 in the front and the handle in the back as seen below.



## Sample Processing

iSED PRO operates via the insertion of hematology racks into any unoccupied rack lane located at the front Rack Port opening.

### To start processing a rack:

1. Insert the rack into an available lane indicated by a **green** status light.
2. 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**.
3. If an ESR test is indicated (as determined by workflow mode), the sample is queued for removal from the rack and sample will be measured. Upon measurement completion, iSED PRO will return the sample tube back to its original Rack Position.
4. At the time the rack is finished processing, 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 lane.



Lane status is indicated by a 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.



## External Controls

- SEDITROL® is the only control material validated for use with iSED PRO.
- SEDITROL Levels 1 and 2 tubes are stored onboard iSED PRO.
- The Quality Control frequency can be set based on laboratory needs. iSED PRO will automatically follow the schedule and measure both SEDITROL levels.
- The QC schedule will be set at initial setup and can be changed later via the General Settings submenu.

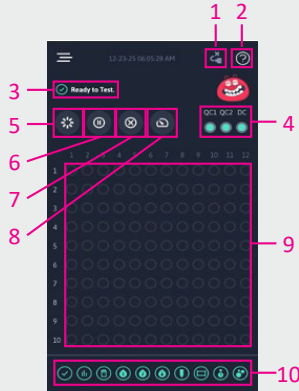
*Please refer to the iSED PRO Instructions for Use for the complete operating procedure.*



## Home Screen

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

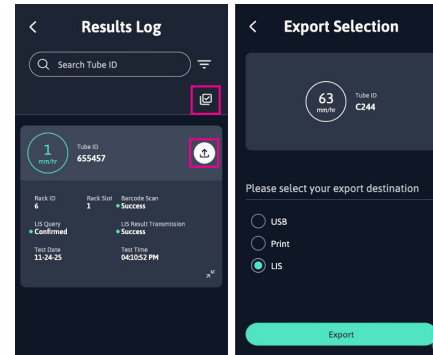
- LIS Connection:** Denotes the LIS connection status – green indicates the analyzer is connected to the LIS.
- Sample Legend:** Color legend for onboard sample status.
- Status Banner:** Displays important information about the status of the analyzer.
- Onboard Consumable Levels:** These 3 circles indicate 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.
- Eject:** Used to eject racks currently onboard iSED PRO.
- STAT:** Used to mark a rack as STAT priority for testing.
- 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 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.



## Results Log

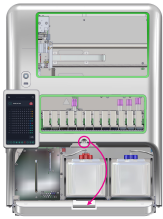
The Results Log is organized with the most recent test results shown first.

- 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
- 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



Results can be automatically transmitted to the LIS and/or manually exported in groups or as individual results. During manual export, the Export Selection screen will appear.

## Replacing the iWASH PRO Wash Fluid

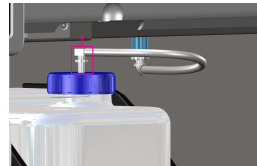
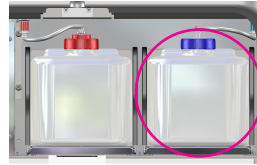


1. Open the front door to access the Bottle Compartment.
2. The iWASH PRO container is located in the bottle tray on the right.

3. Pull out the iWASH PRO container slightly.

4. Disconnect the LUER connector from the iWASH PRO screw cap. DO NOT dispose of the empty container's cap.

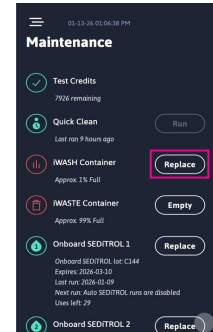
5. Remove the empty iWASH PRO container, unscrew the cap, and replace it with a new iWASH PRO bottle.



6. Place the new iWASH PRO container in the compartment, replace the current container's cap with the vented screw cap (used on the previous bottle), and reconnect the LUER connector on the plastic screw cap with the vent hole positioned at the top. Be careful not to kink the tubing.

7. Close the Bottle Compartment Door.

8. In the Maintenance Menu, press the iWASH Container "Replace" button to reset counter to 100% full.

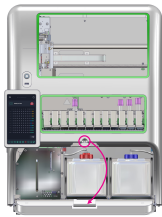


The empty iWASH PRO container can be repurposed as the waste container for iSED PRO. Be sure to label appropriately according to your laboratory's requirements for biohazardous material if reusing as a waste container.

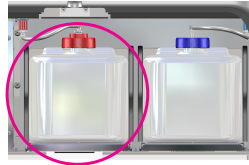
## Replacing the iWASTE PRO Waste Container



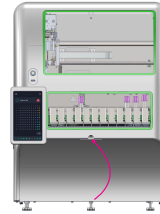
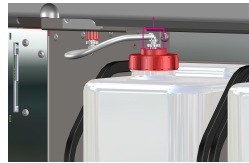
**WARNING:** Wear Personal Protective Equipment (PPE) such as protective gloves and safety glasses during this operation. Dispose liquid waste container contents in a manner consistent with local regulations and laboratory procedures.



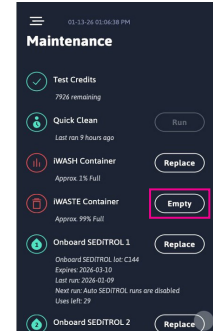
1. Open the front door to access the Bottle Compartment.
2. The iWASTE PRO container is in the bottle tray on the left.
3. Pull out the iWASTE PRO container slightly.



4. Disconnect the LUER connector from the waste bottle screw cap.
5. Remove the iWASTE PRO container and dispose of the waste according to your laboratory's biological waste protocol.



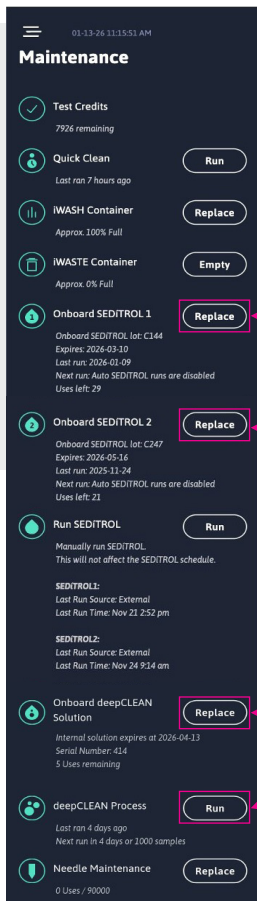
6. Replace the iWASTE PRO container and reconnect the LUER connector on the plastic screw cap. If using a new container, be sure to use the screw cap from the waste container being replaced.
7. Close the Bottle Compartment Door.
8. From the Maintenance Menu, press the iWASTE Container "Empty" button to reset the counter to 0% full.



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.

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





## Replacing Onboard Consumables (SEDiTROL & deepCLEAN® PRO)

- iSED PRO has an Onboard Consumables Holder for storing SEDiTROL Levels 1 and 2 and deepCLEAN PRO.
- The user will be notified when it is time to replace any or all consumables. The process can also 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 Solution.
- Follow the onscreen instructions to prepare a hematology rack containing a maximum of one of each replacement tube. Once a rack with replacement tubes is loaded, iSED PRO will unload the old tubes from the Onboard Consumables Holder and return them to the hematology rack. The new tubes will be scanned to verify the material and ensure correct placement in the Onboard Consumables Holder.

## Deep Cleaning

- The deepCLEAN PRO cleaning solution is stored onboard iSED PRO and is essential for removing build up in the fluidics pathway.
- The analyzer will automatically perform a Deep Clean of the aspiration pathway from the needle to the reading cell once per week or every 1,000 samples, whichever comes first.
- Deep Cleaning can also be performed as needed for troubleshooting purposes by selecting “Run” next to Deep Clean in the maintenance menu.

Please refer to the iSED PRO Instructions for Use for the complete operating procedure.



## 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
High Capacity Thermal Printer Paper	Printer paper for High Capacity Thermal Printer	5 pack	112-12-012



## Contact Information

**ALCOR Scientific Technical Support:**

800.495.5270 / 401.737.3774  
techservice@alcorscientific.com

**ALCOR Scientific Customer Service:**

800.495.5270 / 401.737.3774  
customerservice@alcorscientific.com



←  
*Scan for  
Instructions  
for Use*

