Positioning to Win: iSED vs. YHLO Vision and Vision Pro

Profile of a YHLO Vision and Vision Pro user

- **Location**
  - Ideal customers are hospitals, rheumatology clinics, emergency departments, blood banks, and stand-alone diagnostic laboratories.
- **Volume**
  - Medium to large sample volumes, 25-100 samples/day

- **The ideal Vision/Vision Pro customer profile to switch to the iSED**
  - Labs running 20-50 samples/day, 400-1300 samples/month.
  - Frequent receipt of sample tubes with volume of less than 1 mL, such as pediatric samples that only have 0.5mL sample volume maximum.
  - Testing must occur within 2 hours of blood draw, so labs that struggle with this timing will benefit from the iSED technology advantages that produce accurate results from samples tested within 4 hours, at room temperature, or within 24 hours when refrigerated.
  - Looking to improve the efficiency of their testing workflow with more automated features, less manual intervention and management of bar code labels, and ability to accommodate low volume samples.

- **Workflow**
  - Vision/Vision Pro users will need to run the ESR first to ensure that there will be enough sample for any subsequent tests, such as CBC. No blood is removed during the testing process so sample integrity is maintained.
  - Testing must occur within 2 hours of blood draw. This puts significant constraint on the lab to ensure the test is performed quickly. The iSED sample requirement is within 4 hours, if the sample is at room temperature, and within 24 hours if refrigerated, providing the lab more flexibility to manage their workflow.

YHLO offers the **Vision and the Vision Pro**, the latter of which has a few additional features. Both systems are based on the Westergren method and experience many of the limitations of that procedure, such as large sample volume needs (minimum 2mL), longer TAT (23 minutes), and they are essentially batch analyzers.

One big limitation of these systems is that they require optical reading of the sed rate through a window between the edges of the label on the tube. If the window is covered or if there are too many labels on the sample, the sed rate cannot be read. Patient identification and other information contained in the bar code are necessary for positive sample ID and proper test ordering. Management of the label positioning on the tube is very time consuming and a source of error and/or delayed results for the YHLO systems.

References are listed at the end of the Guide

Competitor Comparison

	iSED	Vision	Vision Pro	WINNING METHOD
				
Testing Methodology	Photometric Rheology RBC aggregation	Optical infrared LED emitter and receiver	Optical infrared LED emitter and receiver	iSED
Total Minimum Volume	Up to 500 µL (varies by tube type)	2mL	1.5mL – 3.5mL	iSED
Testing Volume	100 µL	0	0	YHLO
Time to First Result / Analysis Time	3 minutes 20 seconds 20 seconds / result	3 minutes/mixing 20 minutes / result	3 minutes/mixing 20 minutes / result	iSED
Random access-always ready to accept samples	Yes	No	Yes	Same
Loading Samples	One at a time Prioritize STATs	One at a time	One at a time	Same
# of Positions	20	8 tubes (model A) 16 tubes (model B) 32 tubes (model C)	8 tubes (model A) 16 tubes (model B) 32 tubes (model C)	iSED
Throughput Max tests / hour	180	24 (model A) 48 (model B) 96 (model C)	24 (model A) 48 (model B) 96 (model C)	iSED
Mixing on Board	Yes	Yes	Yes	Same
Size-foot print (in / cm)	13.4 x 10.5 x 14.3 34 x 26.7 x 36.3	13.7 x 11.8 x 11.8 35 x 30 x 30	13.8 x 14.3 x 325 35.2 x 36.5 x 32.5	Same
Automated Washing	Yes After 15 min idle-automatic And/or initiated by user	Not required	Not required	YHLO
Barcode reader	Yes Internal	Yes External	Yes Internal (claims but is external)	iSED
Printer	Yes-Internal	Yes-External	Yes-Internal	iSED
Interface Capability	Uni-directional	Bi-directional	Bi-directional	YHLO
Quality Control	Human-based, bi-level 60-day open vial stability 18-month shelf life RT storage	Human-based, bi-level 31-day open vial stability 18-month shelf life RT storage	Human-based, bi-level 31-day open vial stability 18-month shelf life RT storage	iSED
QC Program	Online	Not offered	Not offered	iSED
Sample Tube Requirements	13X75 EDTA with pierceable cap Compatible: BD MAP, BD Vacutainer Greiner miniCollect, Sarstedt S-Monovette	EDTA 12 or 13 mm tube	EDTA 12 or 13 mm tube	iSED
Sample Stability	4 hours at RT 24 hours at 2-8°C	2 hours at RT	2 hours at RT	iSED
Temperature Control	Yes	Yes	Yes	Same

References are listed at the end of the Guide

Summary of comparison

Key reasons to choose the iSED:

- **Sample requirements**
  - Vision/Vision Pro that require a minimum 2mL of sample. No actual sample is withdrawn from the tube; however, this large sample requirement could lead to a rejection of the sample due to QNS and/or a sample re-draw to have the minimum amount of sample needed to produce a result. This is not ideal for pediatric samples, which typically contain between 400-500µL of sample, or for low volume samples that do not contain the full 2mL.
  - The iSED minimum sample required is up to 500 µL, which includes only 100µL for testing + dead volume (varies by tube type-refer to the ALCOR Tube Compatibility Chart) in the currently validated sample tubes, making it ideal for low volume and pediatric samples.

- **Tube requirements**
  - Vision/Vision Pro require 12 or 13mm EDTA tubes with labels applied so that an open space or "window" is present for the analyzer to be able to scan the tube to read the sedimentation. In addition, only one secondary label other than the tube manufacturer's label is allowed. Multiple labels can cover the reading window and cause the tube to sit at an angle in the analyzer, which will affect the results. Micro-collection tubes, such as those used for pediatrics, cannot be loaded directly into the analyzer, prohibiting these samples from testing.
  - The iSED samples directly from the primary EDTA tube and measures red blood cell aggregation via a direct measurement of the sample in the photometric reading cell. The barcode reader does not require meticulous placement of the barcode label, minimizing hands-on time for sample management. BD MAP and Greiner MiniCollect tubes are validated to place directly on the analyzer, enabling primary tube sampling for pediatrics.

- **Internal barcode reader**
  - Positive sample identification and traceability of the result to the patient ID is important to prevent reporting the wrong results on a patient, potentially causing poor treatment decisions and unnecessary medical care. The Vision has an external barcode scanner that introduces the risk of swapping samples while loading. The Vision Pro claims to have an internal barcode reader, however, it is located on the side of the sample loading area, which means that a sample can easily be scanned but an unscanned sample could be loaded instead. Mis-identified samples with incorrect reporting of results is a common human error in systems that do not have full traceability and positive sample ID.
  - The iSED has an internal barcode reader for positive patient identification and full sample and result traceability.
- **Methodology**
  - The Vision and Vision Pro use optical infrared technology to scan through a window between the label edges on the tube. They use a gravity-based methodology, just like the Westergren method, in which the measurement is based on sedimentation of the aggregated red blood cells. This has the same limitations as the Westergren including effects from HCT, MCV, mixing, and vibrations, therefore the Vision and Vision Pro sed rate results have the potential to be less accurate due to these variables.

References are listed at the end of the Guide

    - The iSED uses photometric rheology to measure the intensity of red blood cell aggregation, which occurs in the first phase of the sedimentation process. The iSED is not impacted by environmental factors, such as temperature and vibrations, or sample variables such as HCT and MCV, and automated mixing in the analyzer is standardized to 3 minutes per sample.
- **Time to result**
    - The Vision and Vision Pro have a 3-minute mixing cycle and analysis time of 20 minutes, leading to a longer turnaround time and impact to lab workflow.
    - The iSED time to first result is 3 minutes for mixing plus 20 second analysis time.

Common objections to switching:

- User just started a X-year contract and penalties are high to break the contract.
    - Find out when the agreement started and if ESR is bundled together as part of a Total Hematology Solution.
    - If the analyzer is in the first half of the agreement, and the customer is not having any issues with it, this opportunity may need to wait a little longer before pursuing it-so keep them on your radar.
    - If the analyzer is in the last half of the agreement and/or the customer is having issues with the system, this could be an opportunity for a "buy-out", where you could compensate the customer for what is still owed to the company that placed it.
- We are happy with our current analyzer; if it's not broken, why fix it?
    - "Happy" is relative. If they have not used anything else, they may not realize that there is a better way. Ask about sample requirements, tube requirements, throughput, and time to result, plus the limitations of the sedimentation methodology in general, as described below in the SPIN questions.

SPIN Questions to Identify and Address Pain Points:

Pain Point #1: Samples require minimum of 2 mL sample volume.

Situation questions:

1) Do you run into many QNS issues with your current analyzer?
2) Do you get many micro-collection tubes? What is the volume of those samples?

Problem questions:

1) What do you do with pediatric samples? Are you able to run them on your current analyzer?
2) How do you handle QNS samples?

Implication questions:

1) What happens when you can't run samples due to the sample volume not meeting the 2mL requirement?
2) Do you have a backup analyzer for pediatric or low volume samples?
    - State that the iSED can run on BD Map tubes and Greiner MiniCollect tubes with minimum sample requirement up to 500 µL, which includes only 100µL for testing + dead volume (varies by tube type-refer to the ALCOR Tube Compatibility

Chart) in the currently validated sample tubes, making it ideal for low volume and pediatric samples.

Needs payoff:

1) Would it be helpful to have an analyzer that requires only 100 µL of sample and maximum 500 µL dead volume in the tube?
2) Would it be helpful to your workflow to be able to run all samples on one analyzer?
    - This question would anticipate that they have a backup analyzer.
3) Would it be helpful to have an analyzer that can run pediatric samples?

Pain Point #2: Analyzer requires an open window on the tube for analysis.

Situation questions:

1) How often do you receive tubes with more than one barcode or label?
2) How often do you have to fix barcode labels prior to loading on the analyzer?
3) What is the average number of samples tubes that require attention to the barcode label daily?

Problem questions:

1) How long does it take to fix tube label issues? How much does it slow down your workflow?
    - Depending on how many tube labels must be addressed prior to loading on the analyzer will impact the hands-on time of the operator and the productivity of the lab.

Implication questions:

1) What happens if there is more than one label on the tube? Do you have to remove a label? How do you know which label to remove? What happens to the positive sample ID when a label is removed?
    - It is common to have multiple barcodes or patient labels on one tube since the patient sample can come from a different facility or department that has their own specific barcode, in addition to the end user's lab barcode. There is a lot of time spent managing these, increasing hands-on time of the operator on a very low value task, risk of mis-labeling a sample or reporting the result on the wrong patient, and reduces the productivity of the lab.

Needs payoff:

1) What if you could just load the sample and the system does the rest?
2) Would it be helpful to have an analyzer that can read the barcode with no intervention by the operator?
3) Would you see workflow improvements if you did not have to address tube labelling issues prior to running sample on the analyzer?

Pain Point #3: External barcode reader

Situation questions:

1) Do you have the Vision or Vision Pro? How many samples with ESR tests ordered do you scan per day?
    - Vision has an external handheld barcode scanner and Vision Pro has a scanning inside the instrument on the side of the analyzer.

Problem questions:

1) Do you ever have issues with the external barcode reader and ensuring the correct sample matches the patient information? How do you ensure positive patient sample ID? Do your techs ever have distractions when manually scanning samples that could cause a sample to be disconnected from its results?
    - External barcode readers increase the risk of scanning one sample but loading a different one instead on the analyzer.

Implication questions:

1) What happens if there is a sample swap and the wrong patient result is reported? How would you know? What is the follow up required when you find out that this happened? How can you ensure that you have sample traceability on this analyzer?
    - The best way to ensure traceability and positive sample ID is to place the tube into a closed system (e.g., our sample port), the barcode is read, the sample is identified and tested, the results are reported, and the sample is removed. There is no interruption in this cycle that could cause a mismatch of results with the patient ID.

Needs payoff:

1) Would it be reassuring to have an analyzer that scans the barcode as it is being inserting into the analyzer, ensuring positive patient identification?

Quick Response Guides for Competitors

Instructions: After a conversation with the prospect you can follow up with a summary of competitive advantages of our analyzers. These key differences are target specifically to the competitor. It is best to leave the competitor name out of the communication (called "current system").

iSED vs. YHLO Vision and Vision Pro
(copy and paste the following in your email)
Key differences vs. your current system and reasons to choose iSED for (Lab/Hospital Name) laboratory

- **Sample requirements:** requires only 100µL of sample for testing and a total minimum sample volume up to 500µL (includes dead volume), reducing risk of QNS and re-draw; ideal for pediatric or low volume samples.
- **Time to Test:** samples are tested within 4 hours after blood draw at room temperature or within 24 hours when refrigerated, providing more flexibility to manage workflow.
- **Time to result:** quick TAT of 20 seconds.
- **Efficiency:** no special or proprietary tubes are needed! Standard 13X75 EDTA tubes, including BD MAP and Greiner MiniCollect, can be loaded directly on the analyzer for primary tube sampling, reducing or eliminating hands-on time transferring samples to required special tubes.
- **Accuracy:** technology is not impacted by bubbles, environmental and sample variables such as HCT, MCV, temperature and vibrations, ensuring accurate patient results and reduced potential for errors.
- **Reduced biohazard risk:** samples directly from the primary EDTA tube via a pierceable cap, eliminating risk of biohazard exposure due to decapping and sample transfer.
- **Traceability:** has an internal barcode reader for positive patient identification and sample traceability, ensuring that the sample result is connected to the correct patient ID.

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