

# Positioning to Win: iSED vs. Alifax Roller Series

## Profile of an Alifax Roller 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 for Roller 20LC and 20PN
  - Small sample volumes, 1-20 samples/day, and frequent low volume samples where the 30µL is necessary as provided by the Roller 20MC and Roller 10PN.
- **The ideal Roller customer profile to switch to the iSED**
  - Labs running 25-100 samples/day will see benefits from reduction of hands-on time for daily maintenance and wash cycle after QC (due to latex material).
  - Labs that would benefit from an analyzer requiring only 100µL sample volume for total minimum volume up to 500µL (depending on the sample tube type-see Tube Compatibility Chart), especially for Roller 20LC users.
  - Take the time to understand the user workflow and how the iSED can maximize/improve their workflow goals.
- **Workflow**
  - Roller 20LC users will run samples first on the CBC analyzer and then load up to 18 samples for automatic sampling (including pediatric samples).
  - Roller 20PN users will run samples first on the CBC analyzer and then load up to 20 samples for automatic sampling, but if they have pediatric or short draw samples, will use the external probe for manual sampling.
  - Roller 20MC users will run samples first on the CBC analyzer and then manually run each sample individually using the external probe.
  - Roller 10PN users will run samples first on the CBC analyzer and then load up to 10 samples for automatic sampling.

Alifax has four models of the Roller, each with a combination of features:

- **Roller 20LC:** The most automated processes of the four analyzers.
  - It has 20 positions on the mixing wheel: 18 positions are dedicated for samples; positions 19 and 20 are dedicated for wash tubes that contain distilled water.
  - The throughput is 100 samples/hour.
  - It requires 800µL of EDTA blood in the sample tube, with 175µL of sample for testing.
  - The analyzer will automatically wash from the two wash tubes per a user programmable time (0-90 minutes) after the last sample was run. The user can perform up to 5 wash cycles from one tube of distilled water. Waste is collected on board and the user is notified if the waste container (250 mL) is full.
- **Roller 20PN:** Both automatic and manual sampling options.
  - It has 20 dedicated positions for samples on a mixing wheel, with no wash tube positions required because the wash fluids are onboard the analyzer.
  - The throughput is 120 samples/hour.

- For automated sampling from the sample wheel, it requires 800µL of EDTA blood in the sample tube, with 175µL of sample for testing. The sample volume required for the manual mode is 100µL.
  - The analyzer is also equipped with an external probe on the front for manual, open tube sampling from decapped tubes. This is helpful when using a tube that is not validated to fit on the sample wheel, or a tube that does not have a pierceable cap, or one that contains a small sample volume and would be held in place for sampling, which minimizes the amount of dead volume required and reduces the risk of QNS.
    - When using the external probe manual sampling option, the user has the option to manually mix the sample or use the automatic mixing feature. After the sample is aspirated, the external probe is wiped off, and a manual wash is performed using a tube of distilled water.
  - The analyzer has wash and waste containers on board for automatic washing that the user can select from a menu on the user interface. Prior to shutting down the analyzer, a three-tube wash is done (two tubes distilled water and one tube 5% sodium hypochlorite, which is diluted bleach) by loading the wash tubes on the sample wheel and selecting “Wash and sleep” on the main menu. The analyzer will alert the user when the waste container (500mL) is full but it will not alert if the wash container (500mL) is empty or near depletion.
- **Roller 20MC:** Only has manual mixing, wash cycle, and sampling with the same external withdraw probe option as Roller 20PN.
    - Requires only 30 µL of sample, ideal for pediatric samples.
    - Given the small sample volume requirement, you will need to fully understand the customer situation to counter this potential objection. If their volume is large enough, manual sampling may negatively impact their workflow and TAT, and if they need this small sample volume for only a small percentage of their samples, they may benefit from the features offered on the iSED.
  - **Roller 10PN:** Only automatic sampling and mixing for samples on the mixing wheel.
    - 10 dedicated sample positions on the sample wheel.
    - The sample volume is 30µL.
    - Washing is manual, like the Roller 20MC
    - Given the small sample volume requirement and the automated mixing and sampling, you will need to fully understand the customer situation to counter this analyzer.

## Competitor Comparison

	<b>iSED</b>	<b>Roller 20LC</b>	<b>Roller 20PN</b>	<b>Roller 20MC</b>	<b>Roller 10PN</b>
					
<b>Testing Methodology</b>	Photometric Rheology RBC aggregation	Photometric Rheology RBC aggregation	Photometric Rheology RBC aggregation	Photometric Rheology RBC aggregation	Photometric Rheology RBC aggregation
<b>Total Minimum Volume</b>	Up to 500 µL (varies by tube type)	800 µL	800 µL (auto) 100 µL (manual)	100µL	100µL
<b>Testing Volume</b>	100 µL	175 µL ( with 87 µL priming)	175 µL (auto) 100 µL (manual) (116 µL priming 1 <sup>st</sup> two samples or 232µL)	30µL	30µL
<b>Time to First Result / Analysis Time</b>	3 minutes 20 seconds / 20 seconds	5 minutes / 20 seconds	5 minutes / 30 seconds	4 minutes / 18 seconds	4 minutes / 18 seconds
<b>Random access-always ready to accept samples</b>	Yes	No	No	Yes	Yes
<b>Loading Samples</b>	One at a time Prioritize STATs	One at a time Prioritize STATs	One at a time Manually with external probe	One at a time Manually with external probe	One at a time Manually with external probe
<b># of Positions</b>	20	18	20	N/A	10
<b>Throughput Max tests/hour</b>	180 samples/hr	100 samples/hr	120 samples/hr	N/A	N/A
<b>Mixing on Board</b>	Yes	Yes	Yes	No, manual	Yes
<b>Size-foot print (in / cm)</b>	13 x 11 x 14 5.1cm x 4.3cm x 5.5cm	12.6in x 26.0in x 22.8in 32cm x 56cm x 58cm	9.4in x 15.4in x 18.1in 24cm x 39cm x 46cm	9.4in x 15.4in x 18.1in 24cm x 39cm x 46cm	9.4in x 15.4in x 18.1in 24cm x 39cm x 46cm
<b>Automated Washing</b>	Yes After 15 min idle-auto And/or initiated by user	No 2 wash tubes made by user, placed in positions 19, 20; replaced after 5 uses; wash user programmed 0-90 minutes after last sample	Yes Initiated by user only	No	No
<b>Barcode Reader</b>	Yes-Internal	Yes-External	Yes-External	Yes-External	Yes-External
<b>Printer</b>	Internal	Internal	Internal	Internal	Internal
<b>Interface Capability</b>	Yes Uni-directional	Yes Bi-directional	Yes Bi-directional	Yes Bi-directional	Yes Bi-directional
<b>Quality Control</b>	Human-based, bi-level 60-day open vial stability 18-month shelf life RT storage Online QC program	Latex Controls, tri-level 42-day open vial stability 6-months shelf life 2-8° storage Online QC program	Latex Controls, tri-level 42-day open vial stability 6-months shelf life 2-8° storage Online QC program	Latex Controls, tri-level 42-day open vial stability 6-months shelf life 2-8° storage Online QC program	Latex Controls, tri-level 42-day open vial stability 6-months shelf life 2-8° storage Online QC program
<b>QAP Program</b>	Online	Not Offered	Not Offered	Not Offered	Not Offered
<b>Sample Tube Requirements</b>	13X75 EDTA/ pierceable cap BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	13X75 EDTA/ pierceable cap BD Vacutainer, Greiner Bio-one, optional adaptor for Sarstedt S-Monovette, Terumo	13X75 EDTA/pierceable cap Pediatric, BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	13X75 EDTA/pierceable cap Pediatric, BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette	13X75 EDTA/pierceable cap Pediatric, BD MAP, BD Vacutainer, Greiner miniCollect, Sarstedt S-Monovette
<b>Sample Stability</b>	4 hours at RT 24 hours at +4°C	24 hours at +4°C	24 hours at +4°C	24 hours at +4°C	24 hours at +4°C
<b>Temperature Control</b>	Yes	Yes	Yes	Yes	Yes

## Summary of comparison

Key reasons to choose the iSED:

- **Quality Control**

- Alifax uses a tri-level latex-based control, which does not behave like human blood. The product needs to be refrigerated, which should raise doubt about the stability of the material, and has a 42-day open vial stability. Plant a seed of doubt in the customer's mind about how stable latex controls really are if they need to be refrigerated and the material is not even real blood. In addition, three wash cycles must be performed prior to running QC on both Roller 20LC and Roller 20PN, another point of discussion regarding the additional maintenance needed as described next.
- Seditrol® is human blood-based material, which means it behaves more like real patient samples. Seditrol has a 60-day open vial stability and does not contribute to additional maintenance procedures observed in Alifax analyzers.

- **Maintenance**

- Roller 20PN has automatic maintenance that is selected from the menu (does not go into a wash cycle on its own) and it does not alert the user when wash fluid is low; this must be checked daily.
- Roller 20LC will self-clean after a user defined period of time after the last sample was run using the two tubes of distilled water in positions 19 and 20 (programmable time is 0 to 90 minutes). Prior to running QC, both Roller 20LC and 20PN must run a manual wash cycle (by selecting manual in the menu) and loading two tubes of distilled water. Prior to shutting off the analyzer, a manual wash cycle is run using two tubes distilled water and one with 5% sodium hypochlorite that are loaded on the sample wheel, and then "Wash and sleep" is selected.
- Roller 20 MC and Roller 10PN require manual wash procedures.

In general, the latex matrix of the Alifax QC causes a buildup in their systems, so in addition to the routine cleaning procedures needed for patient samples, it is important to perform washing procedures to clean the lines after QC. "Gunk" in the lines and clogged needles are two of the biggest complaints from Alifax users.

- Daily maintenance on the iSED is automatic and self-cleans if idle for 15 minutes so it is always clean and ready for new samples.

- **Sample Requirements**

- Roller 20LC/PN require 175µL of sample and 800µL dead volume (almost twice as much), which could lead to QNS and re-draw, not ideal for pediatric or low volume samples. In addition, the Roller 20PN uses 116µL of sample volume from the first two samples for priming after performing a wash cycle, and if only one sample is loaded, it will use 232µL of sample from that sample to prime the system. This is a significant volume for priming and could result in quantity not sufficient (QNS) and redraws, not conducive to physician or patient satisfaction.
- 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.

- **Random access**

- The Roller series cannot be stopped once the system has started.

- The iSED can accept samples at any time if a position is open and STAT samples can be easily prioritized.

#### **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 QC, maintenance, and sample requirements as described below in the SPIN questions.
  - Suggest the iSED as a backup analyzer if their current analyzer is down for maintenance or repairs.

#### **SPIN Questions to Identify and Address Pain Points:**

##### **Pain Point #1: Maintenance**

**Note: Identify which Roller model the customer is using to ensure you are addressing the Maintenance pain point. Look for the Roller 20MC and Roller 10PN as these have manual wash procedures that must be executed by the user. The Roller 20LC and Roller 20PN have automated wash procedures, so users of these analyzers would not be the target of these questions.**

#### **Situation questions:**

- 1) How often do you perform daily maintenance?
  - Users must perform 3 wash cycles before running QC, after the instrument is idle for up to 90 minutes, and at the end of the work shift. A wash cycle is approximately 3-4 minutes. That means if a lab runs daily QC, it can take up to 15 minutes of hands-on time to perform. The process is not automated and the user must initiate each wash cycle manually.
  - The iSED self-cleans after being idle for 15 minutes and is ready for a new sample to be introduced.
- 2) How often do you run the bleach procedure?
  - The User Manual requires a bleach procedure to be run at the end of a work shift and every week, if running >60 samples per day, or every 2 weeks, if running <60 samples per day.
- 3) How many uses do you get from the wash tubes?
  - Each wash tube has about 5 uses before it needs to be discarded, and the user needs to keep an eye on the quantity of wash in the tube, as this is not monitored by the system.

#### **Problem questions:**

- 1) How long is your system down during maintenance?

- It takes ~15 minutes per day to perform the maintenance, and since these cycles are initiated by the user, this means that they cannot walk away during the process. The more hands-on time spent performing maintenance, the less time the user spends running samples or performing high value tasks in the lab, such as generating results. Maintenance is considered a low value task in the lab, and the lab is already challenged with staffing qualified technologists to do the work. The lab has invested in automation to cover this labor shortage and having this valuable resource doing maintenance is not a good ROI for their people. Maintenance can be a big pain point for them and for us to try to relieve.

### Implication questions:

- 1) What happens if the Roller 20PN/LC is undergoing maintenance? (this happens a minimum of 2 times per day for 3-4 minutes)
- 2) What is your monthly QC cost and how quickly do you run through a kit?
  - Alifax QC kits cost between \$48 (6 test kit) and \$181 (30 test kit). Depending on how frequently the lab runs QC, especially if they are open 24/7, they would run through QC quickly.
- 3) What is the response when the lab is asked about ESR QC peer comparison during an inspection?

### Needs payoff:

- 1) Would it improve your workflow and TAT, and reduce hands-on time to have an analyzer that has automated maintenance and doesn't require 3 washes prior to running QC?
  - Our analyzers automatically wash after being idle for 15 minutes with no intervention or preparation of cleaning materials. Deep wash is performed every 31 days or 1,000 samples, which is less frequently than the Roller series that requires a bleach clean every week, for over 60 samples a day, or every 2 weeks if less than 60 samples a day. The iSED requires the operator to insert a single pre-made bleach tube and takes less than 6 minutes for the cleaning cycle, which is easier than creating 3 tubes (two DI and 1 bleach) for the Roller series.
- 2) What if I could impact your (budget, workflow, productivity) by \$X or X% (calculate this based on their answers to previous S, P and I questions). Would you see value in switching if I could save you X time/money?
  - Depending on the answers you are given to the S, P, and I questions above, calculate how much they are spending on controls and/or the amount of time they spend performing maintenance. If techs are spending time performing maintenance vs. running patient samples, that is not a good ROI for the user.

### Pain Point #2: Quality Control

#### Situation questions:

- 1) How frequently do you run controls?
  - Seditrol comes in 2 package sizes, enough to run QC daily for 1 or 3 months; open vial stability of 60 days which provides better utilization, especially for labs that do not run 7 days/week.

- 2) Were you aware that the Alifax QC material is latex based?
  - Seditrol is a human blood-based control product designed to perform like patient samples. We often hear that users of the Alifax control have problems with the latex clogging up their system, requiring more maintenance.
- 3) Do you participate in a QAP or QC peer review program?

### Problem questions:

- 1) How long does it take to perform the maintenance before you run controls?
  - Maintenance is done before QC samples are run, which takes ~14minutes, increasing hands-on time.
    - i. The iSED takes ~14 minutes to run QC, but does not require a wash prior to running.
- 2) How often do you need to order the Alifax controls?
  - Users get 6 or 30 draws out of each Alifax QC kit, depending on the kit purchased. The larger kit is good for approximately one month if the lab runs every day. If they do not run every day, the open vial stability is 42 days, so they would need to ensure they use the kit before then, so they do not waste money.
  - Seditrol comes in 2 kit sizes, one for ~1 month and the other for ~3 months of QC. Once open the vial is stable for 60 days, ensuring that even labs that do not run QC every day can use all the product.
- 3) If you participate in a QAP program, how much does it cost? How many participants are in the program? If you do not participate in a QAP program, why not?

### Implication questions:

- 1) What happens when you do not do the bleach clean procedure before or after you run controls? Have you seen a build-up of control material in your analyzer? How much downtime does this potentially cause? What does this do to your workflow?

### Needs payoff:

- 1) Would you see value in using an analyzer that requires less hands-on time for maintenance, has human-based blood controls, and is up and running-ready to generate results?

### Pain Point #3: Roller 20LC/PN sample volume can lead to QNS and sample redraws.

**Note: Identify which Roller model the customer is using to ensure you are addressing the sample volume pain point. The Roller 20LC and Roller 20PN require 175µL of sample PLUS dead volume in the sample tube; the Roller 20PN external probe uses only 100µL for manual sampling. In addition, the Roller 20PN uses patient sample to prime the analyzer. The Roller 20MC and Roller 10PN require only 30µL of sample and would not be the target of these questions.**

### Situation questions:

- 1) Which Alifax Roller model are you using?
- 2) What types of sample tubes do you receive for sed rate testing?
- 3) Do you run pediatric samples on the Roller (Model)?

- The 175µL sample volume and 800µL dead volume, which can cause QNS issues for pediatric or short draw samples.
  - 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.
  - **Problem questions:**
- 1) How do you handle QNS samples? Do you request a new sample? Were you aware that the Roller 20PN uses patient sample to prime?
    - Most patient blood samples have multiple tests requested and labs need to be conservative on how much sample they use per test to prevent depleting the sample. The Roller 20 PN takes 116µL of sample from the first two samples when running on the analyzer after a wash cycle, which requires the end user to be strategic when loading samples, increasing the chance of QNS issues and human errors. The iSED takes only ~20µL for priming the analyzer after a wash cycle.
  - 2) How do you handle pediatric samples? Do you often run into QNS issues?
    - This would be an issue for Roller 20LC since it does not have an external port like the Roller 20PN.
  - 3) How often do you have to repeat a sed rate?

### Implication questions:

- 1) What happens when you are unable to report a result due to QNS?
  - Nurses and physicians are calling the lab for the results-some are quite vocal and complain to the pathologist when results are not provided as expected.
  - This could cause a delay in diagnosis, treatment, discharge from the hospital or release from the doctor's office if the patient is waiting for their lab results.
- 2) What is the impact of redraws on your patients, especially pediatrics?
  - Cost of employee (time, labor) and the supplies (tubes, needles, etc.) to do the redraw.
  - Turnaround time-labs have overall metrics to hit TAT goals; sed rate is one of the biggest offenders to hitting this metric. If they don't "get it right the first time" and have to do a redraw, the TAT will significantly be impacted.
  - Patient (or in the case of pediatrics, the parent) satisfaction-hospitals have become increasingly aware of the amount of blood they draw and have worked to minimize that by using methods that reduce the amount of blood needed. Parents get especially emotional about repeated blood draws on their children.

### Needs payoff:

- 1) Would it reduce the number of QNS samples to have an analyzer that requires only 100µL sample volume?
  - The iSED would prevent QNS issues and can test pediatric samples directly from the BD MAP tube.
- 2) Would you be interested in a testing method that eliminates QNS and redraws?

**Pain Point #4: Roller series has a fragile needle that requires frequent replacement, is difficult to realign when replacing, and expensive repair if an onsite visit is required.**

**Situation questions:**

- 1) What kind of service events occur with your Roller?
- 2) What parts need to be replaced most frequently?
  - The needle on Roller analyzers is known to break or bend easily and is difficult to realign when the user is replacing it.
- 3) Is it easy to replace parts on the Roller or do you need to have a field service representative perform the repair on site?
  - Onsite service calls are expensive, which is why service contracts can be a large expense for labs. Most labs prefer if they can fix the issue on their own without having to call in a field service representative, so they are running again as quickly as possible.
- 4) Do you have a service contract and if so, are the parts included?
  - Most users will have a service contract either through the distributor or manufacturer that includes parts. However, some users feel the service contract is too expensive and not needed, which can be costly in the event that a service event occurs since they will have to pay a service fee, including parts.
- 5) How are service events handled in your lab? Are you able to call to technical support and receive immediate help troubleshooting?

**Problem questions:**

- 1) What happens when you have a service event and how long are you down?
  - The iSED has a mean time between failure (MTBF) of over 600 days making it a very reliable analyzer. Most repairs can be done by the user and only a few repairs require that the analyzer be sent back to the manufacturer or distributor for repair, such as the piercing system. Labs want to be back up and running as soon as possible to prevent interruption to turnaround time (TAT).
- 2) How many service events do you have on a monthly/yearly basis and how does that impact your budget? (last question is for labs without a service contract)
  - The answer to this question can give you good insight into the reliability of their current analyzer and the cost to the lab. In the US, service contracts for the iSED are ~\$1,500 for one year, including parts and loaner analyzers.
- 3) How reliable is your analyzer and do you have a backup system for when you are down?
  - This could be a good opportunity to suggest the iSED as a backup analyzer if the customer is in a contract that cannot be broken.

**Implication questions:**

- 1) What happens if your analyzer is down more than a few hours or even days? Do you have to use a backup system or send samples out to a reference lab?
- 2) What happens if your analyzer cannot be fixed on site? Do you receive a loaner analyzer until you receive your original analyzer back?

## Needs payoff:

- 1) Would you benefit from having a backup analyzer for when your Roller is down?
  - This is a great option for users still under a contract and cannot switch to the iSED. If they are using the Westergren as a backup method, state that the iSED requires only 100µL of sample and has a shorter time to result than their current system, with time to first result of 3 minutes and 20 seconds. This means their turnaround time will not be impacted in the event they need to use a backup method.
- 2) Would you be interested in an analyzer with high reliability of more than 600 days between repairs? What if, in the event that a part needs to be replaced, you are able to perform the repair yourself? Would that positively impact your workflow?
- 3) Would it help your budget and turnaround time if you had a reliable analyzer?

## 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. Roller 20LC

(copy and paste the following in your email)

**Key differences vs. your current system and reasons to choose iSED for (Lab/Hospital Name) laboratory**

- **Quality Control:** Seditrol® is human whole blood that performs like patient samples, is stored at RT and has open vial stability of 60 days; 1-month and 3-month kit sizes are available; a wash is NOT required before or after running controls, eliminating additional maintenance procedures required due to the latex-based material.
- **Maintenance:** automatically self-cleans after being idle for 15 minutes with no additional wash tubes, no hands-on time or user intervention; Deep Clean is run on demand after 1000 samples or every 30 days.
- **Sample requirements:** requires only 100µL of sample for testing, and a total minimum sample volume up to 500µL (includes dead volume), reducing potential for QNS and re-draws, ideal for pediatric or low volume samples.
- **Throughput:** processes up to 180 samples/hour
- **Random access:** load samples any time a position is open; the run can be stopped at any time making it easy to prioritize STATs