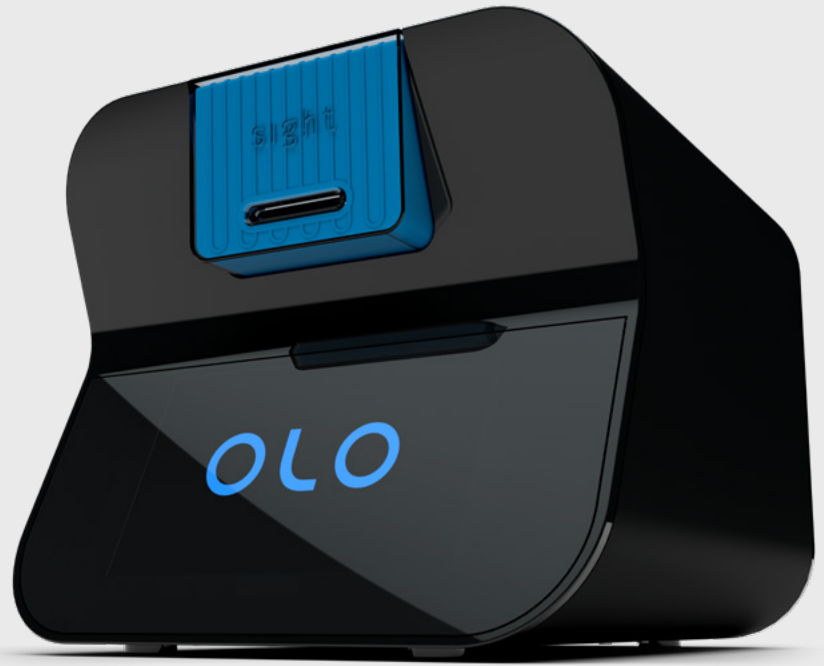


# Blood Diagnostics Reimagined



sight

## OLO Failsafe System

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## Failsafe System Overview

OLO's Failsafe system is a comprehensive set of checks and measurements that work to ensure that all elements which have a direct impact on performance are within manufacturer's specifications. If for any reason a check fails to meet its predefined criteria, the device will automatically lock to prevent any scans from being performed.

This comprehensive mechanism not only ensures analyzer performance, but also mitigates against user errors, consumable defects and blood sample irregularities to ensure that OLO does not return an erroneous result.

OLO's Failsafe system works to:

- Verify Calibration
  - *If the analyzer calibration does not meet factory defined ranges, the device will lock automatically. Details of the elements verified by the Failsafe system to guarantee factory calibration can be found in the next section.*
- Detect System Failures
  - If any of the electrical or software components is not performing according to specification, the analyzer will automatically lock.
- Ensure Accurate Results:
  - Prevent Scanning Outside Allowed Temperature Ranges
  - Detect Consumable Defects
  - Detect Blood Sample Irregularities
  - Mitigate Against User Errors

## Verifying Factory Calibration without Operator Intervention

OLO is factory calibrated and requires no end-user calibration. Upon installation at the customer site, a technician reviews the parameters measured by the Failsafe system to ensure calibration was not affected during transit. The calibration is then continuously monitored by the Failsafe system to ensure that all the parameters do not exceed manufacturer's predefined thresholds.

There are two system elements that have a direct effect on OLO's calibration and are routinely checked by the Failsafe system:

*Optical Stability* - These checks are performed at initialization, periodically and every time a sample is scanned. These checks are designed to ensure that all elements of the optical mechanism (LED intensity, illumination maps, camera performance and focus) are within manufacturer's specifications.

*Mechanical Stability* - These checks are performed at initialization and every time a sample is scanned. These checks are designed to ensure that all mechanical elements that have a direct impact on performance (leveling and positioning of the fork, cartridge and objective) are within manufacturer's specifications.

As these comprehensive checks are performed automatically by the Failsafe system on a routine basis and prior to scanning, Sight is able to verify OLO's factory calibration and ensure performance without the need for the standard liquid QC process required by the conventional flow-cytometry based technologies.



Sight's internal study validates that OLO's calibration stability has been established for at least 15 months. If for any reason, the Failsafe system uncovers an issue with the calibration through its comprehensive checks, the analyzer will automatically lock to ensure that no erroneous results would be returned.

## Detecting System Failures

In addition to routinely verifying the manufacturer's calibration, the Failsafe system also works to prevent system failures unrelated to calibration. The analyzer constantly checks the electrical stability, camera connectivity and software. If an issue is detected, the analyzer will automatically lock or prompt the operator to reboot.

In the event of a lockdown, please contact technical support ([support@sightdx.com](mailto:support@sightdx.com)) to initiate an investigation into the root cause, and if possible, unlock the analyzer.

## Accurate Results

The Failsafe system also runs additional checks on the cartridge and the sample each time a scan is initiated. These checks detect any issues in the inserted cartridge and the blood sample that may affect the accuracy of the results. In the event that an issue has been detected with either the cartridge or the sample, the Failsafe system will automatically reject the sample and withhold any test results.

In case of a sample rejection, the error messages displayed on OLO's graphic user interface will provide clear instructions for the operator to follow. Reasons a sample may be rejected include:

- Sample preparation took too long
- Hemoglobin chamber was not filled properly
- Irregular OLO cell morphology detected
- Hemolyzed sample detected
- Defective cartridge detected
- Improper sample staining detected

In addition to mitigating against user errors, consumable defects and sample irregularities, the analyzer will prevent operators from scanning samples outside the allowed temperature ranges. At any time, if the analyzer is operating outside of the allowed temperature range, an alert will be triggered and scanning will be disabled until the analyzer's temperature returns to the allowed range.

## Sight's QC Recommendations

As OLO is continuously monitored by its Failsafe system and will automatically lockdown to ensure no erroneous results are returned, Sight Diagnostics does not require additional QC measures.

For additional Quality and Safety information please visit our website at [www.sightDX.com](http://www.sightDX.com).

	Check	Initialization Checks	Routine Checks	Scanning Checks	Device Response
Optical Stability	LED Intensity	✓	✓	✓	Lockdown
	Illumination Maps	✓	✓	✓	Lockdown
	Camera Performance	✓	✓	✓	Lockdown
	Focus	✓	✓	✓	Lockdown
Mechanical Stability	Positioning	✓		✓	Lockdown
	Leveling	✓		✓	Lockdown
Environmental Conditions	Temperate Out of Range	✓	✓	✓	Scanning Disabled
	Vibrations during scanning			✓	Sample Rejected
System Failures	Electrical Stability	✓	✓	✓	Lockdown
	Software Exception	✓	✓	✓	Lockdown or Reboot Alert
	Camera Connectivity	✓	✓	✓	Reboot Alert
	Analysis Error			✓	Sample Rejected
User Error	Sample preparation took too long			✓	Sample Rejected
	HB chamber not properly filled			✓	Sample Rejected
	Not enough blood collected			✓	Sample Rejected
	Improper mixing			✓	Sample Rejected
Sample Irregularity	Hemolysis			✓	Sample Rejected
	Irregular OLO cell morphology			✓	Sample Rejected
	Dirt or debris in diluted sample			✓	Sample Rejected
Consumable Defects	Defective cartridge			✓	Sample Rejected
	Scratched surface			✓	Sample Rejected