









Luna-STEM

IQ/OQ Protocol Brochure

1. This IQ/OQ protocol is used to verify:

- The installation and operation of a newly purchased or a previously installed instrument but not qualified Luna-STEM™ Automated Fluorescence Cell Counter.
- Updates or upgrades that may affect the instrument's performance.
- The operation of the instrument that requires regular operation qualifications.
- The requalification of a previously qualified instrument that has been reinstalled or moved to a new location.

2. This IQ/OQ protocol is required by:

• Researchers or customers who need to validate quality management systems such as GMP, GLP, GCP, or ISO standards.

***Note:** Logos Biosystems makes no representation or warranties of any kinds that this IQ/OQ protocol meets or will meet any mandatory requirements of any governmental organization or other entities in any country in the world. The customer acknowledges and agrees that the customer is responsible for meeting governmental regulations and certification requirements.

*Note: The software of the Luna-STEM[™] automated cell counter does NOT meet 21 CFR Part 11.

3. This IQ/OQ protocol consists of:

• 1 bound, hard copy of IQ/OQ test procedures performed by the Customer Representative (CR).

***Note:** The CR is the person appointed by the customer who performs this qualification procedure. The CR may be an employee of the customer, the instrument distributor, or a 3rd party consultant, according to the customer's SOPs.

*Note: This protocol does NOT provide consumables necessary to perform the procedures.

4. This IQ/OQ protocol includes the following:

Installation Qualification (IQ) Procedures	Operation Qualification (OQ) Procedures	
Customer Representative (CR) Verification	Pre-Operation Verification	
Environment Conditions Verification	Counting Verification	
Instrument and Document Verification	Data Saving and Reporting Verification	
Installation and System Verification	Warranty Verification	
Operating System and Firmware Version Verification	User Training Verification	



Luna-STEM Automated Fluorescence Cell Counter



5. Ordering Information

Cat #	Product	Quantity
L30001	Luna-STEM™ Automated Fluorescence Cell Counter	1
L12005	PhotonSlide™, 50 Slides	1 box
L12006	PhotonSlide™, 500 Slides	10 boxes
L12007	PhotonSlide™, 1000 Slides	20 boxes
F23001	Acridine Orange/Propidium Iodide (AO/PI) Stain	2 x 0.5 mL
F23002	Acridine Orange (AO) Stain	2 x 0.5 mL
F23003	Propidium Iodide (PI) Stain	2 x 0.5 mL
F23102	LUNA™ Fluorescence Calibration Beads	1 x 0.5 mL
L34003	Luna-STEM™ IQ/OQ Protocol	1
P10001	Luna™ Printer	1
P12001	Luna™ Printer Paper (Thermal, 700 prints)	3 x 2 rolls
P13001	Luna™ Printer Cleaning Pen	1

*Note: For more information, please contact your local distributor.

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