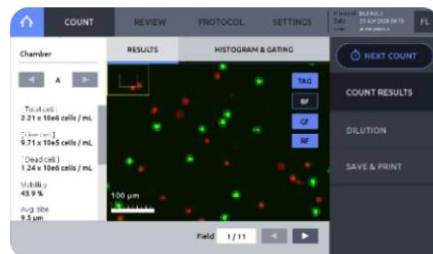
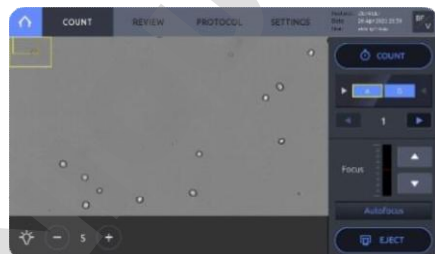


LUNA FX7™

Automated Cell Counter

Installation & Operational Qualification (IQ/OQ)



Installation & Operational Qualification (IQ/OQ)

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

- The installation and operation of a newly purchased or a previously installed but not qualified LUNA-FX7™ 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:** LUNA-FX7™'s optional software, CountWire™ is compliant with 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 third 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	Operational Qualification (OQ) Procedures
Customer Representative (CR) Verification	Pre-Operation Verification
Environment Conditions Verification	Bright field Counting Verification
Instrument and Document Verification	Bright field Counting Data Saving and Reporting Verification
Installation and System Verification	Fluorescence Cell Counting Verification
Operating System and Software Version Verification	Fluorescence Counting Data Saving and Report Verification
	Data Transfer Verification
	Warranty Verification
	User Training Verification

Installation & Operational Qualification (IQ/OQ)

5. Ordering Information

Item	Cat #	Product	Quantity	
LUNA-FX7™	70001	LUNA-FX7™ Automated Cell Counter	1 unit	
	70002	LUNA-FX7™ Automated Cell Counter, Bioprocess Package	1 unit	
Counting Slides	1-channel	L72011	LUNA™ 1-Channel Slides, 50 Slides	1 box
		L72012	LUNA™ 1-Channel Slides, 500 Slides	10 boxes
		L72013	LUNA™ 1-Channel Slides, Sterile - gamma-irradiated, 500 Slides	10 boxes
	3-channels	L72021	LUNA™ 3-Channel Slides, 50 Slides	1 box
		L72022	LUNA™ 3-Channel Slides, 500 Slides	10 boxes
		L72023	LUNA™ 3-Channel Slides, Sterile - gamma-irradiated, 500 Slides	10 boxes
	8-channels	L72001	LUNA™ 8-Channel Slides, 50 Slides	1 box
		L72002	LUNA™ 8-Channel Slides, 500 Slides	10 boxes
		L72003	LUNA™ 8-Channel Slides, Sterile - gamma-irradiated, 500 Slides	10 boxes
	2-channels (Fluorescence)	L12005	PhotonSlide™, 50 Slides	1 box
		L12006	PhotonSlide™, 500 Slides	10 boxes
		L12007	PhotonSlide™, 1000 Slides	20 boxes
	2-channels (Brightfield)	L12001	LUNA™ Cell Counting Slides, 50 Slides	1 box
		L12002	LUNA™ Cell Counting Slides, 500 Slides	10 boxes
		L12003	LUNA™ Cell Counting Slides, 1000 Slides	20 boxes
Calibration/Validation Slides	L72040	Cell Counter Validation Slide-BF	1 unit	
	L72030	Cell Counter Validation Slide-FL	1 unit	
	F73101	LUNA-FX™ Calibration Beads Kit	2 x 0.5 mL	
Reagents	T13001	Trypan Blue Stain, 0.4%	2 x 1 mL	
	T13011	Trypan Blue Stain, 0.4%, Sterile-filtered	2 x 1 mL	
	L13002	Erythrosin B Stain	2 x 1 mL	
	F23001	Acridine Orange/Propidium Iodide Stain	2 x 0.5 mL	
	F23011	Acridine Orange/Propidium Iodide Stain, Sterile-filtered	2 x 0.5 mL	
	Software	L71001	CountWire™ Basic	1 set
L71002		CountWire™, additional PC license	1 unit	
IQ/OQ	F23102	LUNA-FX7™ IQ/OQ Protocol	1 copy	
Printer-related Items	P17001	Thermal Printer for LUNA-FX™	1 unit	
	P17002	Thermal Printer Refills, Paper and Ribbon for LUNA-FX™	2 x 5 rolls	

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