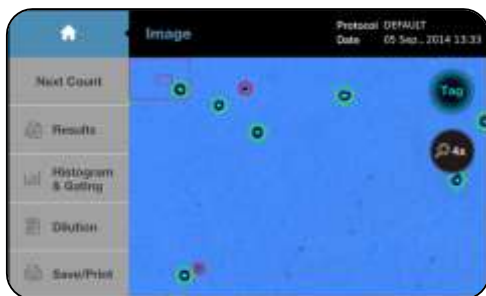
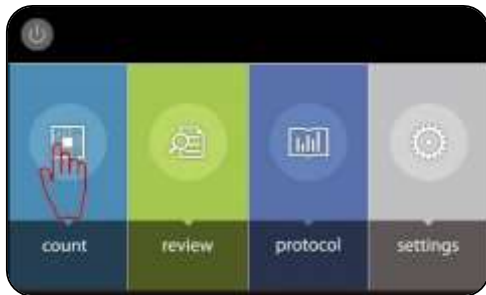


LUNA-IITM Automated Cell Counter

Installation & Operation Qualification (IQ/OQ)



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

- The installation and operation of a newly purchased LUNA-II™ Automated Cell Counter.
- The installation and operation of a previously installed but not qualified instrument.
- Updates or upgrades that may affect the instrument’s performance.
- The re-qualification of a previously qualified instrument that has been reinstalled or moved to a new location.
- The operation of the instrument that requires regular operation qualifications.



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-II™ 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, an employee of the instrument distributor/supplier, or a third party consultant, in compliance with the SOP of the customer.*

**Note: This protocol does NOT provide the 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

5. Ordering Information

Cat #	Product	Quantity
L44003	Luna-II™ IQ/OQ Protocol	1 copy
L40001	LUNA-II™ Automated Cell Counter (with built-in printer)	1 unit
L40002	LUNA-II™ Automated Cell Counter (without printer)	1 unit
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
B13001	LUNA™ Standard Beads	2 x 1 mL
T13001	Trypan Blue Stain, 0.4% (200 tests)	2 X 1.0ml
L13002	LUNA™ Biosafe Stain	2 x 1 mL
U10004	USB Drive, 4 GB	1 unit
P12002	LUNA-II™ Printer Paper - thermal, 700 prints	2 x 5 rolls

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

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