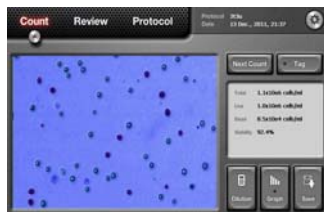


Luna™ Automated Cell Counter

Installation & Operation Qualification (IQ/OQ) Protocol

IQ/OQ
Protocol

Document No.: L14004



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™ Automated Cell Counter.
- Updates or upgrades that may affect the instrument's performance.
- The operation of the instrument that requires regular operation qualifications.
- The re-qualification 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™ 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 provides consumables necessary to perform the procedures.

4. This IQ/OQ protocol includes the followings:

Installation Qualification (IQ) Procedures	Operation Qualification (OQ) Procedures
<ul style="list-style-type: none"> ● Customer Representative (CR) Verification ● Environment Conditions Verification ● Instrument and Document Verification ● Installation and System Verification ● Operating System and Firmware Version Verification 	<ul style="list-style-type: none"> ● Pre-Operation Verification ● Counting Verification ● Data Saving and Reporting Verification ● Warranty Verification ● User Training Verification

5. Ordering Information

Cat. No.	Product	Unit
L10001	Luna™ Automated Cell Counter	1 each
L12001	Cell counting slides, 50 slides (100 counts)	1 box
L12002	Cell counting slides, 500 slides (1,000 counts)	10 boxes
L12003	Cell counting slides, 1,000 slides (2,000 counts)	20 boxes
L12004	Cell counting slides, 2,500 slides (5,000 counts)	500 boxes
T13001	Trypan blue stain 0.4% (for use with Luna™ cell counter)	2 X 1 ml
L14003	Luna™ Automated Cell Counter Installation Qualification & Operation Qualification Protocol	1 each

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