Installation Qualification/Operational Qualification (IQ/OQ)

Instructions for a documented installation and functional test

Inlabtec Serial Diluter UA Part No. 140000

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1. Introduction

The formal qualification of a laboratory instrument is the documented confirmation that the instrument fulfils the requirements and specifications for its intended use.
This present procedure defines and documents the general steps that should be executed to ensure that the Inlabtec Serial Diluter UA (Part No. 140000) is installed and functioning correctly. This document references sections from the Inlabtec Serial Diluter Operation Manual 1400001 (OM) which is available under www.inlabtec.com.

1.1. Installation Qualification (IQ)

Installation Qualification (IQ) determines if the Serial Diluter is properly installed. Installation Qualification tests should be performed at the following times:

- When the Serial Diluter is installed in the lab
- When the Serial Diluter is moved to a new location
- When software or hardwares update have been made

The IQ ensures that the Serial Diluter is installed in the appropriate environment and all system components and the connections between the individual components are properly installed: connection Serial Diluter to a reservoir (bottle/ bag/ etc.) with diluent, correct installation of the sterile/ sterilized system components.

1.2. Operational Qualification (OQ)

The Operational Qualification (OQ) ensures that the Serial Diluter is functioning to specification. Operational Qualification tests should be performed:

- When the system is taken for the first time in operation
- When the system is moved to a new location
- When another type or a new batch/ lot no. of graduated 10 ml pipettes is used
- When software or hardware updates have been made
- At least 1x per year

The OQ ensures that the Serial Diluter functions reliably. The functional parameters accuracy and precision of dispensing and the mixing time are checked and documented.

Based on the results of bacterial counts of food samples by the plate count method (pour plate technique, spreading-spatula technique) the equivalence of the Serial Diluter is verified against the dilution method used so far.

2. Installation Qualification (IQ)

2.1. Identification Serial Diluter

Serial Diluter Type/Part No.	UA/ 100000 or
Serial Number (SN)	
Inventory number/internal device number	
Company/ Site	
System location	
Reason for IQ	
Comments:	
Place/ Date:	Signature:

2.2. IQ: Scope of delivery Serial Diluter

Position	Component	Part. No.	Checked (mark)
1	1x Serial Diluter	UA/ 140000	
2	1x Serial Dilution Bags Lot. Nr.:	100100	
3	1x Tubing Set	100010	
4	1 x Dispensing Nozzle	140011	
5	1 x Bag Shell	100030	
6	1 x Connector Cap GL 45 cpl.	100020	
7	1 x Serological Pipette, 10 ml		
8	1 x Bag Stopper UA	140022	
9	1 x 24V Power Supply		
10	1 x Operation Manual (OM). Version:	140001	
Acceptance criteria: Impeccable, complete and in accordance with delivery note			
Procedure for deviations: Missing or defective components must be re-supplied or replaced. Missing documents must be re-delivered or downloaded from www.inlabtec.com.			
Comments:			
Place/ Date:		Signature:	

2.3. IQ: Installation Serial Diluter

Step	Description	Checked (mark)
1	Place Serial Diluter at an appropriate place (check OM chap. 5.2 Installation site)	
2	Make the electrical connections and switch on Serial Diluter (check chap. 5.5 Electrical connections)	
3	Function control of the Bag Holder mechanics (check OM chap. 3.2.3 Bag Holder): Dosing arm can be easily moved vertically and horizontally. yes/no: The bag flap holders can be opened and closed. yes/no: Bag support correctly placed in Bag Holder. yes/no: Mixer rocker moves freely (see OM chap. 7.4). yes/no: Inserted Serial Dilution Bags can be opened correctly. yes/no:	
4	Check function level sensor (see OM chap. 5.5.1 Check level sensor) Level sensor does work. yes/no:	
5	Check installed software version (see chap. 10 Software Update: Check software version) Installed bootloader software: bo Installed application software: AP	
6	10 ml graduated pipette used corresponds to the requirements and can be installed (see OM chap. 3.3 Specifications & chap. 5.6 Assembly tubing set and graduated pipette) yes/no:	
7	Installation of autoclaved/sterile diluent, autoclaved tubing set and autoclaved/sterile graduated pipette (see OM Chap. 5.5 Assembly tubing and graduated pipette) Installation according to the operation manual possible yes/no:	
8	Adjust dosing volume, typical 9 ml for 1:10 serial dilutions, (see OM chap. 6.1 Adjusting dosing volume) Setting of dosing volume possible yes/no:	

Acceptance criteria: Steps 1 - 8 must be met and answered yes	
Procedure for deviations: Deviations (no) must be checked critically. If the deviations cannot be corrected, the device must be repaired or replaced.	
Comments:	
Place/Date Qualification:	Signature:

3. Operational Qualification (OQ)

3.1. Identification Serial Diluter

Serial Diluter Type/ Part No.	UA/ 140000
Serial Number (SN)	
Inventory number/internal device number	
Company/ Site	
System location	
Reason for OQ	
Comments:	
Place/Date:	Signature:

3.2. OQ: Basic Functions Serial Diluter

Note: Serial Dilution Bags and pipette tips required for the OQ.

Step	Description	Checked (mark)
1	Adjust settings of Serial Diluter for OQ: SPEED [%]: **50** yes/no: TIME [s]: **bL 3** yes/no:	
2	Can the desired volume of 9 ml be precisely adjusted by moving the optical sensor yes/no:	
3	Is there an acoustic signal (beep) and the STATUS LED lights green if the set volume is reached yes/no:	
4	Is the liquid in the graduated pipette dispensed into a serial dilution bag by swivelling the dispensing arm forwards yes/no: After the liquid is dispensed into the Serial Dilution Bag, an acoustic signal sounds (beep - beep) and the graduated pipette is refilled automatically yes/no: Are 9 ml of liquid at SPEED [%] 50 aspirated again within approx. 6 seconds yes/no: An acoustic signal sounds (beep) and the status LED lights up green when the set volume is present in the graduated pipette yes/no:	
5	Is the bag blender started when the dosing arm is moved to the right to the next position yes/no: Is the blender started when the dosing arm is swivelled back to the parking position yes/no: Is the bag mixer started when the dosing arm is raised and lowered in the parking position yes/no: Is the mixing time displayed as a countdown in the TIME field yes/no:	

Acceptance criteria: Steps 1 - 5 must be met and answered yes.	
Procedure for deviations: Deviations (no) must be checked critically. If the deviations for step 1 – 5 cannot be corrected, the device must be repaired or replaced.	
Comments:	
Place/ Date Qualification:	Signature:

3.3. OQ: Functional Parameter

Step	Description	Checked (mark)
1	Verification of dispensed volume (see OM chap.9 Verification of dispensed volume) „Test Report Inlabtec Serial Diluter“ used * yes/no: Test passed and maximum error of 9 ml diluent ≤ 2.2 %** yes/no: Test report completed and signed yes/no: Name and place of filing test report: *: Test_Report_Serial_Diluter.xlsx available under www.inlab-tec.com **: if failed: see OM chap. 9.7 Assessment of test result	
2	Checking the mixing time bL Set the mixing time bL with keys + / - in the TIME [s] field (Factory setting: 3 s). Raise dosing arm in parking position and start mixer by lowering. Measure mixing time. Measured mixing time ≥ set mixing time bL. yes/ no	
3	Have the serial dilutions prepared by the Serial Diluter verified against the previously used dilution technique based on a comparison of bacterial counts of the same samples yes/no: If yes, when was the verification carried out (Date/ Name of document/ Name and place of filing): If no, why verification has been omitted:	
Acceptance criteria: Step 1 must be met with allowed maximum error for 9 ml Diluent ≤ 2.2% (ISO 6887-1:2017). Step 2 must be fulfilled i.e. the measured mixing time must correspond to the set mixing time bL. Step 3 must be met or justified if the verification has currently been omitted.		
Procedure for deviations: Deviations (no) must be checked critically. If the deviations for step 1 & 2 cannot be corrected, the device must be repaired or replaced.		

Comments:	
Place/ Date Qualification:	Signature: