Installation Qualification/Operational Qualification (IQ/OQ)

Instructions for a documented installation and functional test

Inlabtec Serial Diluter TA Part No. 100000
Inlabtec Serial Diluter SA Part No. 110000

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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 (Part No. 100000 and 110000) is installed and functioning correctly. This document references sections from the Inlabtec Serial Diluter Operation Manual 1000001 (OM) which is available under www.inlabtec.com (Resources).

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
- 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 another brand/ type of 1 ml pipette tips is used
- When software or hardware updates have been made
- At least 1x per year

The OQ ensures that the Serial Diluter functions reliably and the set volume is dispensed according to the specifications. For this, the basic functions of the Serial Diluter are checked, verified and documented as well as the function parameters accuracy, precision and speed of dispensing.
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. A verification template and instructions are available on www.inlabtec.com (library) if there are no laboratory-internal standards for method comparisons at hands.

2. Installation Qualification (IQ)

2.1. Identification Serial Diluter

Serial Diluter Type/Part No. (mark appropriate)	□ TA/ 100000 or □ SA/ 110000 (straw version)
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 – SN:

Position	Component	Part. No.	Checked (mark)
1	1x Serial Diluter	□ TA/ 100000 or □ SA/ 110000	
2	1x Serial Dilution Bags **Lot. Nr.:**	100100	
3	1x Tubing Set	□100010 □110010	
4	1 x Dispensing Nozzle	□100011 □110011	
5	2 x Bag Shell	100030	
6	1 x Connector Cap GL 45 cpl.	100020	
7	1 x Serological Pipette, 10 ml		
8	3 x 1.5 ml micro test tube, PP		
9	1 x 24V Power Supply		
10	1 x Screw driver Torx T10		
11	1 x Operation Manual (OM). **Version:**	100001	
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 (library).			
Comments:			
Place/ Date:		Signature:	

2.3. IQ: Installation Serial Diluter – SN:

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. 5.4 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: Inserted Serial Dilution Bags can be opened correctly. yes/no:	
4	Check function level sensor (see OM chap. 5.4.1 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. 5.5 Assembly tubing set and graduated pipette) yes/no:	
7	Check setting pipette table for 1 ml pipette tips / pipette straws used (see OM chap. 5.3.1 Adjustment of pipetting table of bag holder) Hang the 1 ml pipette tips hanging loosely, resp. stand the pipette straws without jamming in the receiving openings of the Bag Holder*. yes/no: If no, Adjust the pipetting table for the pipette tips/ pipette straws used as described in OM chap. 5.3.1. Adjustment of pipetting table of bag holder *: Factory setting is for Inlabtec LO Pipette Tips or ø.4 mm pipette straws	
8	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:	
9	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 - 9 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. (mark appropriate)	□ TA/ 100000 oder □ SA/ 110000 (straw version)
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: Set volume/optical sensor position [ml] **9** yes/no: SPEED [%]: **50** yes/no: TIME [%]: **AU** 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 set volume dispensed by pressing the grey dispensing key on the Bag Holder. yes/no: Does follow an air blast of about one second after the complete dispensing of the liquid. yes/no: Is there an acoustic signal (beep - beep) after the air blast and is the pipette again filled automatically within 6 seconds. yes/no: 9 ml of liquid are re-aspirated at SPEED [%] 50 within 6 seconds. yes /no: Is there an acoustic signal (beep) and the STATUS LED lights green if the set volume is reached. yes/no:	

5	Is the dispensing time displayed during filling of the graduate pipette in the display TIME [s] yes /no*: *: if not, an older software version is installed (<AP17). With a software version <AP 17, the dispensing time must be measured manually (see 3.3 OQ: Serial Diluter function, step 2). If necessary, carry out a software update ((see BA Chapter 10 Software Update) in 6 seconds. yes/no:	
Acceptance criteria: Steps 1 - 4 must be met and answered yes. Step 5 depends on the software version and answer no is acceptable.		
Procedure for deviations: Deviations (no) must be checked critically. If the deviations for step 1 – 4 cannot be corrected, the device must be repaired or replaced.		
Comments:		
Place/ Date Qualification:	Signature:	

3.3. OQ: Function Serial Diluter

Step	Description	Checked (mark)
1	Verification of dispensed volume (see OM chap.9 Verification of dispensed volume) Test report* „Test Inlabtec Serial Diluter“ used yes/no: Test passed and maximum error of 9 ml diluent ≤ 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.inlabtec.com (Library) **: if failed: see OM chap. 9.7 Assessment of test result	
2	Check and logging of the dispensing speed for 9 ml of liquid Reference values for the dispensing time of 9 ml liquid incl. air blast are: 1 ml LO pipette tips/ wide bore pipette tips as well as pipette straws: 3.0 - 4.5 s 1 ml pipette tips Standard: 4.6 - 8.0 s Used 1 ml pipette tips / pipette straws: Supplier/manufacturer: Article number / type: Dispensing speed for 9 ml including air blast* [s]: Dispensing time within reference values for pipette tips/pipette straws used ** yes / no: *: If software AP170918 (September 2017) is installed value in	

	the display TIME [s] during the automatic filling of the pipette corresponds to the dispensing time including air burst. If necessary, perform a software update (see BA Chapter 10 Software Update). Otherwise, use a stopwatch to measure and record the time between start dispensing (pressing the grey button) and start filling of the 10 ml pipette (after the end of the air burst). **: If the reference values are not complied with the 1 ml pipette tips/pipette straws used then the tips/ straws are unsuitable (too narrow opening) or there is a malfunction of the Serial Diluter (see OM chap. 6.2 Serial dilution process).	
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 food 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: *: Verification according to ISO 17025: Instructions and verification template available under www.inlabtec.com (library)	
Acceptance criteria: Step 1 must be met with allowed maximum error for 9 ml Diluent ≤ 2%. Step 2 must be met and for that the dispensing speed for 9 ml including the air blast must be within the reference values for the pipette tips/ straws uesd. Step 3 must be met or substantiated if the verification has currently been waived.		
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:	