Waters™ | Andrew Alliance™

Pipette+

Qualification Procedure

Works with OneLab design & execute

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About this manual

The procedure defines the general steps that should be performed to ensure that Pipette+ is installed and functioning properly.

1. Installation Qualification (IQ)

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	Function	**Name**	**Date**
Author	**Lab Automation Service & Support Engineer**	**L.M. Turrado**	**25 Feb 2022**
Reviewed by	**Global Service & Support Sr Manager**	**N. Vamvoukas**	**25 Feb 2022**

The Installation Qualification (IQ) is documented proof that equipment has been delivered and installed in accordance with the requirements and statutory safety regulations stipulated in the design qualification. The documentation for an Installation Qualification consists of:

- IQ test plan
- IQ report

1.1. IQ procedure

The **IQ procedure** contains detailed information of the tests to be performed on the respective equipment in the context of the Installation Qualification. The IQ procedure is composed of the following series of basic checks:

- Verification that all documents required for the correct use of Pipette+ and its software are given to the customer.
- Verification that the environmental conditions where Pipette+ is installed fulfills the requirements present in the “Quick Start Guide”.
- Verification of the correct installation of Pipette+.

After completion of the Installation Qualification, the results are summarized, evaluated and compiled in an IQ report.

The Installation Qualification template for Pipette+ is reported in the next page.

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INSTALLATION QUALIFICATION			
System name:		Pipette+	
Serial number:		**618._____**	
Document #	618.002	Revision	7

A) User manuals and documents

Verification that all the documentations and manuals are correctly delivered		
Pipette+ Quick Start Guide	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

B) Installation of Pipette+

Pipette+ Installation		
Verify that the bench on which Pipette+ is placed is stable, flat enough and dry.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

C) Power On the device

Installation of the power line.		
Verify that the power supply provided by Andrew Alliance is used with Pipette+.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Equip the power supply with the correct power adaptor based on the wall socket present in the lab.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Connect the power cord of the power supply to a compatible socket. Afterwards, plug the cable of the power supply into the back of Pipette+. 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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Verify that the "Plus" LED indication present on the front body of Pipette+ is blinking white. After few minutes, its color will turn blue or green.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

D) Placement of pipettes on Pipette+ rack

Verification that the right type of pipettes is installed on Pipette+		
Verify that the pipettes installed on Pipette+ stand are Andrew Alliance pipettes.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Verify that the pipette display is oriented towards the user, as shown below. 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Verify that the display color of each pipette placed in the rack of Pipette+, matches the color of the main button of the pipette (ex. Orange, blue, purple etc.) Note: this indicates that the pipette is properly connected and charging.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

E) Pairing of Pipette+ to OneLab

Association of Pipette+ to OneLab. **This procedure is necessary only if Pipette+ hasn't been already paired to OneLab.**		
If the Cloud version of OneLab is used, verify that the network, which Pipette+ will be connected to has Internet access and the webpage https://onelab.andrewalliance.com can be reached.	OK ☐ NOK ☐ N/A ☐	Comment *(if none, check this checkbox ☐)*
If the Cloud configuration of OneLab is used, make sure you have an OneLab account for the admin user that this device will be associated with. Visit https://onelab.andrewalliance.com to create a new free account.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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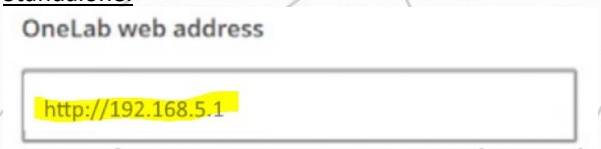
In case of a Standalone local server verify that the server hosting OneLab is placed preferably on the right side of Pipette+ and at least 3 meters away from the Pipette+ device (if used on Wi-Fi) or as far as the Ethernet cable allows in case of wired connection. Note: placing the server closer could create interference with the pipettes placed on the Pipette+.	OK ☐ NOK ☐ N/A ☐	Comment *(if none, check this checkbox ☐)*
In case of local server (Standalone) or Enterprise configuration, verify that the server hosting OneLab is turned ON and the network is available.	OK ☐ NOK ☐ N/A ☐	Comment *(if none, check this checkbox ☐)*
Follow the procedure of "Getting started" as explained in Pipette+ Quick Start Guide. After the pairing procedure is successful, Pipette+ should be visible in the Device page of OneLab having the status "Ready".	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
If Ethernet connection will be used with Pipette+ instead of Wi-fi, make sure you use the Ethernet cable provided by Andrew Alliance. Note: if a longer cable is required, the customer IT who provided the cable must make sure the cable is properly functional. 	OK ☐ NOK ☐ N/A ☐	Comment *(if none, check this checkbox ☐)*
In case of pairing to an OneLab Standalone or Enterprise server, make sure to specify the correct OneLab address during the pairing process: Standalone:  Enterprise: Note: the Standalone Server is equipped with two Ethernet ports: the one on top must be used in case of Ethernet connection.	OK ☐ NOK ☐ N/A ☐	Comment *(if none, check this checkbox ☐)*

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After the pairing is successfully completed, access your OneLab. In that moment, select the Lab you would like to link the Pipette+.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Select the current Pipette+ in the list of available devices present in OneLab Device Tab. Click on "Locate Me" to verify that the communication between OneLab and Pipette+ is successful. Pipette+ should make a sound and its "Plus" LED should blink violet until you click again on "Locate Me".	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the button "Refresh tools" and verify that the pipettes present on Pipette+ stand are visible in OneLab.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

1.2.IQ test report

Below Installation Qualification Report is shown. The Installation Qualification is successful if the instrument passed **ALL** the tests. The report should be signed by both the person who executed the IQ process, as well as the owner of the device.

INSTALLATION QUALIFICATION REPORT				
IQ test	***DESCRIPTION***	***RESULT***	***COMMENT (if none, bar the cell)***	***Evaluation (Pass/Fail)***
A	User Manual and Documents	OK ☐ NOK ☐		PASS ☐ FAIL ☐
B	Software installation	OK ☐ NOK ☐		PASS ☐ FAIL ☐
C	Installation of Pipette+	OK ☐ NOK ☐		PASS ☐ FAIL ☐
D	Placement of pipettes on Pipette+	OK ☐ NOK ☐		PASS ☐ FAIL ☐
E	Power On the device	OK ☐ NOK ☐		PASS ☐ FAIL ☐
F	Pairing of Pipette+ to OneLab	OK ☐ NOK ☐		PASS ☐ FAIL ☐

	Function	**Name**	**Date**	**Signature**
Performed by				
Approved by				

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2. Operational Qualification (OQ)

Document #: 618.002		Revision: 7	
	Function	**Name**	**Date**
Author	**Lab Automation Service & Support Engineer**	**L.M. Turrado**	**25 Feb 2022**
Reviewed by	**Global Service & Support Sr Manager**	**N. Vamvoukas**	**25 Feb 2022**

The **Operational Qualification (OQ)** is a test process that evaluates the proper functioning of a facility or an appliance. The Operational Qualification (OQ) may only be performed after a successfully completed Installation Qualification (IQ). The documentation for an Operational Qualification consists of:

- OQ test plan
- OQ report

2.1. OQ test plan

The **OQ test plan** contains detailed information of the tests to be performed on the respective equipment in the context of the Operation Qualification (OQ). This test plan contains detailed specifications on the course of the test itself.

After completion of the OQ test plan, the results are summarized, evaluated and combined in an OQ report. All deviations, as well as measures taken to eliminate these, are documented. After the deviations have been eliminated, they must be tested again, documented, and evaluated in a new OQ report.

The Operational Qualification template for Pipette+ is reported in the next page.

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OPERATION QUALIFICATION			
System name:		Pipette+	
Serial number:		618._____	
Document #	618.002	Revision	7

2.2.Getting started

This Operational Qualification procedure is based on the execution of a set of protocols to test the correct functionality of different modules of the system. Installation Qualification must be successfully performed before starting the Operation Qualification procedure.

It is suggested to use distilled water and a solution of Ponceau S with a concentration of 0.5 g/l. The use of dye is suggested to have a better visibility of the correctly filled wells and consumables.

As Pipette+ handles electronic pipettes, there is no need to test the fluidic performances of the system at the time of the installation. The latter have been tested during the manufacturing process of the pipettes. A performance qualification document is delivered along with the pipettes.

A) Experiment execution and verification correct execution

Select one of the options below depending on your Pipette setup.

OPTION 1 **Starter Kit configuration**		SELECTED☐ N/A ☐
Verify that the following Andrew Alliance pipettes are installed on Pipette+ stand: - Single channel AA pipette 100-5000 µL - Single channel AA pipette 10-300 µL - 8-channel AA pipette 50-1200 µL	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Verify the availability of the following Sartorius pipette tips (one pet type) for the execution of the experiment: - 300uL: 790350, 790351, 790352, 790353, LH-L790350, LH-L790352, 790301F or LH-LF790301 - 1200uL: 791210, 791211, 791212, 791213, LH-L791210, 791211F or LH-LF7991211 - 5mL: 780304, 780305, 780300, 780308	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Verify the availability of the following labware for the execution of the experiment: - 50mL conical tube Corning #352070 or comparable to it. - Flat bottom 96-well plate Greiner™ #655101 or comparable to it. - 8-channel reservoir Integra #4332. - 1.5mL centrifuge conical microtube Eppendorf Safe-Lock #0030120086 or comparable to it.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Execute the protocol "OQ Pipette+ v1.0" with Pipette+ and verify that all the pipettes in the list below have been selected (as shown on the picture below): - Single channel AA pipette 100-5000 µL - Single channel AA pipette 10-300 µL	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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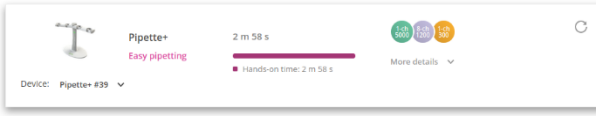
- 8-channel AA pipette 50-1200 µL 		
During the experiment execution observe that in step #1 of the protocol: • 100-5000 µL pipette has been selected. • A mixing step at 5mL volume has been done five times	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
During the experiment execution observe that in step #2 of the protocol: • The same pipette tip pre-wetted in the previous step has been used • Repetitive dispensing of 1mL aliquot has been done in five different microtube	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
During the experiment execution observe that in step #3 of the protocol: • A different pipette tip is used (tip ejection) • A volume of 5mL has been dispensed using reverse pipetting technique. • The excess volume has been purged back to the source	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
During the experiment execution observe that in step #4 of the protocol: • 8-channel 50-1200 µL has been selected • A volume of 100 µL has been dispensed using forward pipetting technique from the reservoir to column 1 and 2 of the 96-well plate using an air cushion after the aspiration • For each dispensing, new pipette tips have been used	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
During the experiment execution observe that in step #5 of the protocol: • 1-channel 10-300 µL has been selected • Mixing of 70µL in A1 well of the 96-well plate two times • Aspiration of 50µL volume from A1 of the 96-well plate • Dispensing of 50µL volume in A2 of the 96-well plate • Mixing of 100µL volume two times	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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During the experiment execution observe that in step #6 of the protocol: • A different pipette tip has been used • 1-channel 10-300 µL has been selected • Mixing of 70µL at the in B1 well of the 96-well plate two times • Aspiration of 50µL volume from B1 of the 96-well plate • Dispensing of 50µL volume in B2 of the 96-well plate • Mixing of 100µL volume two times	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The protocol was executed without errors.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

OPTION 2 **Custom Pipette configuration**		SELECTED☐ N/A ☐
Select one of the below configurations: • **Option 1:** The pipettes present in the Pipette+ can handle volumes from 0.5uL up to 1200uL with single and/or multi-channel pipettes. • **Option 2:** The pipettes present in the Pipette+ can handle volumes from 10uL to 5mL with single ONLY or single/ multi-channel pipettes. • **Option 3:** The pipettes present in the Pipette+ can handle volumes from 10uL to 1200uL with multi-channel ONLY pipettes. • **Option 4:** The pipettes present in the Pipette+ can handle big volumes only (5mL and/or 10mL pipettes)	Option 1 ☐ Option 2 ☐ Option 3 ☐ Option 4 ☐	Comment *(if none, check this checkbox ☐)*
Execute the relevant operation test protocol depending on the option selected in the previous step: • **Option 1:** "OQ custom from 0.5uL up to 1200uL Single and_or Multi.onp" • **Option 2:** "OQ custom 10uL to 5mL with single ONLY or Single Multichannel.onp " • **Option 3:** "OQ custom from 10uL to 1200uL multi-channel ONLY.onp " • **Option 4:** "OQ custom big volumes only 5mL and_or 10mL pipettes. onp" Note: It might be required to replace the labware used in the OQ test protocol with a labware of similar properties that you have available.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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Follow the instructions stated in OneLab and perform the steps of the chosen protocol.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The protocol was executed without errors.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

B) Collection of Logfiles

Following the completion of the OQ protocol(s), collect the logfiles. **Important note:** the collection of logfiles must be performed right after the protocols have been completed and without power cycling the device. If for any reason the unit had to be power cycled, the OQ process and protocol execution must be restarted from the beginning.	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

2.3.OQ test report

Below Operation Qualification Report is shown. The Operation Qualification is successful if the instrument passed **ALL** the tests. The report must be signed by both the person who executed the OQ process, as well as the owner of the device.

OPERATION QUALIFICATION REPORT				
OQ test	***DESCRIPTION***	***RESULT***	***COMMENT (if none, bar the cell)***	***Evaluation (Pass/Fail)***
A	Experiment execution and verification of correct operation	OK ☐ NOK ☐		PASS ☐ FAIL ☐
B	Collection of logfiles	OK ☐ NOK ☐		PASS ☐ FAIL ☐

	Function	**Name**	**Date**	**Signature**
Performed by				
Approved by				

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3. Contact

For any questions or information, do not hesitate to:

- Visit our website www.andrewalliance.com
- Contact us through our Intercom messenger present in OneLab
- Send us an email at aa_support@waters.com

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