Microlab® 600 Qualification Procedure

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HAMILTON®

Table of Contents

Introduction

This procedure defines the general steps that should be performed to ensure that the Microlab 600 is installed and functioning correctly. This document references sections from the Microlab 600 Basic Manual (p/n 61440-01).

Section 1: Installation Qualification

1.1 Select the proper location for the Microlab 600 (Section 2.2).

☐ Complete

1.2 Unpack the Microlab 600.

☐ Complete

1.3 Record the pump and controller serial numbers here:

Serial Number
Pump
Controller

1.4 Connect the power supply with the power cord to the pump.

☐ Complete

Note: The valve(s) will already be installed on the Microlab 600. For questions on removing or installing new valves, reference Section 2.4.1.

1.5 Install the fill and dispense tubing assemblies (Section 2.4.3).

☐ Complete

1.6 Install the Accessory Holder and Tubing Management System or Cable Management System if using the Disposable Tip Hand Probe (Section 2.4.4 – 2.4.5).

☐ Complete

1.7 Record the hand probe or foot switch to be used here:
(e.g. Concorde CT, Dual Push Button or other)

Probe/Switch

1.8 Install the hand probe or foot switch (Section 2.4.6).

☐ Complete

1.9 Install the controller (Section 2.5).

☐ Complete

1.10 Turn the instrument On.

☐ Complete

1.11 Record the syringe volumes to be used here:

Syringe Volumes
Left
Right

Note: If using a single syringe dispenser, there will only be one syringe (left).

1.12 Prepare the syringe(s) for use (Section 2.4.2).

☐ Complete

1.13 Install the syringe(s) on the instrument (Section 2.4.2).

☐ Complete

Print Name: _____

Signature: _____ Date: _____

Section 2: Operational Qualification

2.1 Power the instrument On.

☐ Complete

2.2 Configure the instrument.

2.2.1 In the Hardware Configuration screen, select the Syringe and select the size of syringe(s) (Section 4.2.1).

☐ Complete

2.2.2 In the Hardware Configuration screen, select the Valve and select the type of valve configuration (Section 4.2.2).

☐ Complete

2.3 Prime the instrument with deionized water (Section 4.4).

☐ Complete

2.4 Create a new method.

☐ Complete

2.4.1 For Basic controlled instruments, select the volume to the capacity of the syringe(s) (Section 4.5).

2.4.2 For Advanced controlled instruments, select the Quick Start button and run the method using the Basic Run Screen (Section 4.5).

2.4.2.1 For Advanced Dual Syringe Dispensers, set the left and right side to the capacity of the syringes. Perform a dispense, testing both sides of the instrument.

2.4.2.2 For Advanced Dual Syringe Diluters, set the left side to the capacity of the syringe and the right side to zero to verify the left syringe. Then repeat this step with the left side set to zero with the right side at the syringe capacity.

2.4.2.3 For Dual Syringe Continuous Dispensers, set the volume of both syringes to capacity as one syringe fills the other dispenses. Triggering the pump will test the left side and then triggering the pump again will test the right side.

2.4.3 Record Firmware FPGA, Firmware Runtime Version, Software Version and Operating System Version.

Version
Firmware FPGA
Firmware Runtime
Software
Operating System

2.5 Run the new method (Section 4.5).

☐ Complete

2.6 Dispense the deionized water on an analytical balance to determine whether the instrument is dispensing as expected.

☐ Complete

Note: The diluter configuration will aspirate from the right syringe. The probe must be submerged into the reservoir when the aspiration step is triggered. For a dilution method, the total volume dispensed will be equal to the left diluent volume plus the right sample volume.

Print Name: _____

Signature: _____ Date: _____

Section 3: Performance Qualification

3.1 Getting Started

This is a general qualification procedure for methods run on the Microlab 600. The technique is based on weighing deionized water samples delivered by the instrument. The true volume is then calculated based on the density of water at the sampling temperature.

Note: This method is not recommended for volumes below 2 µL. There is no upper volume limit.

3.1.1 Create a method to be validated (Section 4.5).
☐ Complete

3.1.2 Identify critical dispenses where gravimetric verification is required.
☐ Complete

3.1.3 Identify acceptable accuracy and precision criteria for the critical dispenses.
☐ Complete

3.1.4 Test the Microlab 600 by running the method and verify dispense accuracy and precision (Section 4.5).
☐ Complete

3.2 Equipment, Materials and Environment

☐ Complete

3.2.1 Laboratory balances required for the test method should meet or exceed the following performance specifications. They must be regularly maintained and calibrated with the appropriate N.I.S.T. traceable weights. Reference Table 3-1 for details.

Table 3-1: Required Balance Sensitivity for Dispense Volumes

Test Volume, µL	Balance Sensitivity, mg
1 – 10 µL	0.001 mg
10 – 100 µL	0.01 mg
100 – 1,000 µL	0.1 mg

3.2.2 Use a balance table or suitable equivalent to minimize vibration. Cover the working surface directly in front of the balance with a dark, smooth, non-glare material. Keep the balance area reasonably free of draft currents and the ambient area free of excessive dust.

3.2.3 Use a weighing vessel that has a total volume 12 to 40 times the test volume, or 500 µL, whichever is larger (this is for evaporation control). If possible, use a cover that fits over the outside of the vessel top (do NOT allow the cover to come into contact with the test liquid). The vessel should be plastic, glass, metal or some other non-porous material. The cross-sectional area of the opening should be as small as possible to further control evaporation.

3.2.4 Handle the vessel with forceps or tweezers.

3.2.5 Use deionized water that has equilibrated to room temperature.

3.2.6 Use a calibrated thermometer to measure the temperature of the water.

3.3 Test Procedure

3.3.1 Turn on all equipment and allow all test materials to equilibrate to room temperature.

3.3.2 Place a small amount of water in the weighing vessel (between 2 and 30 test volumes).

3.3.3 Prime the Microlab 600 to eliminate all air bubbles from the fluid path.

3.3.4 Run the method to be validated.

3.3.5 Open the door of the balance chamber, place the weighing vessel on the balance pan and close the door of the balance chamber.

3.3.6 Tare the balance. Retrieve the weighing vessel from the balance chamber, deliver the sample, and return the vessel to the balance pan, closing the door to the chamber. Observe and record balance readout.

3.3.7 Deliver a total of *n* samples (*n*=10 is recommended) into the weighing vessel, and weigh each sample after delivery. Replicate all motions and time intervals in each sampling cycle as precisely as possible. Keep the distance between the balance and the diluter/dispenser to a minimum. Use Table 3-2 to record the dispense masses.

3.3.8 Measure and record the water temperature below:

Test Volume 1 Temperature: Start _____ Finish _____ Average _____

Test Volume 2 Temperature: Start _____ Finish _____ Average _____

Test Volume 3 Temperature: Start _____ Finish _____ Average _____

Table 3-2: Recorded Masses of Each Dispense

Dispense Replicate	Test Volume 1 (grams)	Test Volume 2 (grams)	Test Volume 3 (grams)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

3.4 Calculations

3.4.1 Calculate the volume of each dispense (V_i) by dividing each mass value by the density of water at the measured temperature. Refer to Table 3-3 below for density values. Use Table 3-4 to record the calculated values.

Table 3-3: Density of Water at Various Temperatures

°C	g/mL	°C	g/mL
17	0.998774	24	0.997296
18	0.998595	25	0.997044
19	0.998405	26	0.996783
20	0.998203	27	0.996512
21	0.997992	28	0.996232
22	0.997770	29	0.995944
23	0.997538	30	0.995646

Taken from CRC Handbook of Chemistry and Physics, 50th Edition, 1969, page F–4

Table 3-4: Calculated Dispense Volume

Dispense Replicate V_i Value	Test Volume 1 (mL)	Test Volume 2 (mL)	Test Volume 3 (mL)
V_1			
V_2			
V_3			
V_4			
V_5			
V_6			
V_7			
V_8			
V_9			
V_{10}			

3.4.2 Calculate the average dispensed volume from the individual dispensed volumes, V_i (where "i" is 1 to 10): $V_{avg} = (V_1 + V_2 + V_3 + \ldots + V_{10}) / 10$.
Use the data collected in Table 3-4 to calculate the V_i and record below:

Average Dispense Volume (V_{avg}) for Test Volume 1: _____

Average Dispense Volume (V_{avg}) for Test Volume 2: _____

Average Dispense Volume (V_{avg}) for Test Volume 3: _____

3.4.3 Calculate the syringe accuracy: Accuracy (%) = 100 x (V_{avg} – V_o) / V_o. Use Table 3-5 to record the data.

Note: V_o is equal to the expected dispense volume

3.4.4 Calculate the standard deviation (STDEV) = $\frac{\sqrt{(V_1\text{-}V_{avg})^2 + (V_2\text{-}V_{avg})^2 + (V_3\text{-}V_{avg})^2 \ldots}}{n-1}$ of the calculated volumes, then determine the coefficient of variation: CV (%) = 100 x STDEV / V_{avg}. Use Table 3-5 to record the data.

Table 3-5: Accuracy and Precision

	Test Volume 1	Test Volume 2	Test Volume 3
Calculated Accuracy			
Allowable Accuracy			
Calculated Precision			
Allowable Precision			

Test Results (Pass/Fail):

Observations: _____

Print Name: _____

Signature: _____ Date: _____

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