

ML500 Installation Procedure

This procedure defines the general steps that should be performed to ensure that the ML500 is installed and functioning correctly. This document references page numbers from the ML500 A series manual (p/n 69175) and the ML500 B/C series manual (p/n 69176).

Section 1 Installation Qualification

- 1.1 Unpack the ML500
- Select the proper location for the ML500 (A Series page 2-3, B Series page 2-3)
 Complete
- 1.3 Install the accessory holder (A Series page 2-3, B Series page 2-3) Complete
- 1.4 Set the proper communication options (A Series page 2-4, B Series page 2-4 & 5)

 Complete
- 1.5 Install the electrical connections including power, hand probe, and controller (A Series page 2-4 & 5, B Series page 2-6 & 7)
 Complete
- 1.6 Install the valve assembly (A Series page 2-6 & 7, B Series page 2-8 & 9) Complete
- Select and install the correct syringes (A Series page 2-8 to 13, B Series page 2-10 to 13)
 Complete
- Select and install the correct gauge for fill and dispense tubing (A Series page 2-14 to 19, B Series page 2-16 to 21)
 Complete

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Section 2 Operational Qualification

- 2.1 Switch on the instrument (A Series page 3-3, B Series page 3-6 & 7) Complete
- 2.2 Prime the instrument with distilled water (A Series page 3-4 & 5, B Series page 3-8 & 9)
 Complete
- 2.3 Create a new method Complete
 - 2.3.1 For A series instruments select the appropriate syringes size and set the volume to the capacity of the syringe (A Series page 3-6 to 9)
 - 2.3.2 For B/C series Single and Dual Syringe dispensers create an aliquot dispense method (B Series page 3-13 to 18, online help for software users). Simply accept the default method which should completely fill and dispense the syringe(s)
 - 2.3.3 For B/C series Dual Syringe Diluters create a dilution method (B Series page 3-13 to 16 & 3-20 to 23, online help for software users). Simply accept the default method and record the Left diluent value and the right sample value.
- 2.4 Run the new method (A Series page 3-9 & 10, B Series page 3-29 & 30, online help for software users)Complete
- 2.5 Collect the dispense into a graduated cylinder or onto a scale to determine if the instrument is dispensing as expected.Complete

Note: The diluter model will aspirate from the right syringe so the probe must be in the liquid when the aspiration step is triggered. The final volume dispensed will be equal to the left diluent volume and the right sample volume from the method.

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Section 3 Performance Qualification

3.1 Getting Started

This is a general qualification procedure for methods run on the ML500. The technique is based on weighing diH₂O samples delivered by the syringe pump. True volume is then calculated based on the density of water at the sampling temperature.

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

- 3.1.1 Create a method to be validated (A Series page 3-6 to 9, B Series page 3-1 to 30, online help for software users).
 Complete
- 3.1.2 Identify critical dispenses where gravimetric verification is required.
- 3.1.3 Identify acceptable accuracy and precision criteria for the critical dispenses.
- 3.1.4 Test the ML500 by running the method and using sections 3.2-3.4 to verify dispense accuracy and precision.

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Signature	 Date



3.2 Equipment, Materials, Environment

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.

Test Volume, uL	Balance sensitivity, mg	
1-10 uL	0.001 mg	
10-100 uL	0.01 mg	
100-1000 uL	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 of about 10 times the test volume, or 500uL, 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 distilled water that has equilibrated to room temperature.
- 3.2.6 Use a calibrated thermometer to measure the temperature of the water.
- 3.3 <u>Test Procedure</u>
 - 3.3.1 Turn on all equipment and allow all test materials to equilibrate to room temperature.



- 3.3.2 Prime the ML500 to eliminate all air bubbles from the fluid path (A Series page 3-4 & 5, B Series page 3-8 & 9).
- 3.3.3 Run the method to be validated (A Series page 3-9 & 10, B Series page 3-30 & 31, online help for software users).
- 3.3.4 Open door of balance chamber, place the weighing vessel on the balance pan and close the door of the balance chamber.
- 3.3.5 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.
- 3.3.6 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.
- 3.3.7 Measure and record the water temperature.
- 3.4 <u>Calculations</u>
 - 3.4.1 Calculate the volume of each dispense (Vi) by dividing each mass value by the density of water at the measured temperature. Refer to the table below for density values.

C°	g/cc	C°	g/cc
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	0.995646
22	0.997770	29	0.995944
23	0.997538	30	0.995646

Density of Water at Various Temperatures

Taken from CRC Handbook of Chemistry and Physics, 50th edition, 1969, page F-4



- 3.4.2 Calculate the average dispensed volume from the individual dispensed volumes, Vi (where I is 1 to10): V avg = V1 + V2 + V3 + ... + V10) / 10
- 3.4.3 Calculate the syringe accuracy: Accuracy (%) = 100 x (Vavg Vo) / Vo

Note: Vo is equal to the expected dispense volume

3.4.4 Calculate the standard deviation (SDEV) of the calculated volumes, then determine the coefficient of variation: CV (%) = 100 x SDEV / V avg