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IQ/OQ Protocol Installation Qualification/ Operation Qualification

WaterPro[®] BT System

Purpose and Scope

This Qualification Protocol is intended to be used with Labconco WaterPro® BT Systems only, which are new or recently relocated.

Models:

WaterPro® BT System	Electrical Configuration
9015020, -120	115V, US
9015030, -130	230V, EU
9015040, -140	230V, US
9015060, -160	230V, UK
9015070, -170	230V, AUS
9015080, -180	230V, INDIA
9015220, 320	115V, US
9015230, 330	230V, EU
9015240, -340	230V, US
9015260, -360	230V, UK
9015270, -370	230V, AUS
9015280, -380	230V, INDIA

This document is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning for the piece of equipment and therefore is of value prior to receipt of delivery.

Responsibilities

End-User – The end user or appointed personnel in the lab is responsible for ensuring the WaterPro® BT System is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through cautious forethought.

End-User – The end user is responsible for supporting the validation through the use of appropriate testing equipment and training. The organization shall also ensure the validation process has been fully carried out prior to use of the WaterPro® BT System. Records should be stored in a safe, easily retrievable location. The site of the WaterPro BT System filter replacement records and validation schedules should be documented in the company's quality system.

Product Validation – All WaterPro® BT Systems utilize a Pretreatment filter, a Reverse Osmosis filter, and an Ion Exchange filter to remove organic and inorganic contaminants from

the supplied feed water. The resistivity of the WaterPro BT System water may be tested by a qualified technician using a third party (NIST – traceable) resistivity monitor with the correct sensor cell and sample port to validate the WaterPro BT resistivity monitor ‘By Reference’.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test the WaterPro® BT system prior to shipment. The manufacturer must retain these records. Labconco staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for carrying out the actual installation or validation processes.

Performance Qualification

Once the WaterPro® BT System has been checked for proper installation and operation, its performance may be validated. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

In general this performance qualification requires the establishment of internal acceptance criteria, inspecting and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning and Proper Installation	<p>Do not install the WaterPro BT directly over equipment that uses electrical service. Routine use and maintenance of the unit may involve water spillage and the potential for electrical shock if improperly located.</p> <p>Is the WaterPro BT System location away from any electrical outlets below the installation site, which might cause a shock hazard?</p>	Y	N
1a	Space Requirements	Has adequate space been provided for placement of the WaterPro BT and remote stand if equipped?	Y	N
1b	Electrical Service	<p>Refer to the Electrical Requirements section of the User's Manual for a list of model numbers and their corresponding electrical ratings.</p> <p>Are services available for the WaterPro® BT System to be connected to an appropriate electrical circuit with over-current protection of adequate size and the proper voltage?</p>	Y	N
1c	Drain	<p>The WaterPro BT Systems have one drain line. The open drain connection must be able to handle a minimum of 7.9 gal/hour water flow.</p> <p><u>The facility drains must be located below the exit points of the WaterPro BT System.</u></p> <p>Does the selected installation location have the proper drain connection?</p>	Y	N
1d	Water Supply	<p>The supplied feed water tubing is flexible plastic tubing with ½ inch male GAZ, NPTM or BSPM fitting. A user supplied shut/off valve should be installed on the supply line so the WaterPro BT System may be isolated from the feed water supply when required. Line pressure should not exceed 87 psi (6 Bar). See Feed water Tubing Installation in the User's Manual.</p> <p>Has a water supply source been identified and a line been installed near the WaterPro BT System?</p>	Y	N
1e	Optional Stand Installation	The WaterPro BT System has an optional wall mounting bracket (9037900) with instructions. The surface must be able to support at least 50 lbs. Have accommodations been made for placement of the WaterPro BT System with wall mounting bracket on a wall with suitable weight bearing support studs?	Y	N NA

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1f	Product Manual	The User's Manual is shipped with the WaterPro BT System. Has the manual been unpacked and made accessible?	Y	N
1g	Damage Claims	Has WaterPro® BT System been inspected for any signs of damage that may have occurred while in transit or within the building? Keep packaging materials until inspection is complete. If so, refer to the User's Manual for information on shipping damage claims.	Y	N
2	Prior to Operation Filter Pack, and UV light Installation	WaterPro BT System performance and filter life spans are directly related to the feed water quality and the volume of purified water produced. All WaterPro BT Systems require a Filter Pack be installed. The filter pack has a finite capacity for purifying water before being exhausted. As the cartridges approach exhaustion, the system will require longer recirculation times to achieve 16–18.2 MegOhm-cm resistivity and the water quality may fluctuate during dispensing. Upon exhaustion, the resistivity will decrease rapidly without recovery. Replacement of the Filter Pack will restore water purity. <ul style="list-style-type: none"> • Replace these filters when water purity levels drops below the acceptable resistivity values for laboratory applications. Some WaterPro BT Systems include an Ultra Violet light. <ul style="list-style-type: none"> • Replace the Ultra Violet Light every 500 days See Filter Pack and UV Light Installation Instructions in the User's Manual Have the filter pack and UV light (if equipped) been installed properly.	Y	N
2a	Electrical Connections	A protected 1 phase ac supply ranging from 100 volts to 240 volts and rated for 2 amps is required for all systems. The outlet should be within 8 ft. (2.5m) of the unit and match the power cord that was shipped with the unit. Is the WaterPro BT System connected to an electrical circuit of proper voltage and amperage?	Y	N
2b	Tap Water Connections	The WaterPro BT System requires a potable water feed with a pressure of 7.3-87.0 psig (.5-6 bar) and a minimum flow rate of 10 GPH (40 LPH). Does the feed water supplied conform to these limits?	Y	N
2c	Tap Water Connections	The WaterPro BT System requires a feed water supply with a temperature range of 5° to 35° C and conductivity should be <2000uS/cm. Does the supplied tap water conform to these limits?	Y	N

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2d	Basic Operational Start Up	The user installed, water shut/off valve on the feed water supply tubing must be in the open position for water to flow into the WaterPro BT System. Has the water shut/off valve been opened?	Y	N
	2d-1	Filter Pack Flush, Rinse and Tank Fill. See installation instructions to flush, rinse and fill the system. Has the Filter Pack been flushed, rinsed and RO tank filled?	Y	N
	2d-2	Vent Filter and Clear Tubing Installation. See installation instructions to install the Vent Filter on the RO Tank. Has the Vent Filter been installed?	Y	N
	2d-3	Purging Air from the System and Hydrating. See installation instructions to purge air from the system and hydrate. Has air been purged from the system and allowed to hydrate?	Y	N
	2d-4	Install and Rinsing the Final Filter if required. See installation instructions to install and rinse the final filter if required. Has the Final Filter been installed and rinsed?	Y	N
	2d-5	Calibrating the flow rate. See installation instructions to calibrate the units flow rate. Has the flow rate been calibrated?	Y	N
	2d-6	Selecting the displayed Units of measure. See installation instructions to select units of measure. Have the desired units of measure been selected?	Y	N
	2d-7	Setting the Resistivity Set Point. See installation instructions select the resistivity set point. Has the resistivity set point been determined and set?	Y	N
	2d-8	Verify Display operation. See installation instructions to understand the display. Does the display operate properly?	Y	N
	2d-9	Dispense water from the WaterPro BT System. See installation instructions to dispense Ultra-Pure and RO Water. Does the unit dispense Ultra-Pure and RO Water properly?	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Initial Validation	<p><u>If Required</u>, have a qualified technician test the WaterPro BT System's water using a third party (NIST Traceable) Conductivity/Resistivity monitor with the required sensor cell constant of 0.01. The sensor cell <u>must</u> be placed in a 'flow through' sample cell fitting, attached to the dispensing tubing on the WaterPro BT System. Air in-trained in to the Sensor's sampling fitting will cause an error in the resistivity reading.</p> <p>Typical Water Production Rate: The WaterPro BT Systems with a new Filter Pack will produce water with a resistance of 16-18 MegOhm with a flow rate of 11.1 GPH (42 LPH). The RO water flow rate is .8GPH (3 LPH)</p> <p>Have the operational Conductivity or resistivity and flow rates above been confirmed by a qualified technician?</p>	Y	N
2	User Training	Have all users been properly trained on the benefits, theory of operation and limitations of the WaterPro BT System?	Y	N
		<p>Do all users understand procedures for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Turning ON the WaterPro BT System? <input type="checkbox"/> Turning OFF the WaterPro BT System? <input type="checkbox"/> How and When to change the filters in the WaterPro BT System? <input type="checkbox"/> What the resistivity reading means? <input type="checkbox"/> How and When to change the Ultra Filter and Ultra Violet Light? 	Y	N
3	Exterior Cleaning	Has the exterior been cleaned of dust that accumulated throughout shipment and installation?	Y	N

C. Performance Qualification

NOTE: This Performance Qualification section is only a recommendation of some basic items to consider for your protocol. Your protocol should include tests and inspections that are pertinent to the applications performed with the equipment.

Step	Description	<u>Suggested Criteria</u>	Result	
			YES	NO
1	Periodic Certification			
1a	Cabinet Performance	WaterPro BT System validation should be done annually, at a minimum. An experienced technician with the proper third party testing instruments can validate the WaterPro BT System's performance to manufacturer's specifications. Does the WaterPro BT System's current validation fall within the acceptable timeframe set by your organization? Has there been a procedure established if the WaterPro BT System is found to have exceeded its validation due date?	Y	N
		Is the next required validation noted in your WaterPro BT System's preventive maintenance schedule?	Y	N

2	Maintenance		
2a	Filter Replacement	<p>One replacement Filter Pack, Vent Filter and other optional Filters should be kept on hand for use when required. Replace these filters when water purity levels drops below the acceptable resistivity values for laboratory applications.</p> <p>Replacement Filter Pack #9019200 Vent filter (2) #9041400 Optional filters: The .22um Final filter #9037700 when efficiency or production rates drop below acceptable levels.</p>	
	Sanitization	<p>The frequency of sanitizing the WaterPro BT Systems will depend directly on the quality of the feed water and the operating environment of the unit. It is recommended that the unit be sanitized at least once each year. The unit should be cleaned when needed, such as when the bacterial or organic containment concentrations become unacceptable.</p> <p>The method for sanitizing the WaterPro BT Systems is located in the product manual.</p> <p>Remove the all filters and replace with new filters after sanitization.</p>	

D. Summary

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Equipment Location _____

Serial. No. _____ Model No. _____

User Protocol _____ Revision (or Date published) _____

Contact (print name): _____

Title: _____

Review the “Response” columns for answers of “NO.” Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for “Corrective Actions.” Once acceptable results are obtained, the deficiency is “accepted” by initialing the Corrective Action.

Step	Deficiency followed by Corrective Action	Initial