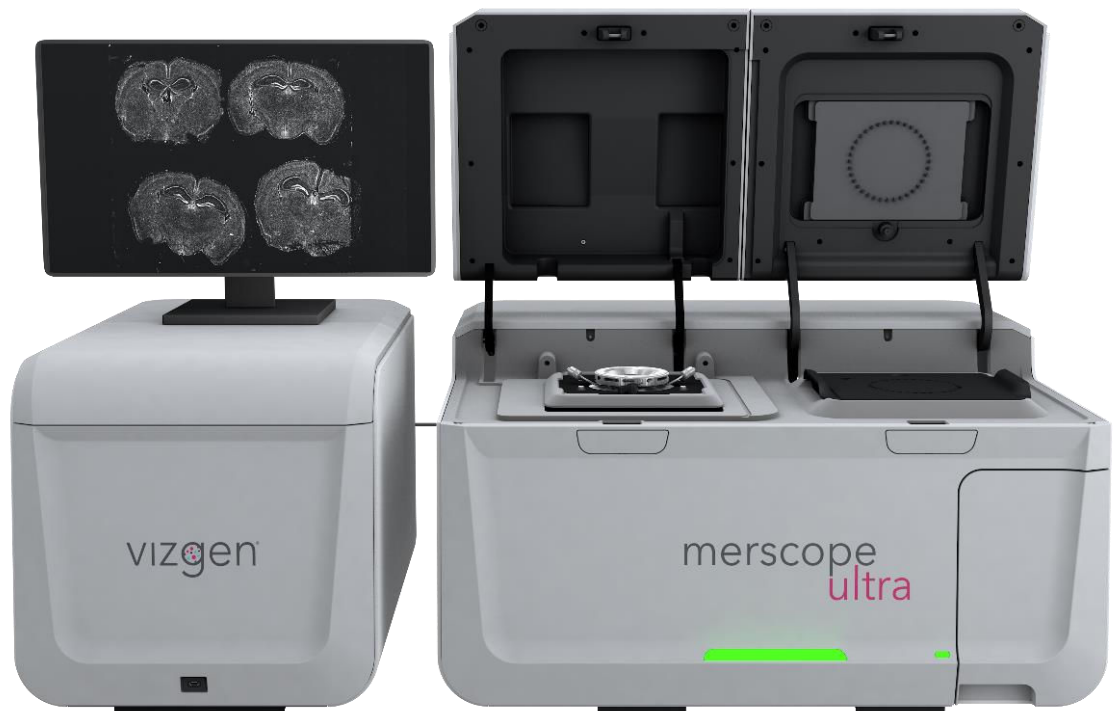


MERSCOPE ULTRA™ Instrument Installation Checklist



vizgen

NOTICES

Document number	91500104
Document revision	Rev B
Revision date	March 2026

Legal notices

ALL PRODUCT(S) AND SERVICES DESCRIBED HEREIN ARE INTENDED FOR RESEARCH USE ONLY, AND NOT FOR USE IN DIAGNOSTIC OR TREATMENT PROCEDURES OR FOR ANY OTHER USE.

FAILURE TO COMPLETELY READ AND EXPLICITLY FOLLOW ALL OF THE INSTRUCTIONS CONTAINED HEREIN MAY RESULT IN DAMAGE TO THE PRODUCT(S), INJURY TO PERSONS, INCLUDING TO USERS OR OTHERS, AND DAMAGE TO OTHER PROPERTY. VIZGEN, INC. ("Vizgen") DOES NOT ASSUME ANY LIABILITY ARISING OUT OF THE IMPROPER USE OF THE PRODUCT(S) DESCRIBED HEREIN (INCLUDING PARTS THEREOF OR SOFTWARE) OR ANY USE OF SUCH PRODUCT(S) OUTSIDE THE SCOPE OF THE EXPRESS WRITTEN LICENSES OR PERMISSIONS GRANTED BY VIZGEN IN CONNECTION WITH CUSTOMER'S ACQUISITION OF SUCH PRODUCT(S).

Nothing contained herein shall constitute any warranty, express or implied, as to the performance of any product(s) described herein. Any and all warranties applicable to any product(s) and software are set forth in the applicable terms and conditions of sale accompanying the purchase of such product(s). Vizgen provides no warranty and hereby disclaims any and all warranties as to the use of any third-party product(s) or protocols described herein. The use of product(s) described herein is subject to certain restrictions as set forth in the applicable terms and conditions of sale accompanying the purchase of such product(s).

Updates to product(s) and software may be required to enable customers to use product(s). If you fail to update the product(s) or software when provided by Vizgen, any warranty thereon shall immediately terminate. In the event of a product failure resulting from an update, such failed product will be subject to the warranty set forth in the terms and conditions agreed to in connection with the purchase of such product, if any, only if such product is covered by such warranty at the time of such failure. Vizgen is not required to repair, replace, or take any other remedial action with respect to any product not covered under such warranty.

Vizgen® and MERSCOPE® are trademarks of Vizgen. All rights in the trademarks, service marks, trade dress, logos and copyrights are owned by Vizgen, Inc. and fully reserved. All other brands and names contained herein are the property of their respective owners.

This document and its contents are proprietary to Vizgen, Inc. and its affiliates, and are intended solely for the contractual use of its customer in connection with the use of the product(s) described herein and for no other purpose. This document and its contents shall not be used or distributed for any other purpose and/or otherwise communicated, disclosed, or reproduced in any way without the prior written consent of Vizgen. Vizgen does not convey any license under any patent, trademark, copyright, or common-law rights, nor similar rights of any third parties, by this document. The instructions in this document must be strictly and explicitly followed by qualified and properly trained personnel in order to ensure the proper and safe use of the product(s) described herein. All of the contents of this document must be fully read and understood prior to using such product(s).

© 2026 Vizgen, Inc. All rights reserved.

SUPPORT

Contact information

support@vizgen.com

150 Bear Hill Road

Waltham, MA 02451 USA

Other Vizgen references, available online at <https://vizgen.com/>

TABLE OF CONTENTS

1	INTRODUCTION.....	5
2	PRE-INSTALLATION	5
3	INSTRUMENT SETUP.....	7
4	INSTRUMENT INSTALLATION	8
5	MERSCOPE INSTRUMENT VALIDATION.....	9
6	DOCUMENTATION AND REPORTING	10
7	REQUIRED ATTRIBUTES	10

1 INTRODUCTION

The MERSCOPE Ultra System Installation Qualification (IQ) protocol is performed on the Vizgen MERSCOPE Ultra System. This protocol delineates the process and documentation used to verify correct installation of the MERSCOPE Ultra Instrument. Successful completion of this protocol confirms that the MERSCOPE Ultra Instrument has been correctly installed.

Installation checks are performed to document that this MERSCOPE Ultra Instrument is installed with proper connections and utilities (where applicable).

Qualification of Vizgen MERSCOPE Ultra instruments is performed by properly trained Vizgen personnel or Authorized Distributors. All specifications listed on this IQ are taken from the MERSCOPE Ultra Instrument Installation Guide 91500103.

2 PRE-INSTALLATION

Once the instrument is received follow the steps below to ensure all components are present.

Step	Action	Completed
1	Inspect all shipping crates for physical damage; note any damage and create an installation complaint case if needed.	<input type="checkbox"/>
2	Confirm the laboratory Bench is level and meets the specifications outlined in 91500102 MERSCOPE Ultra Instrument Site Prep Guide.	<input type="checkbox"/>
3	Confirm all components are present according to the checklist in Table 1 .	<input type="checkbox"/>

Table 1: MERSCOPE Ultra Instrument Components

Component	Required Materials
MERSCOPE Ultra Imaging Box Crate	<ul style="list-style-type: none"> <input type="checkbox"/> MERSCOPE Ultra Imaging Box <input type="checkbox"/> Autofocus Camera USB Cable (Located in Imaging Box)
MERSCOPE Ultra Control Box Crate	<ul style="list-style-type: none"> <input type="checkbox"/> MERSCOPE Ultra Control Box <input type="checkbox"/> MERSCOPE Ultra Monitor Planar <ul style="list-style-type: none"> - HDMI - DVI Cable - USB Cable <input type="checkbox"/> MERSCOPE Ultra Monitor Power Cord <input type="checkbox"/> MERSCOPE Ultra Wireless Keyboard and Mouse <input type="checkbox"/> Leveling Base Subassembly <input type="checkbox"/> MERSCOPE Ultra Instrument Waste Container <input type="checkbox"/> MERSCOPE Ultra Instrument Power Cord (regional) <input type="checkbox"/> MERSCOPE Ultra Instrument Connections <ul style="list-style-type: none"> <input type="checkbox"/> Fiber-optic cable

MERSCOPE® Ultra Instrument Installation Checklist

	<input type="checkbox"/> USB cable 2.0 A-B, Male, Black, 1M <input type="checkbox"/> Teledyne Camera Communication cable <input type="checkbox"/> Power Supply Harness
MERSCOPE Ultra APC Box	<input type="checkbox"/> MERSCOPE Ultra Analysis Computer <input type="checkbox"/> 10 GBPS Ethernet Cable <input type="checkbox"/> Cbl, PWR Cord, 3C (US) <input type="checkbox"/> Cable USB 2.0, A-B, Male, Black
MERSCOPE Ultra FCX-S Flow Chamber	<input type="checkbox"/> Top <input type="checkbox"/> Aqueduct <input type="checkbox"/> Base
MERSCOPE Ultra FCX-L Flow Chamber	<input type="checkbox"/> Top <input type="checkbox"/> Aqueduct <input type="checkbox"/> Base
MERSCOPE Ultra Instrument Accessory Kit	<input type="checkbox"/> MERSCOPE FCX-S and FCX-L Gasket <input type="checkbox"/> Imaging Fluid Line Adapter <input type="checkbox"/> Fluidic Line Connector <input type="checkbox"/> Immersion Oil <input type="checkbox"/> Hobby Blade Handle <input type="checkbox"/> Hobby Blades (pack) <input type="checkbox"/> High Precision Tweezers <input type="checkbox"/> Serrated Tweezers <input type="checkbox"/> Lens Cleaning Tissue (5x) <input type="checkbox"/> Luer-lock Syringe (5x) <input type="checkbox"/> Fluidic Fitting Torque Adapter Tool <input type="checkbox"/> Standard Size Wedge Tool <input type="checkbox"/> Large Size Wedge Tool
MERSCOPE Ultra Analysis Computer Box	<input type="checkbox"/> MERSCOPE Ultra Analysis Computer <input type="checkbox"/> Ethernet Cable <input type="checkbox"/> Power cord (regional)
MERSCOPE Ultra Uninterruptible Power Supply (UPS)	<input type="checkbox"/> Uninterruptible Power Supply (UPS) <input type="checkbox"/> Power cord (regional)

3 INSTRUMENT SETUP

Follow the steps below to set up the instrument and verify that no damage occurred during shipping.

Step	Action	Completed
1	Before proceeding with the installation, verify that all customer site criteria are met IAW with the MERSCOPE Site Prep Guide 9150001. If the customer site does not meet the standards outlined in the MERSCOPE Site Prep Guide 9150001, notify the customer of potential effects to experiment performance, notify the FAS and RAM of the deficiencies, and have the customer sign off that they are aware of the deficiencies and still wish to proceed with the installation. Document all deficiencies in the reporting section of this document and the SFDC case.	<input type="checkbox"/>
1a.	Lab Ambient Temperature: Lab Ambient Humidity: Lab Bench Size: Instrument Clearance Requirements Met: Environmental Factors (Excessive Vibration, Direct Sunlight, Etc.): UPS Present: UPS Make / Model: Network Access:	<input type="checkbox"/>
2	Unpack and place the MERSCOPE Ultra Imaging Box and Control Box on the laboratory bench.	<input type="checkbox"/>
3	Inspect the MERSCOPE Ultra Imaging box for physical damage; note any damage and create an installation complaint case if needed.	<input type="checkbox"/>
4	Inspect the MERSCOPE Ultra Control box for physical damage; note any damage and create an installation complaint case if needed.	<input type="checkbox"/>
5	Inspect the MERSCOPE Ultra APC for physical damage; note any damage and create an installation complaint case if needed.	<input type="checkbox"/>
6	Remove all packaging materials and the shipping lockouts from the optical block. Store the Shipping Brackets in the Control Box or a secure location in the event they are needed for an instrument move or return.	<input type="checkbox"/>
7	With the exterior panels of the MERSCOPE Ultra Imaging and Control Box removed, inspect for physical damage; note any damage and create an installation complaint case if needed.	<input type="checkbox"/>

Proceed with Instrument Installation in accordance with MERSCOPE Ultra Instrument Installation Guide 91500103.

4 INSTRUMENT INSTALLATION

Follow the steps below to perform the initial instrument setup and installation.

Step	Action	Completed
1	Verify the 10X and 40X objectives are secure	<input type="checkbox"/>
2	Inspect and Install the Stage Leveling Plate to the XY Stage.	<input type="checkbox"/>
3	Verify all fluidic fittings and components are securely fastened.	<input type="checkbox"/>
4	Connect all cables between the MERSCOPE Ultra Imaging and Control Box and verify the strain reliefs are properly installed.	<input type="checkbox"/>
5	Connect the APC to the MERSCOPE Ultra Control Box using the supplied Ethernet Cable.	<input type="checkbox"/>
6	Power on the APC and the MERSCOPE Ultra Control Box. Verify successful system boot up and connectivity.	<input type="checkbox"/>
7	Set the proper time, date, and region for the installation location.	<input type="checkbox"/>
8	Verify all network and drive mapping IAW MERSCOPE Ultra Instrument Installation Guide 91500103.	<input type="checkbox"/>
9	Verify all USB power settings IAW MERSCOPE Ultra Instrument Installation Guide 91500103.	<input type="checkbox"/>
10	Verify the Gener8 FW GUI is present, and the system FW is on the most current version.	<input type="checkbox"/>
11	Install all approved Windows Updates and restart the MERSCOPE Ultra instrument if required.	<input type="checkbox"/>
12	Launch the MERSCOPE Ultra Instrument Software and initialize the MERSCOPE Ultra Instrument to verify successful initialization.	<input type="checkbox"/>

Proceed to the Instrument Validation section.

5 MERSCOPE INSTRUMENT VALIDATION

Perform the following steps to calibrate and verify the optical and fluidic systems of the instrument.

Step	Action	Completed
1	Verify the Focus laser spots are centered in the ROI and correct if necessary, using the QPD ROI Check Test IAW MERSCOPE Instrument installation Guide 91500103.	<input type="checkbox"/>
2	Verify the Focus LED Power is between 150 - 225 in Vimba viewer. Optimal range will be where focus spot intensity is most stable. Saturation occurs when measurement is above 250 and can result in focus laser reaching lasing threshold, Reduce laser power and adjust power threshold to maintain stability	<input type="checkbox"/>
3	Perform Stage Leveling IAW MERSCOPE Ultra Instrument Installation Guide 91500103.	<input type="checkbox"/>
4	Verify Focus Lock occurs at a Z height of 1985 ±30.	<input type="checkbox"/>
5	Perform XY Stage Offset Calibration for both the FCX-S and FCX-L Flow Chambers IAW MERSCOPE Instrument installation Guide 91500103.	FCX-S Offsets X= Y= FCX-L Offsets X= Y=
6	Perform the Imageable Area Check for the FCX-S and FCX-L Flow Chamber	Pass/ Fail
7	Perform the XY Stage Integrated Test. Analyze results and assess system performance IAW MERSCOPE Ultra Instrument installation Guide 91500103.	Pass / Fail
8	Perform the Fluidics Analysis Test and verify system performance IAW MERSCOPE Ultra Instrument Installation Guide 91500103.	<input type="checkbox"/>
9	Perform the U2OS Instrument Experiment and verify the system completes the experiment successfully and analyzes the output data successfully.	<input type="checkbox"/>
10	Perform the MERSCOPE Ultra Maintenance Wash procedure.	<input type="checkbox"/>
11	Proceed to MERSCOPE Ultra Instrument Final Checks and Procedures.	<input type="checkbox"/>
12	Launch the MERSCOPE Instrument Software and initialize the MERSCOPE Instrument to verify successful initialization.	<input type="checkbox"/>
13	Verify all MERSCOPE Instrument cabling is secure and properly managed.	<input type="checkbox"/>
14	Perform a final review of the MERSCOPE Ultra Instrument Installation Guide and verify that all procedures have been completed.	<input type="checkbox"/>

15	Perform a final visual inspection of the MERSCOPE Ultra Instrument and verify that there is no damage to any part of the system prior to releasing the system to the customer.	<input type="checkbox"/>
----	--	--------------------------

Proceed to Documentation and Reporting.

6 DOCUMENTATION AND REPORTING

The following steps describe how to document and report the installation.

Step	Action	Completed
1	Document and store all configuration parameters IAW MERSCOPE Ultra Instrument Installation Guide 91500103. It is the best practice to store a copy of all configurations externally.	<input type="checkbox"/>
2	Document any deviations of the MERSCOPE Site Prep Guide 9150001 in Salesforce and or the Distributor CRM Software and obtain Customer acknowledgement and sign off.	<input type="checkbox"/>
3	Document the completion of the installation along with any deviations or defects in Salesforce and/or the Distributor CRM Software.	<input type="checkbox"/>
4	Update all asset attributes in Salesforce including Ambient Lab Temperature, Ambient Lab Humidity, and UPS make and model. Distributors submit asset attributes to Vizgen Support at techsupport@vizgen.com to maintain proper records.	<input type="checkbox"/>

7 REQUIRED ATTRIBUTES

This section is to provide proper documentation of all installed instrument configurations to Vizgen.

Attribute	Location	Value
Control SW Version	In the Merscope ULTRA UI	
Box 1 Firmware Version	Firmware Tab in the G8 GUI	
Box 2 Firmware Version	Firmware Tab in the G8 GUI	
Imaging Camera Firmware Version	PVCam Test SW	
Imaging Camera Serial Number	PVCam Test SW	
XY Stage Serial Number	Can be requested from Instrument Traveler	
Z Stage Serial Number	Can be requested from Instrument Traveler	
Syringe Pump Serial Number	Can be requested from Instrument Traveler	
Imaging Laser Serial Number	Laser in MERSCOPE Control Box	
Flow Chamber Serial Numbers FCX-S and FCX-L	FCX-S Flow Chamber Base SN: FCX-L Flow Chamber Base SN:	
APC Serial Number	Rear panel of APC	

Step	Action	Completed
1	Ensure all validation and configuration documentation is uploaded to Salesforce. Distributors submit to Vizgen Support at techsupport@vizgen.com to maintain proper records.	<input type="checkbox"/>

vizgen

Certification

I certify that all information I have provided in this document is accurate and that all tests I have performed were performed in accordance with MERSCOPE Instrument Installation GUIDE 91500002.

Vizgen Personnel or Authorized Distributor Signature _____

Printed Name _____

Printed Title _____

Date _____

Customer / Institution Approval Information _____

Serial Number _____