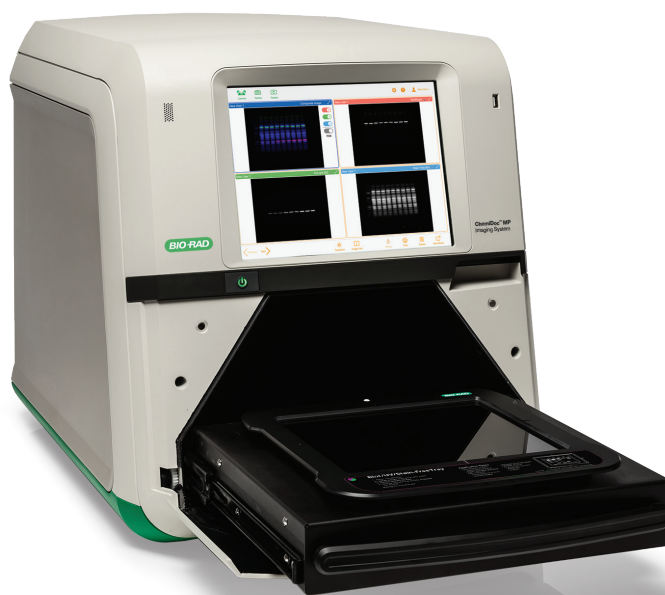

ChemiDoc™ and ChemiDoc MP Imaging Systems with Image Lab™ Touch Software

Installation Qualification Protocol (IQ)

Catalog #17001401 and 17001402



BIO-RAD

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Section 1: General Information

1.1 Scope

This Installation Qualification protocol applies to the ChemiDoc™ (12003153) and ChemiDoc MP (12003154) Imaging Systems with Image Lab™ Touch software.

This protocol has been prepared to encompass U.S. regulatory requirements. In regions where requirements differ, such differences or additions shall be noted in Section 4.

1.2 Protocol Guidelines

The protocol guidelines in this procedure shall be followed. If any element does not apply, it shall be indicated by N/A (not applicable). If any section has not been successfully completed, indicate the appropriate protocol exceptions and actions taken in Section 4.1.

1.3 Executor and Reviewer Identification and Signatures

This section identifies the persons who will execute and review the installation qualification protocol.

Executor

Printed Name	Institution	Signature	Initials	Date

Reviewer

Printed Name	Institution	Signature	Initials	Date

1.4 Site Information

Table 1-1. Site information.

Reference or work order number	
Date of installation	
PO number	
Primary contact (name)	
Primary contact phone number	
Primary contact email	
Installation site (lab/dept.)	
Institution name	
Address	

1.5 Section 1 Signatures

Upon completion of this section, the executor and reviewer shall indicate the results, and then sign and date this page.

Section 1 Completed Successfully		Executor Signature	Date
Yes	No		
Section 1 Completed Successfully		Reviewer Signature	Date
Yes	No		

Section 2: Delivery and Inspection

2.1 Delivery Confirmation

Inspect the outside of the shipment to confirm receipt of all items listed in Table 2-1.

Table 2-1. Delivery confirmation.

Document	Present (Executor Initial)
Shipping manifest (packing list)	
Itemized purchase order	
Unpacking the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide	
Observations/comments:	

2.2 Inspection/Identification of Components

Inspect the shipment for receipt of all items listed in Table 2-2 and any shipping damage. Record serial numbers (where applicable) of items listed in Table 2-2.

Table 2-2. Inspection/identification of components.

Description	Present/Not Present	Serial Number
ChemiDoc or ChemiDoc MP Imaging System		
Accessory box contents		
AC power cord		N/A
Cat 6 Ethernet cable, 10 ft		N/A
Foot leveling wrench		N/A
Bubble level		N/A
Blot/UV/Stain-Free Tray		N/A

Table 2-2. Inspection/identification of components (continued).

Description	Present/Not Present	Serial Number
Accessory box contents (continued)		
ChemiDoc and ChemiDoc MP Imaging Systems Safety and Regulatory Compliance		N/A
Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide		N/A
Getting Started with ChemiDoc and ChemiDoc MP Sample Trays Quick Guide		N/A
Gel/Blot Alignment Templates for the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide		N/A
Band Excision Using the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide		N/A
Acquiring an Image with the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide		N/A
V3 Western Workflow™ Imaging Target		N/A
Declaration of conformity		N/A
Warranty card		N/A
Returned goods authorization form		N/A
Optional accessories		
White Sample Tray (12003026)		N/A
Blue Tray (12003027)		N/A
UV Safety Shield (12003914)		N/A
Thermal Printer (1708089)		

Section 3: Installation Qualification Procedure

Before proceeding with this Installation Qualification, unpack and set up the instrument in accordance with the Unpacking the ChemiDoc and ChemiDoc MP Imaging Systems and Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems quick guides.

3.1 Environment

Locate the ChemiDoc or ChemiDoc MP Imaging System so that there is sufficient room to open and close the front door and UV transilluminator without obstruction (52 x 56 x 62 cm, W x H x D), as well as 8 cm of clearance from the back for ventilation and access to the AC power cord. Keep the area clean and free of excessive dust or moisture. It is important to connect the ChemiDoc or ChemiDoc MP Imaging System to a properly grounded circuit. Image quality can be affected if other lab equipment, such as centrifuges, shakers, oil-type vacuum pumps, or freezers, share the same AC power line and/or bench area with the imager.

Record Pass/Fail information in Table 3-1.

Table 3-1. Environment.

Parameter	Specification	Pass/Fail
Front door clearance	No obstruction when fully opened	
Ventilation clearance	Requires ≥ 8 cm of rear clearance for both the air intake and exhaust ports	
Environment	Clean, free of excessive dust, humidity 10–80%, and temperature 10–28°C	
Power circuit	Properly grounded (100–240 VAC, 50–60 Hz)	
Observations/comments:		

3.2 Thumb Screw Removal

Remove the thumb screw in accordance with the Unpacking the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide.

Record Pass/Fail information in Table 3-2.

Table 3-2. Thumb screw removal.

Description	Specification	Pass/Fail
Thumb screw	Remove thumb screw and label	

3.3 Power Cord Installation

Locate the AC power receptacle on the back of the imager and connect the power cord to the AC power receptacle in accordance with the Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide. Plug the other end of the AC power cord into an AC outlet.

Record Pass/Fail information in Table 3-3.

Table 3-3. Power cord installation.

Description	Specification	Pass/Fail
Power cord	From the AC power receptacle to the AC outlet	

3.4 Startup and Transilluminator Clearance

Start the ChemiDoc or ChemiDoc MP Imaging System as described below and check that there is sufficient room to open the UV transilluminator without obstruction in accordance with the Unpacking the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide.

To start the ChemiDoc or ChemiDoc MP Imaging System

1. Press the power switch on the front of the imager. Verify that the power light illuminates green and steady within a few seconds.
2. Verify that the instrument initializes and that the Welcome screen appears.

Record Pass/Fail information in Table 3-4.

Table 3-4. Startup.

Description	Specification	Pass/Fail
ChemiDoc or ChemiDoc MP Imaging System startup	Power on and power light illumination steady	
	Image Lab Touch Software starts and Welcome screen appears	
Transilluminator clearance	No obstruction when fully opened	
Observations/comments:		

3.5 Administrator Setup

The designated on-site or IT administrator shall log in in accordance with the Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide instructions.

To log in to the ChemiDoc or ChemiDoc MP Imaging System

1. Tap anywhere on the screen. Using the onscreen keyboard, enter a user name and then tap **Create**.
2. When prompted, tap **OK** to become an administrator and create a password in the box that appears.
3. Review the Administrator Options dialog and tap **Close**.

Record Pass/Fail information in Table 3-5.

Table 3-5. Administrator setup.

Description	Specification	Pass/Fail
Administrator setup	Create user	
	Create password	
Observations/comments:		

3.6 Instrument Leveling

Use the bubble level and foot-leveling wrench to ensure that the instrument is level, in accordance with the Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide instructions.

Record Pass/Fail information in Table 3-6.

Table 3-6. Instrument leveling.

Description	Specification	Pass/Fail
Level instrument	Instrument is level	

3.7 Printer Installation (Optional)

If a thermal printer is present, connect it to the imager and AC outlet in accordance with the Setting Up the ChemiDoc and ChemiDoc MP Imaging Systems Quick Guide instructions.

Record Pass/Fail information in Table 3-7.

Table 3-7. Printer installation.

Description	Specification	Pass/Fail
Thermal printer installation	Power cord from printer to the AC outlet	
	USB cord from printer to the imager	
Observations/comments:		

3.8 Section 3 Signatures

Upon completion of this section, the executor and reviewer shall indicate the results and then sign and date this page.

Section 3 Completed Successfully		Executor Signature	Date
Yes	No		
Section 3 Completed Successfully		Reviewer Signature	Date
Yes	No		

Section 4: Protocol Exceptions and Actions Taken

4.1 Protocol Exceptions and Actions Taken

If an exception or deviation has been made to the protocol, or if a part requires replacement, the executor must document the reason for the exception and list the action taken to correct the situation. The executor should provide a description, including the section in which the problem occurred, and list any parts that were replaced.

Table 4-1. Protocol exceptions and actions taken.

Exception(s)		
1.		
2.		
3.		
Action(s) Taken		
1.		
2.		
3.		
Executor Name	Signature	Date



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