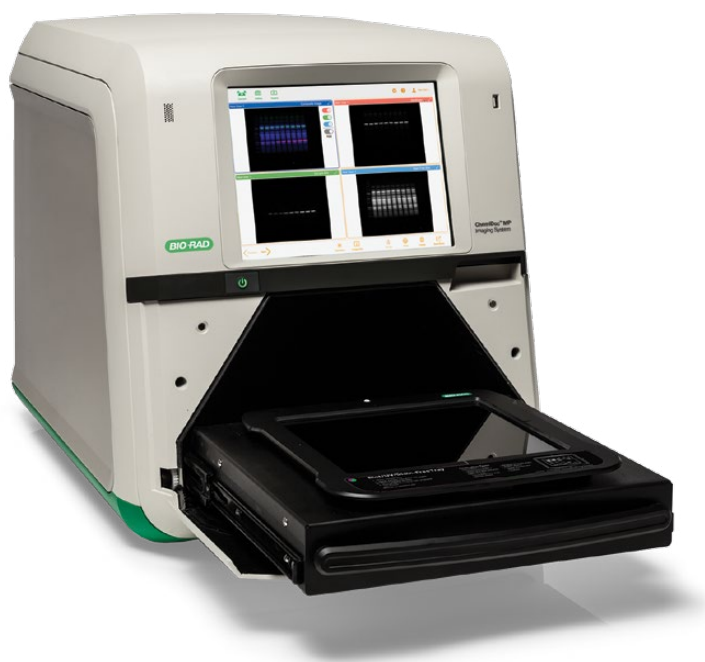


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# ChemiDoc™ and ChemiDoc MP Imaging Systems with Image Lab™ Touch Software

## Operational Qualification Protocol (OQ)

Catalog #17001401 and 17001402



**BIO-RAD**

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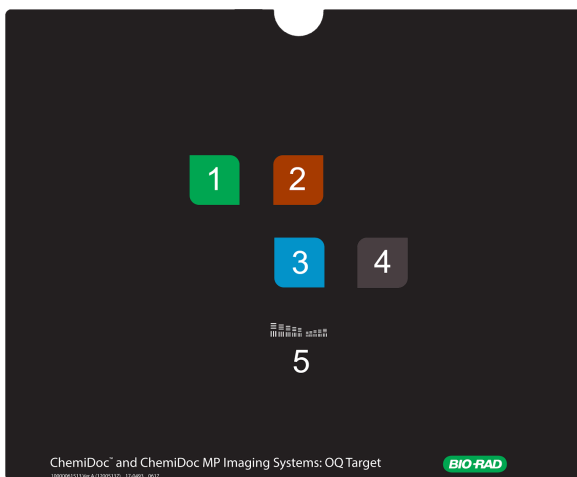
# Section 1: General Information

## 1.1 Scope

This Operational Qualification protocol is applicable to the ChemiDoc™ (17001401) and ChemiDoc MP (17001402) Imaging Systems with Image Lab™ Touch software version 2.1 or later.

This protocol has been prepared in accordance with U.S. regulatory requirements. In regions where requirements differ, such differences or additions shall be noted in Section 5 if this protocol is to be used.

This protocol and target are designed to verify that the excitation sources and emission filter wheel of the ChemiDoc or ChemiDoc MP are functional and being controlled properly by the system software and firmware. Each combination of excitation source and emission filter will produce a unique image pattern of the OQ target.



**Fig. 1. Schematic of the ChemiDoc and ChemiDoc MP Imaging Systems: OQ Target. The numbers label the major features of the target, including the four fluorescent squares (1-4) and the resolution pattern (5).**

Images acquired in this protocol can be printed using a dedicated Mitsubishi P95 printer (1708089) or saved and exported. The exported images can be printed from a computer.

The master copy of the protocol is supplied in a three ring binder and is intended to be photocopied to generate working copies as needed. It is suggested to not write on the pages included in this manual in case you wish to perform this protocol again.

## 1.2 Protocol Guidelines

This protocol assumes that the ChemiDoc and ChemiDoc MP Imaging Systems with Image Lab Touch Software Installation Qualification Protocol has already been performed.

The protocol guidelines in this procedure shall be followed. If an 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 5.1.

Test results are recorded by the user in results tables located throughout the protocol. It is recommended that the original OQ Protocol document be photocopied and results recorded on the copy.

### **1.3 Care and Maintenance of OQ Target**

The target is delivered in a static-shielding bubble bag. This target should be stored in this bag in a dark location to protect it from physical damage and photobleaching. Accumulated dust can be removed with dry compressed air or a lint free soft cloth. Do not use solvents to clean the surface as they may alter the properties of the target. The inks used to produce the fluorescent and phosphorescent signals from the OQ target have been tested with 1400 OQ imaging cycles with intensity variability of less than 15%.

### **1.4 Warning for UV Radiation**



Transilluminators are powerful sources of UV radiation, which can cause serious damage to unprotected eyes and skin. The accessory UV safety shield (catalog #12003914) provides some UV protection to users facing the imaging system. However, if the shield is not fully closed it does not protect others standing in the area around the imager. Before testing the UV lamps in Section 3.4, the user and other lab personnel in proximity to the imager must put on protective gear including UV protective safety glasses, a face shield, lab coat, and gloves to ensure that no skin is exposed. Bystanders without protective gear must stand at least 1.5 meters (five feet) away from the imager and limit their exposure to no longer than one hour per day.

### **1.5 Executor and Reviewer Identification and Signatures**

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

#### **Executor**

Printed Name	Institutional Affiliation	Signature	Initials	Date

#### **Reviewer**

Printed Name	Institutional Affiliation	Signature	Initials	Date

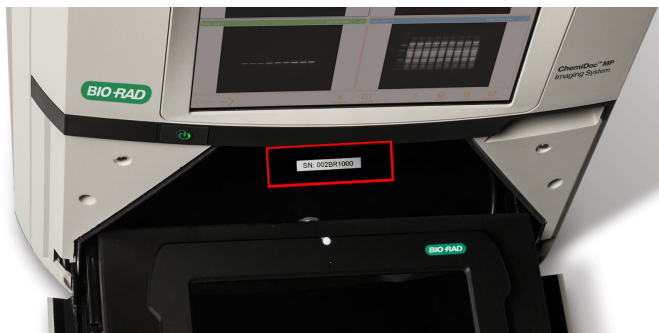
**1.6 Site and System Hardware Information**

Record information about the installation site in Table 1-1.

**Table 1-1. Site Information.**

<b>Case or reference number</b>	
<b>Date of installation</b>	
<b>PO number</b>	
<b>Primary contact (name)</b>	
<b>Primary contact phone number</b>	
<b>Installation site (lab/dept)</b>	
<b>Institution name</b>	
<b>Address</b>	

Record the system serial number and model type in Table 1-2. This serial number information is located under the transilluminator on the floor of the instrument as shown in Figure 2. The model type is found to the right of the touch screen.



**Fig. 2. Serial Number label location.**

**Table 1-2. System Hardware Identification.**

<b>Item</b>	<b>Record</b>
<b>Model</b>	
<b>Serial number</b>	
<b>Observations/comments:</b>	

**1.7 Target Information**

Record the target PO number in Table 1-3. This PO number information is located on the label on the bubble envelope the target is stored in.

**Table 1-3. OQ Target Identification.**

Item	Record
PO number	
Observations/comments:	

**1.8 Section 1 Signatures**

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

<b>Section 1 Completed Successfully</b>		<b>Executor Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		
<b>Section 1 Completed Successfully</b>		<b>Reviewer Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		

## Section 2: System Startup and Information

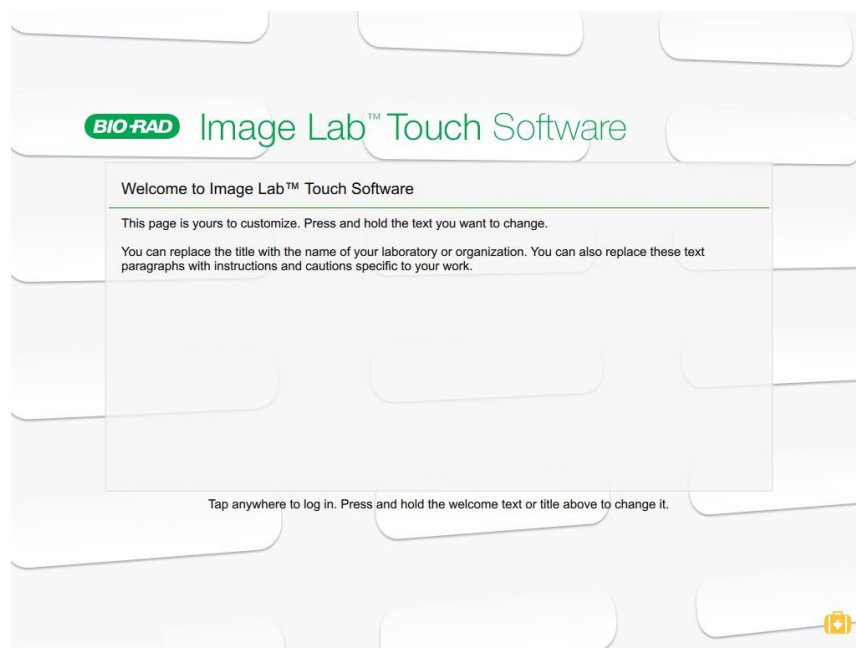
### 2.1 System Startup

Before working with this section, ensure that Image Lab Touch Software version 2.1 or later has been installed on the ChemiDoc MP or ChemiDoc imaging system and is properly functioning. Refer to the ChemiDoc and ChemiDoc MP Imaging Systems with Image Lab Touch Software Installation Qualification Protocol (IQ) if necessary.

This test checks for proper startup of the ChemiDoc and ChemiDoc MP Imaging Systems.

#### 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 (Fig. 3).  
If the Auto Exposure Calibration box opens, tap No.



**Fig. 3. Image Lab Touch Welcome Screen**

3. Open the front door and pull out the transilluminator drawer.
4. Remove the sample tray (if present), slide the transilluminator back in place, and shut the front door.

**Logging in as a new user**

1. Tap anywhere on the Welcome screen. The login dialog box appears.
2. Tap inside the text box.
3. Using the on-screen keyboard that appears, tap in a user name and then tap Create.

**Logging in as a returning user**

1. Tap anywhere on the Welcome screen. The login dialog box appears.
2. On the right hand side of the box, scroll the list of users to find your user name.
3. Tap your user name.
4. If prompted, enter your password.

**Testing Camera View**

When you log into the imaging system, Camera View displays a real-time picture of the imaging stage while a tray is present. To test this, you will place a leveling bubble on the Blot/UV/Stain-Free tray and verify that Camera View displays the image.

1. After selecting your user name, verify the following:
  - a. Image Lab Touch starts.
  - b. Camera View is active. The Camera icon in the upper left corner of the main toolbar appears in blue.
  - c. A message appears directing you to place a tray on the transilluminator imaging stage.
2. Open the front door and pull out the transilluminator drawer.
3. Place the Blot/UV/Stain-Free tray on the imaging stage.
4. Place the leveling bubble provided with your system in the center of the tray.
5. Slide the transilluminator drawer back into the imager and close the front door.

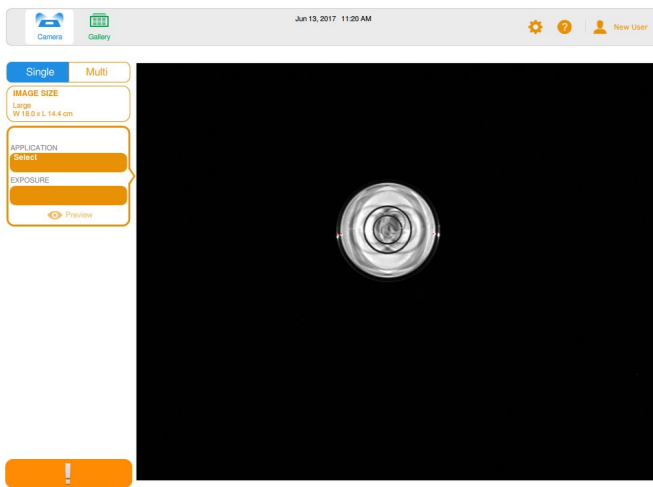
Imaging settings tiles appear on the left side of the screen.



6. Tap the Image Size tile.
7. Tap the preset size setting Large W 18.0 x L 14.4 cm. When selected, the setting will appear in blue.



8. Tap the X to close the Choose Image Size box.
9. Verify that the screen displays a view of the leveling bubble. The screen should look similar to Figure 3.



**Fig. 3. Camera View Screen.**


10. Record your findings in Table 2-1.

**Table 2-1. System Startup.**

Description	Specification	Pass/Fail
Instrument	Power on	
Power Button	Turns green in On state	
Touch screen	Display is active	
System Initialization	Welcome screen appears	
User Login	Administrator login successful	
Camera	Camera View is active	
Tray Visible	Leveling bubble is visible in Camera View	

## **2.2 System and Serial Number Identification**

### **To verify the system information**

1. In Camera View tap the Settings  icon in the right corner of the main toolbar.
2. Tap About This Imager.
3. Record the Image Lab Touch Software information listed in Table 2-2.
4. Verify that the ChemiDoc or ChemiDoc MP serial number shown in the information box on screen matches the number recorded in Table 1-2 in section 1.6.

**Table 2-2. System Information.**

Description	Item	Record
Software	Version	
Instrument	Type	
ChemiDoc or ChemiDoc MP	Serial number	
Firmware	Version	
MZL Firmware	Version	
Tray Sensor Firmware	Version	
LED Boards Firmware (ChemiDoc MP only)	Version(s)	
Camera	Serial number	
Camera Firmware	Version	
Disk Image	Version	
MAC	Address 1	
MAC	Address 2	
Disk Space Free	Percent (%)	

4. Tap the X in the upper right corner to close the Image Lab Touch Software info box.

### **2.3 Section 2 Signatures**

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

<b>Section 2 Completed Successfully</b>		<b>Executor Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		
<b>Section 2 Completed Successfully</b>		<b>Reviewer Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		

## **Section 3: Operational Qualification Procedure**

In this section, proper control of each light source, emission filter, and zoom mechanism will be tested and the results recorded. This workflow consists of using representative imaging applications in a series of multiplex fluorescence protocols.

### **3.1 Required Materials**

This protocol requires the following materials, some of which are included with the ChemiDoc and ChemiDoc MP Imaging Systems:

- OQ Imaging Target (10000061513, included)
- Blot/UV/Stain-Free Tray (12003028, included)
- (Optional) Mitsubishi P95 printer (1708089, not included)
- (Optional) UV Safety Shield (12003914, not included)
- USB flash drive (FAT32 formatted, not included)
- Windows or Mac computer (not included) with Image Lab software version 6.0 or later installed (1709690, not included)

Image Lab software version 6.0 or later is a free software package included with each ChemiDoc and ChemiDoc MP purchase. If the DVD has been misplaced please contact Bio-Rad Technical Support via [www.consult.bio-rad.com](http://www.consult.bio-rad.com) or one of the region specific phone number on the back cover of this manual.

### **3.2 Protocol 1: Colorimetric and Chemiluminescence**

In this section, a multiplex protocol will be used to test two imaging channels: colorimetric and chemiluminescence. The colorimetric channel consists of white light illumination combined with a 590/110 emission filter. The chemiluminescence channel detects phosphorescence from the target through a 647SP emission filter. To activate the phosphorescent material that provides the signal for the chemiluminescence test, expose the target to strong room light for several minutes immediately prior to beginning this protocol. In the second part of this test, the zoom mechanism is tested by acquiring a

second set of images at a different image size. For each test, the instrument will be deemed to pass if the imager successfully captures images at each setting.

**Note:** This protocol applies to both the ChemiDoc MP and the ChemiDoc Imaging Systems.

### Testing the Colorimetric and Chemiluminescence imaging channels

1. Open the front door, pull out the transilluminator drawer, and place the Blot/Stain-Free/UV tray on the imaging stage.
2. Place the OQ imaging target face up in the tray.
3. Slide the transilluminator drawer back into the ChemiDoc or ChemiDoc MP and close the front door.
4. In Camera View, choose the following settings in the imaging settings tiles:

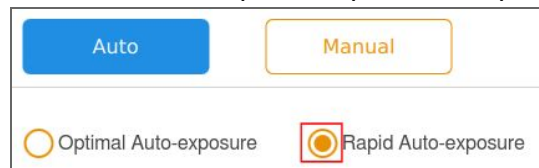
- Multichannel Acquisition



- Image Size -- Tap the Image Size box and then tap the preset setting Large (W 18.0 x L 14.4 cm).
- In the top channel settings tile, tap the box under Application to open the Choose Application Category box.
- Tap Colorimetric.



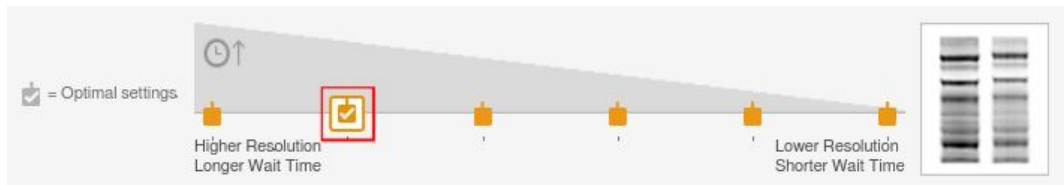
- In the same tile, tap the box under Exposure. If a Quick Help screen appears, close it.
- Tap Auto, and then tap the Rapid Auto-exposure checkbox.



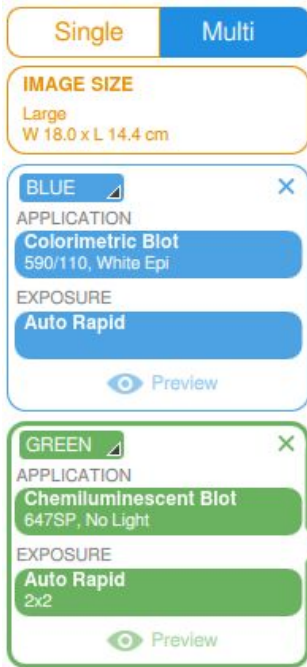
- To add a second channel, tap inside the add-channel tile:




- In the new channel settings tile, tap the box under Application to open the Choose Application Category box.
- Tap Chemiluminescence.
- In the same tile, tap the box under Exposure. If a Quick Help screen appears, close it.
- Tap Auto and then tap the Rapid Auto-exposure checkbox.
- On the resolution bar, tap the checkbox for 2x2 binning if necessary.



5. The imaging settings tiles should appear as follows:



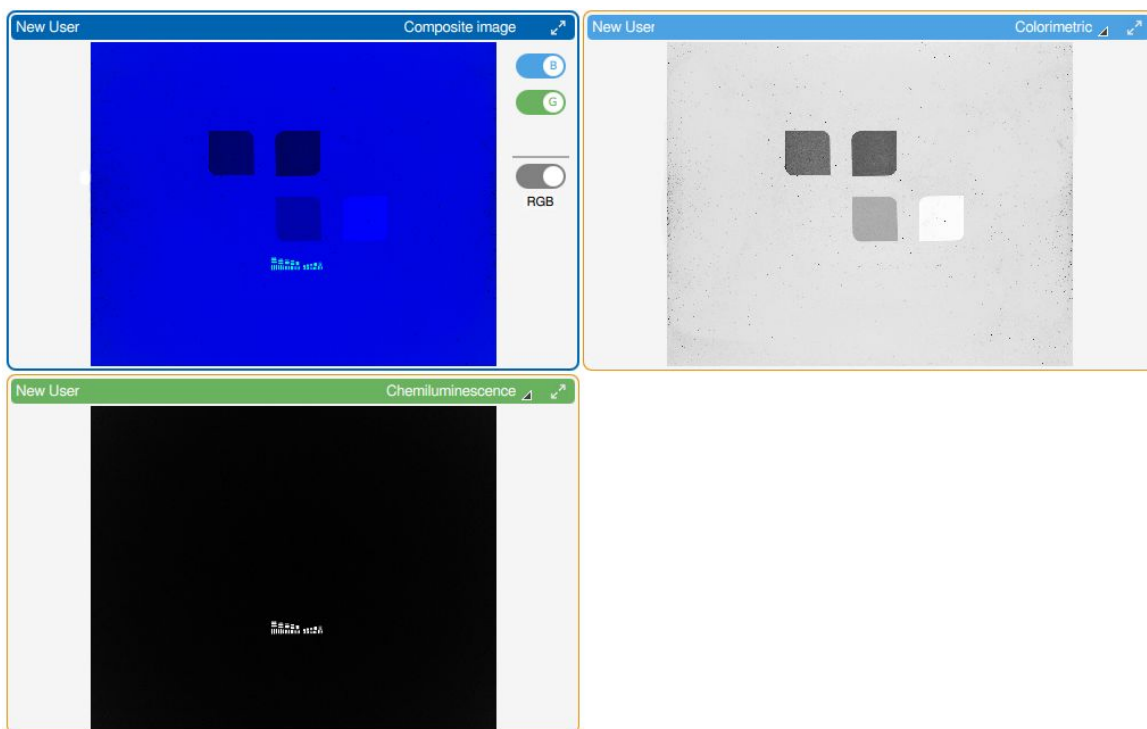
**To acquire the images**

1. In the lower left corner of the screen, verify that the Camera  button is green.
2. (Optional) If the button is not green, tap the button that appears instead to view an error message.
  - a. Correct the error.
  - b. Verify that the Camera button is now green.
3. Tap the Camera button to begin the exposure.
4. Wait for the imager to acquire the images. This might take a few minutes. When acquired, the images appear on screen.

**Note:** The phosphorescent ink charges by exposure to light. If the signal is too faint to record a chemiluminescent image, open the instrument, pull the transilluminator drawer out, and let the target sit in ambient light for 5 minutes. Then push the drawer closed and repeat the steps for image acquisition.

### Assessing the Results

Figure 4 shows the expected images from Protocol 1 Large Image.



**Fig. 4. OQ Imaging Target. Protocol 1 expected results. Colorimetric image (upper right), chemiluminescence image (bottom left), and composite image (upper left).**

The colorimetric image (Figure 4, top right image) should show a black and white image

of the target surface. All four rounded squares. If the acquired image has these features, the Colorimetric Test, Large Area is considered passed.

The chemiluminescent blot image (Figure 4, bottom left image) should show only the phosphorescent resolution pattern. If it does, the test Chemiluminescence, Large Imaging Area is considered passed.

### **Documenting the Test Results**

You can rename and save the acquired image and print it on the Mitsubishi P95 thermal printer for inclusion in reports.

#### **To rename the image**

1. Tap Image Info in the bottom toolbar.
2. Tap inside the Name box to activate the onscreen keyboard. Clear the default image name and tap in a new name in the form

OQ [date] Protocol 1 Large Image

3. Tap OK and then tap the X in the upper right corner of the Image Info box to close it.

**Note:** You will export this data in Section 3.7.

#### **To print the image**

1. (Optional) If a thermal printer is installed, tap Print in the bottom toolbar.
2. When the message Print Image appears, tap OK.
3. Otherwise, image files can be exported and printed from ImageLab Desktop software (Section 3.7).

### **Testing the zoom mechanism**

In this section, the colorimetric/chemiluminescence multiplex protocol will be repeated with a different Image Size setting in order to validate that the zoom mechanism is working properly.

#### **To acquire the images**

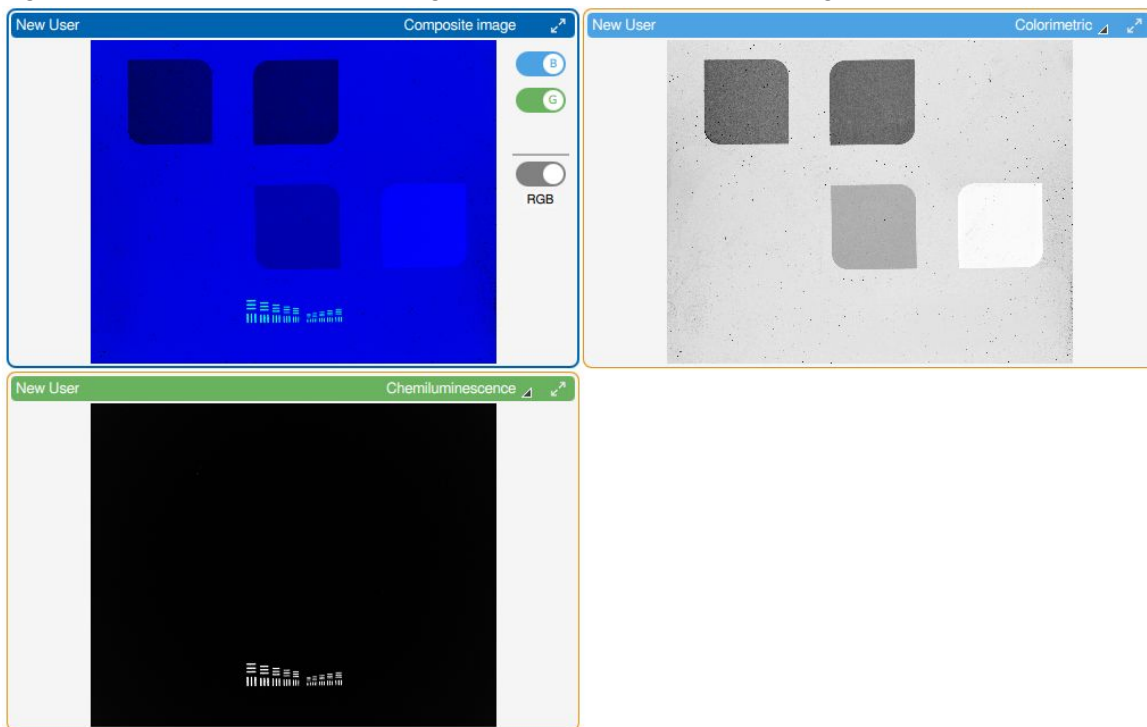
1. Tap the Camera icon in the upper left corner of the main toolbar to return to Camera View.
2. Tap the Image Size box and then tap Small to change the image size to this preset size (W 9.5 x L 7.6 cm).

3. Verify that the Camera button in the lower left corner of the screen is green.
4. (Optional) If the button is not green, tap the button that appears to view an error message.
  - a. Correct the error.
  - b. Verify that the Camera button is now green.
5. Tap the Camera button to begin the exposure.
6. Wait for the imager to acquire the images. This might take a few minutes.

When acquired, the images appear on screen.

### Assessing the Results

Figure 5 shows the expected images from Protocol 1 Small Image.



**Fig. 5. OQ Imaging Target. Protocol 1 expected results for the zoom test image. Composite image (upper left), Colorimetric image (upper right), and Chemiluminescence image (lower left).**

The colorimetric image (Figure 5, top right image) should show a black and white image of the target surface, including all four rounded squares and the resolution pattern. Some squares may be clipped by the edge of the screen.

The chemiluminescent blot image (Figure 5, bottom left image) should show only the phosphorescent resolution pattern.



To verify that the zoom mechanism worked properly, compare the Small size image collected above to the Large size image collected in the color/chemi test.

1. Tap the Gallery icon in the top left corner of the screen to access Gallery View.

**Note:** The Gallery displays thumbnail images of all acquired images in order of date acquired, most recent image acquired displayed first.

2. To select Protocol 1 Small Image, tap the top-left thumbnail. A blue checkbox appears in the upper right corner of the selected image.
3. To select the Protocol 1 Large Image, tap the thumbnail named OQ [date] Protocol 1 Large Image.
4. Tap the View Selected Images button in the bottom toolbar. The two images appear on screen side by side.
5. Compare the relative feature sizes of the two images. If the Protocol 1 Large Image has smaller features than the Protocol 1 Small Image, the Zoom Mechanism Test is considered passed.

### Documenting the Test Results

You can rename and save the acquired images and print them on the Mitsubishi P95 thermal printer for inclusion in reports.

**Note:** You can also export and print image files from ImageLab Desktop software (Section 3.7).

### To rename the image

1. Tap Image Info in the bottom toolbar.
2. Tap inside the Name box to activate the onscreen keyboard. Clear the default image name and tap in a new name in the form

OQ [date] Protocol 1 Small Image

3. Tap OK and then tap the X in the upper right corner of the Image Info box to close it.

**Note:** You will export this data in Section 3.7.

### To print the image (optional)

1. If a thermal printer is installed, tap Print in the bottom toolbar.
2. When the message Print Image appears, tap OK.

### **Recording Section Test Results**

Record the chemiluminescence test results in Table 3–1. Attaching the image printouts to Section 4.1 is optional.

**Table 3-1. Chemiluminescence Test.**

Description	Specification	Pass/Fail
<b>Colorimetric, Large Imaging Area</b>	<b>The colorimetric image shows four squares, resolution pattern</b>	
<b>Chemiluminescence, Large Imaging Area</b>	<b>The chemiluminescent blot image shows only resolution pattern</b>	
<b>Zoom Mechanism Test</b>	<b>The composite image shows four rounded squares and the resolution pattern as larger features than in the Large Imaging Area test results</b>	

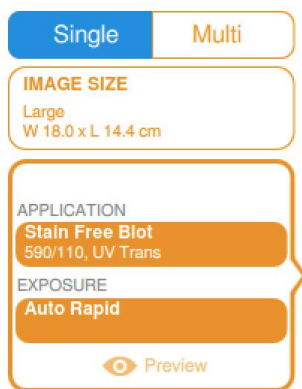
### **3.3 Protocol 2: UV Excitation Test**

In this section, a singleplex protocol will be used to test the UV (Stain-free) imaging channel. The Stain-free blot application consists of UV illumination combined with a 590/110 emission filter. The instrument will be deemed to pass if it successfully captures an image of the UV-fluorescent ink on the OQ target.

**Note:** This protocol applies to both the ChemiDoc and ChemiDoc MP Imaging Systems

#### **To Simulate Acquiring Stain-free Blot (UV) Images**

1. Place the OQ Imaging Target face up in the Blot/Stain-Free/UV tray and place the tray inside the imager.
2. Tap the Camera icon in the upper left corner to return to Camera View.
3. In the image settings tiles, choose the following settings:
  - Single Channel Acquisition
  - Image Size: Large (W 18.0 x L 14.4 cm)
  - In the active channel settings tile, select the following:
    - Tap the box under Application to open the Choose Application Category box.
    - Tap Blots.
    - Under Choose Application, tap Stain Free Blot.
    - Under Exposure, tap Auto and then tap Rapid Auto-Exposure.
4. The channel settings tile should appear as follows:



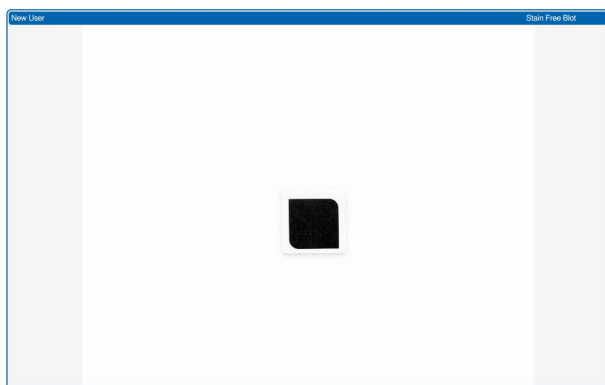
### To acquire the image

1. Verify that the Camera button in the bottom left corner of the screen is green.
2. (Optional) If the button is not green, tap the button that appears instead to view an error message.
  - a. Correct the error.
  - b. Verify that the Camera button is now green.
3. Tap the Camera button to begin the exposure.
4. Wait for the imager to acquire the image. This might take a few minutes.

When acquired, the image appears on screen.

### Assessing the Results

Figure 6 shows the expected image from Protocol 2:



**Fig. 6. OQ Imaging Target. Protocol 2 UV test expected results.**

The UV image (Figure 6) should show a single bright square (Square 3, see Figure 1 for reference). If it does, the UV test is considered passed.

## Documenting the Test Results

You can rename and save the acquired image and print it on the Mitsubishi P95 thermal printer for inclusion in reports.

**Note:** Image files can also be exported and printed from ImageLab Desktop software (Section 3.7).

### To rename the image

1. Tap Image Info in the bottom toolbar.
2. Tap inside the Name box to activate the onscreen keyboard. Clear the default image name and enter a new name in the form

OQ [date] Protocol 2 Image

3. Tap OK and then tap the X in the upper right corner of the Image Info box to close it.

**Note:** You will export this data in Section 3.7.

### To print the image

1. If the Mitsubishi P95 thermal printer is installed, tap Print in the bottom toolbar.
2. When the message Print Image appears, tap OK.

## Recording Section Test Results

1. Record the UV test results in Table 3–2.
2. (Optional) Attach the image file printouts to Section 4.1.

**Table 3-2. UV Test.**

Description	Specification	Pass/Fail
UV	The UV image (example Figure 6) shows an image of rounded square (square 3) illuminated on the OQ target. If so the UV test is considered passed.	

### 3.4 UV Safety Shield and Lamps Test (Optional)

**Warning:** Execution of this test can result in exposure to UV radiation. Wear proper protective equipment during the execution of this test. UV protective eyewear, gloves, and long sleeved garments are recommended.

In this section, the UV Safety Shield is temporarily installed to determine whether the

ChemiDoc or ChemiDoc MP Imaging System UV safety protocols are properly functioning.

**Note:** This test applies only to ChemiDoc and ChemiDoc MP Imaging Systems equipped with an accessory UV safety shield 12003914.

### To test the UV safety shield and UV lamps

1. Open the front door, pull out the transilluminator drawer, and place the Blot/Stain-Free/UV tray on the imaging stage.
2. Place the OQ Imaging Target face up in the tray.
3. Insert the UV safety shield into the transilluminator drawer.
  - a. Hold the UV shield by diagonal corners so you can guide it accurately.
  - b. Insert the two locking tabs that extend from the front of the UV shield into the two slots on the front of the transilluminator drawer.



- c. Ensure that the two wedges on the front of the UV shield snap into position on the transilluminator handle.
4. In Camera View, tap Turn Transilluminator ON in the center of the screen.
  5. Verify that the UV lamps on the transilluminator turn on by observing a green glow from the square illuminated in the UV Excitation test above.

**Warning:** During adjustment of the UV safety shield in the next step, UV radiation is emitted from the tray.

6. Lift the lid of the UV safety shield until it is about 45 degrees above the surface of the transilluminator drawer.
7. Verify that the UV lamps on the transilluminator remain turned on.

- Remove the UV safety shield completely and verify that the lamps turn off.

### Recording Test Results

Record the UV safety shield and lamps test results in Table 3-3.

**Table 3-3. UV Safety Shield and UV Lamps Test Results.**

Optional Tests: Perform only if equipped with a UV safety shield		
Description	Specification	Pass/Fail
UV safety shield connected	Lamps illuminate	
UV safety shield adjustment	Lamps remain on when the UV safety shield is adjusted	
UV safety shield removal	Lamps turns off when the UV safety shield is removed	

### 3.5 Protocol 3: Red, Green, and Blue Excitation Test

In this section, a multiplex protocol will be used to test three imaging channels: red, green, and blue. The red channel consists of red illumination combined with a 700/50 emission filter. The green channel consists of green illumination combined with a 602/50 emission filter. The blue channel consists of blue illumination combined with a 532/28 emission filter. For each test, the instrument will be deemed to pass if the imager successfully captures the expected image of the fluorescent materials on the OQ target.

**Note:** This test applies **only** to the ChemiDoc MP Imaging System.

#### **To simulate acquiring fluorescent blot images**

- Place the OQ imaging target face up in the Blot/Stain-Free/UV tray, and then place the tray inside the imager.
- Return the imager to Camera View by tapping the Camera icon in the main toolbar.
- Clear previous multiplex settings by tapping the X in the bottom channel settings tile.

**Note:** Clearing the channel settings tiles in the stated order preserves the channel color designation listed in this manual. Channel color can be changed at any time to match these instructions by tapping the corner to view the color list and then tapping the desired color. There is no correlation between channel color and emission wavelength; channel color sets the color scheme in which channel information is presented.

**To set up the multiplex protocol**

1. In Camera View, choose the following settings in the imaging settings tiles:

- Multichannel Acquisition
- Image Size:
  - Large (W 18.0 x L 14.4 cm).
- In the top channel settings tile, select the following:
  - Application: Tap DyLight 488.
  - Exposure: Tap Auto, and then tap Rapid Auto-Exposure.
- Tap the add-channel tile to add a second channel.
- In the new channel settings tile, select the following:
  - Application: Tap DyLight 550.
  - Exposure: Tap Auto, and then tap Rapid Auto-Exposure.
- Add a third channel by tapping the add-channel tile.
- In the third channel settings tile, select the following:
  - Application: Tap DyLight 650.
  - Exposure:
    - Tap Manual.
    - Tap Set Manual Exposure Time.
    - Tap the sec (seconds) box to display the keypad.
    - Enter the exposure time of 2 seconds.
    - Tap Done.

2. The imaging settings tiles should appear as follows:



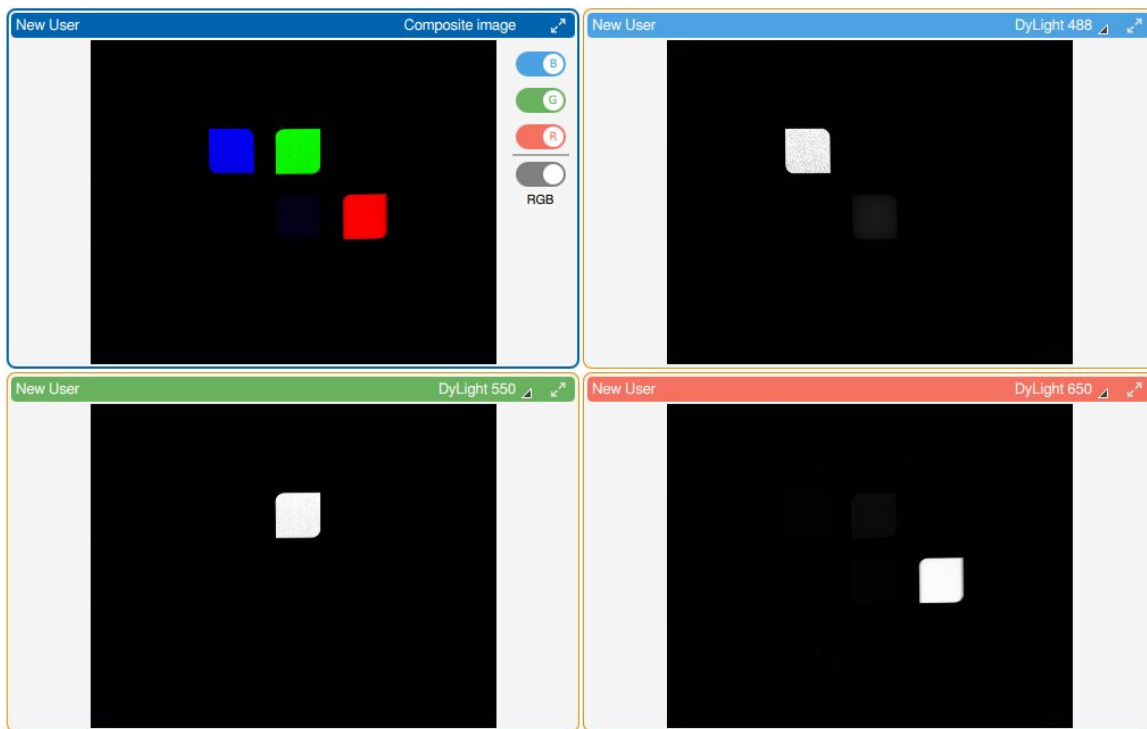


### To acquire the images

1. Verify that the Camera button is green.
2. (Optional) If the button is not green, tap the button that appears instead to view an error message.
  - a. Correct the error.
  - b. Verify that the Camera button is now green.
3. Tap the Camera button to begin the exposure.
4. Wait for the imager to acquire the images. This might take a few minutes. When acquired, the images will appear on screen.

### Assessing the Results

Figure 7 shows the expected images from Protocol 3.



**Fig. 7. OQ Imaging Target, fluorescence Multiplex Image. Protocol 3 expected results. Composite image (upper left), blue-fluorescence image (upper right), green-fluorescence image (lower left), and red-fluorescence image (lower right).**

In the blue channel image (Figure 7, top right), square 1 should represent the brightest feature, with a fainter image for square 4 (other squares may be faintly visible, see Figure 1 for reference). If this pattern is observed, the test Blue Fluorescence is considered passed.

In the green channel image (Figure 7, bottom left), square 2 should represent the brightest feature (other squares may be faintly visible). If this pattern is observed, the test Green Fluorescence is considered passed.

In the red channel image (Figure 7, bottom right), square 4 should represent the brightest feature (other squares may be faintly visible). If this pattern is observed, the test Red Fluorescence is considered passed.

### Documenting the Test Results

You can rename and save the acquired images and print them on a thermal printer for inclusion in reports.

**Note:** Image files can also be exported and printed from ImageLab Desktop software (Section 3.7).

**To rename the image**

1. Tap Image Info in the bottom toolbar.
2. Tap inside the Name box to activate the onscreen keyboard.
3. Clear the default image name and tap in a new name in the form  
OQ [date] Protocol 3 Image
4. Tap OK and then tap the X in the upper right corner of the Image Info box to close it.

**Note:** You will export this data in Section 3.7.

**To print the images (optional)**

1. If a thermal printer is installed, tap Print in the bottom toolbar.
2. When the message Print Image appears, tap OK.

**Recording Section Test Results**

1. Record the fluorescence test results in Table 3–4.
2. (Optional) Attach the image printouts to Section 4.1.

**Table 3-4. Blue, Green, Red LED Test Results.**

Description	Specification	Pass/Fail
Blue Fluorescence	Blue-fluorescent pattern of the target is visible (image shall match Fig. 7)	
Green Fluorescence	Green-fluorescent pattern of the target is visible (image shall match Fig. 7)	
Red Fluorescence	Red-fluorescent pattern of the target is visible (image shall match Fig. 7)	

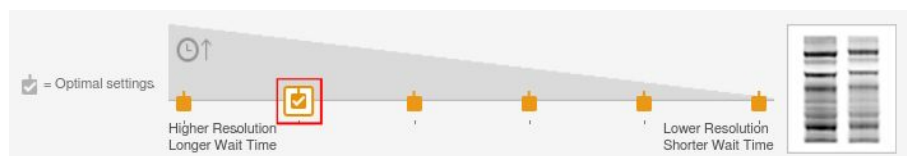
**3.6 Protocol 4: Far-Red and IR Excitation Test**

**Note:** This test applies **only** to the ChemiDoc MP Imaging System.

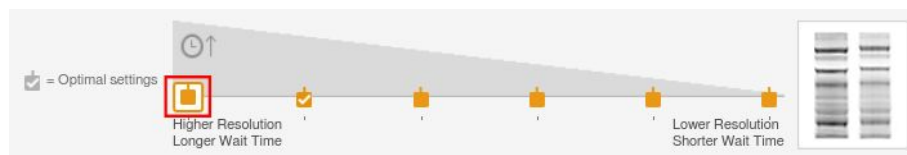
In this section, a multiplex protocol will be used to test two imaging channels: Near-IR and Far-Red fluorescence. The Near-IR channel consists of IR illumination combined with an 835/50 emission filter. The Far-Red channel consists of Far-Red illumination combined with a 715/30 emission filter. For each test, the instrument will be deemed to pass if the imager successfully captures an image of the specific fluorescent materials on the OQ imaging target.

**To simulate acquiring a multiplex gel image**

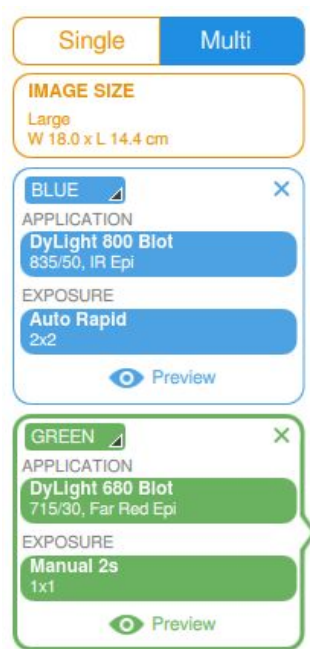
1. Place the OQ imaging target face up in the Blot/Stain-Free/UV tray, and place the tray inside the imager.
2. Tap the Camera icon in the main toolbar to return to Camera View.
3. Tap the X in the image settings tile for each channel to clear previous multiplex settings.
4. To set up the multiplex protocol, choose the following settings
  - Select Multichannel Acquisition.
  - Image Size:
    - Tap Large (W 18.0 x L 14.4 cm).
  - In the top channel settings tile, select the following:
    - Application: Tap Blots, and then tap DyLight 800.
    - Exposure:
      - Tap Auto.
      - Tap the Rapid Auto-Exposure check box.
      - Tap the 2x2 resolution box.



- Add a second channel by tapping the add-channel tile and choose the following settings:
  - Application: Tap Blots, then tap DyLight 680.
  - Exposure:
    - Tap Manual.
    - Tap Set Manual Exposure Time.
    - Tap the sec (seconds) box to display the keypad.
    - Enter the exposure time of 2 seconds.
    - Tap Done.
    - Tap the 1x1 resolution box.



The imaging settings tiles should appear as follows:

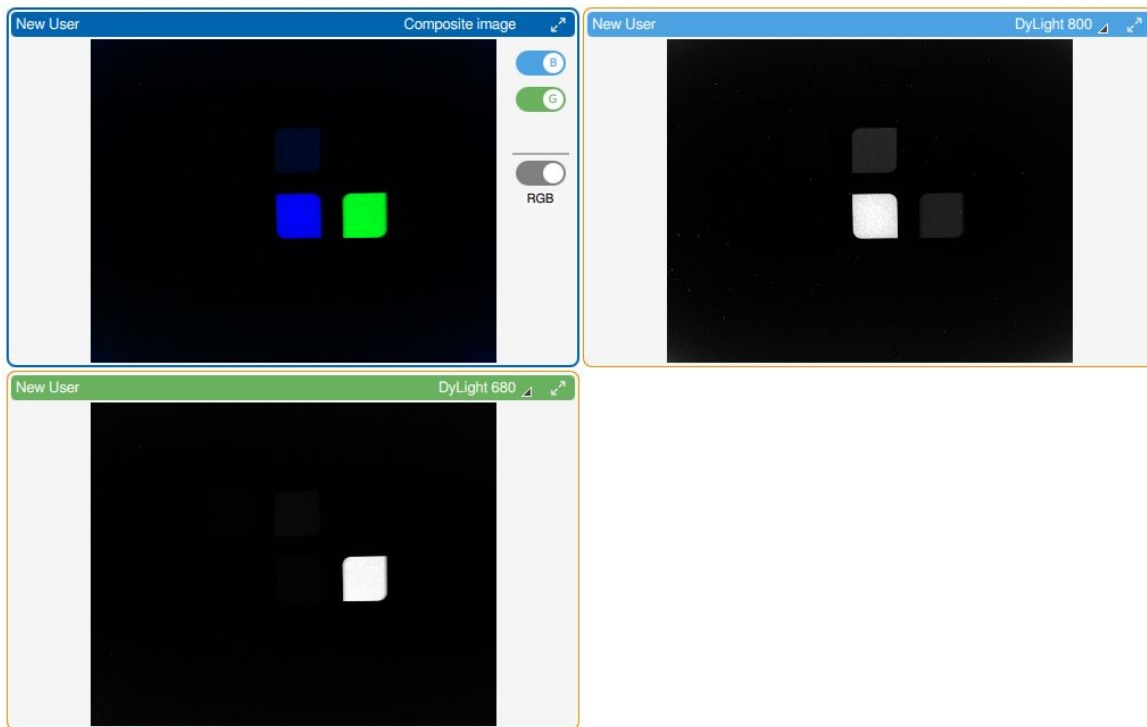


### To acquire the images

1. Verify that the Camera button is green.
2. (Optional) If the button is not green, tap the button that appears to view an error message.
  - a. Correct the error.
  - b. Verify that the Camera button is now green.
3. Tap the Camera button to begin the exposure.
4. Wait for the imager to acquire the images. This might take a few minutes. When acquired, the images will appear on screen.

### Assessing the Results

Figure 8 shows the expected images from Protocol 4.



**Fig. 8. OQ Imaging Target, fluorescence Multiplex Image. Protocol 4, expected results. Composite image (upper left), IR-fluorescence image (upper right), and far-red fluorescence image (lower left).**

In the Near-IR channel image (Figure 8, upper right), square 3 should represent the brightest feature, with fainter images for square 4 and square 2 also prominent (see Figure 1 for reference). If this pattern is observed, the test IR Fluorescence is considered passed.

In the Far-Red channel image (Figure 8, bottom left), square 4 should represent the brightest feature (other squares may be faintly visible). If this pattern is observed, continue to the next step.

### Calculating relative intensity of Red and Far-Red acquired images

#### To open multiple images

1. Tap the Gallery icon in the top left corner of the main toolbar to view the Gallery.

**Note:** The gallery displays thumbnail images of all acquired images in order by date acquired, most recent image acquired displayed first.

2. Select the IR and Far-Red Protocol image by tapping on the top-left thumbnail. The image is selected when a blue checkbox appears in the upper right corner.

3. Select the Blue, Green, and Red protocol image by selecting the thumbnail named OQ [date] Protocol 3 Image.

4. Tap the View Selected Images button in the bottom toolbar.

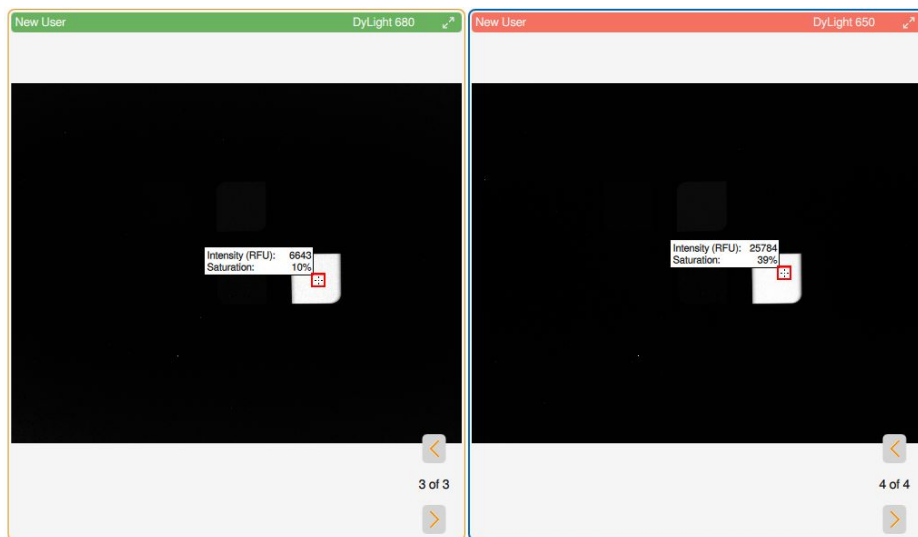
### To compare feature intensities

1. In the Protocol 4 IR and Far-Red Image, tap the orange arrows in the right corner of the bottom toolbar to navigate to the Dylight 680 image.
2. In the Protocol 3 image, tap the orange arrows in the right corner of the bottom toolbar to navigate to the Dylight 650 image. In the IR/Far-Red image, tap inside the bright square.

An information box displays an Intensity value and a Saturation percentage (Fig. 9).

3. Ensure that the cursor is well inside the square feature.
4. Note the intensity value. The information box disappears after several seconds.  
Intensity Dylight 650= \_\_\_\_\_
5. In the Protocol 4 Image, tap inside the bright square. An information box displays an Intensity value and a Saturation percentage (Fig. 9).
6. Note the intensity value. The information box disappears after several seconds.  
Intensity Dylight 680= \_\_\_\_\_

**Note:** Ensure that the cursor is well inside the square feature.



**Figure 9. Gallery view of intensity readings for selected Protocol 4 and Protocol 3 images.**

The Dylight 650 intensity value should be >2 times than the Dylight 680 value. If it is, the test Far-Red Fluorescence, Relative Intensity is considered passed.

Dylight 650/Dylight 680= \_\_\_\_\_

## Documenting the Test Results

You can rename and save the acquired images and print them on a thermal printer for inclusion in reports.

**Note:** Image files can also be exported and printed from ImageLab Desktop software (Section 3.7).

### To rename the image

1. Tap the Protocol 4 IR and Far-Red image.
2. Tap Image Info in the bottom toolbar.
3. Tap inside the Name box to activate the onscreen keyboard.
4. Clear the default image name and tap in a new name in the form  
OQ [date] Protocol 4 Image
5. Tap OK and tap the X in the upper right corner of the Image Info box to close it.

**Note:** You will export this data in Section 3.7.

### To print the image (optional)

1. If a thermal printer is installed, tap Print in the bottom toolbar.
2. When the message Print Image appears, tap OK.

## Recording Section Test Results

1. Record the Far-Red Fluorescence and IR Fluorescence test results in Table 3–5.
2. (Optional) Attach the image file printouts to Section 4.1.

**Table 3-5. Far-Red and IR LED test results.**

Description	Specification	Pass/Fail
Far-Red Fluorescence, Image Appearance	Only far-red fluorescent areas of the target are visible (image shall match Fig. 8)	
Far-Red Fluorescence, Relative Intensity	Intensity value of far-red fluorescent feature is approximately 1/4 of red fluorescent value in Protocol 3	
IR Fluorescence	Only IR fluorescent areas of the target are visible (image shall match Fig. 8)	



### **3.7 File Export and Integrity Test**

In this section we will determine if images can be properly exported to a USB drive using Image Lab Touch. All the files from previous tests will be exported to a USB drive using built-in features of Image Lab Touch. The USB drive will be connected to an external computer with Image Lab software installed, and a file will be opened to verify successful transfer.

#### **To export image files**

1. Tap the Gallery icon in the upper left corner of the main toolbar.
2. To select the image files acquired in sections **3.2** through **3.6**, tap the image thumbnails.

Selected images display a checkbox in the upper right corner.

3. Insert a FAT32 formatted USB drive into the USB port.
4. Tap Send/Save on the bottom toolbar, and then tap Save to USB Drive to export the acquired images as Image Lab files.

A progress box monitors the image export.

5. When the export is complete, tap OK.

The system dates and saves the image files to the USB drive in a folder located in the root of the USB.

#### **To verify successful image file transfer**

1. Connect the USB drive to a computer with Image Lab software installed.
2. Examine the contents of the USB drive and check to verify that all images exported were transferred to this USB drive.
3. Using Image Lab software, confirm that one of the files exported to the USB drive can be opened.

#### **Printing Exported Images from Image Lab software (optional)**

1. Open all images acquired and exported in the last procedure.
2. Select a singleplex or multiplex image to be printed.
3. Select the Report button on the main toolbar to open the Report Print Preview.

4. Select the Print Report Icon.

Image Lab sends the report to the printer.

5. Repeat steps 2-4 to print each of the remaining test images.

### Assessing the Results

The following 3 (ChemiDoc) or 5 (ChemiDoc MP) test images should have been printed:

- OQ [date] Protocol 1 Large Image
- OQ [date] Protocol 1 Small Image
- OQ [date] Protocol 2 Image
- OQ [date] Protocol 3 Image (ChemiDoc MP only)
- OQ [date] Protocol 4 Image (ChemiDoc MP only)

6. Attach the printed files to section 4.1.

### Recording Section Test Results

Record the file export test results in Table 3–6.

**Table 3-6. File export test.**

Description	Specification	Pass/Fail
Colorimetric and Chemiluminescence Test, large imaging area	OQ [date] Protocol 1 Large Image Saved on USB Drive	
Colorimetric and Chemiluminescence Test, small imaging area	OQ [date] Protocol 1 Small Image Saved on USB Drive	
UV Test	OQ [date] Protocol 2 Image Saved on USB Drive	
Red, Green, Blue Test	OQ [date] Protocol 3 Image Saved on USB Drive (ChemiDoc MP only)	
Far Red, IR Test	OQ [date] Protocol 4 Image Saved on USB Drive (ChemiDoc MP only)	
File export integrity test	One of the exported images was successfully opened on an external PC using Image Lab software.	

**3.8 Section 3 Signatures**

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

<b>Section 3 Completed Successfully</b>		<b>Executor Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		
<b>Section 3 Completed Successfully</b>		<b>Reviewer Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		

## Section 4: Test Images

**Note:** If test images were printed as optional in previous sections please attach them to this section. If not please skip this section.

Attach Operational Qualification test images to this section.

### 4.1 Test Image Attachments

**Table 4-1. OQ Imaging Target Test Images.**

### 4.2 Section 4 Signatures

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

Section 4 Completed Successfully		Executor Signature	Date
Yes	No		
Section 4 Completed Successfully		Reviewer Signature	Date
Yes	No		

## Section 5: Protocol Exceptions and Actions Taken

### 5.1 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 a list of any parts that were replaced.

**Table 5-1. Protocol Exceptions and Actions Taken.**

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

### 5.2 Section 5 Signatures

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

<b>Section 5 Completed Successfully</b>		<b>Executor Signature</b>	<b>Date</b>
Yes	No		
<b>Section 5 Completed Successfully</b>		<b>Reviewer Signature</b>	<b>Date</b>
Yes	No		

## Section 6: Final Approval and Signatures

### 6.1 Final Approval and Signatures

By signing in the appropriate section below, the executor and reviewer confirm the successful or unsuccessful completion of the Operational Qualification. Further acknowledgment of successful completion verifies that the instrument is performing in accordance with the parameters tested at the site indicated.

<b>Operational Qualification Completed Successfully</b>		<b>Executor Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		
<b>Operational Qualification Completed Successfully</b>		<b>Reviewer Signature</b>	<b>Date</b>
<b>Yes</b>	<b>No</b>		



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