SecurView®

Breast Imaging Workstation

SecurView DX Workstation
Quality Control Manual

MAN-11726 Revision 002

HOLOGIC®

SecurView® DX

Breast Imaging Workstation

Quality Control Manual

For Software Version 12.0

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HOLOGIC®

Product Support

USA: +1.877.371.4372

Europe: +32 2 711 4690

Asia: +852 37487700

Australia: +1 800 264 073

All Other: +1 781 999 7750

Email: BreastHealth.Support@hologic.com

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Chapter 1 Introduction

This manual provides procedures developed to ensure the consistency of the brightness, contrast, and image presentation of the displays used with Hologic's SecurView® diagnostic review workstations.

Use the procedures and quality control (QC) forms in this manual to maintain an effective QC program that conforms to the rules of the United States Mammography Quality Standards Act (MQSA) or to become accredited by an accreditation body. This manual may also be used as a guide by facilities outside the United States to establish a QC program to conform to the applicable local standard acts and regulations. This manual is intended for use by Radiologic Technologists and Medical Physicists who are qualified to operate the SecurView system.

1.1 Descriptions of Warnings, Cautions, and Notes

Descriptions of Warnings, Cautions, and Notes used in this manual:

WARNING!
The procedures that you must follow accurately to prevent possible dangerous or fatal injury.

Warning:
The procedures that you must follow accurately to prevent injury.

Caution:
The procedures that you must follow accurately to prevent damage to equipment, loss of data, or damage to files in software applications.

Note
Notes show additional information.

1.2 Safety

Observe all electrical, mechanical, and radiation safety standards.

Caution:
Always obey Electrostatic Discharge (ESD) precautions when working with electronics and electronic components.

Note
It is recommended that you read through this document fully before starting to work.

Note
The Service Engineers must complete Hologic training courses before they operate or service a system.

1.3 Product Complaints

Report any complaints or problems regarding the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to a Hologic Authorized Representative and Competent authority of the respective member state or country.

The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

1.4 Terms and Definitions

Table 1: Terms and Definitions

Terms	Definitions
cd/m^2	Candela per square meter (cd/m^2), the standard unit of luminance. It represents a luminous intensity of one candela radiating from a surface whose area is one square meter. Luminance is used to specify the brightness of computer displays.
DICOM	Digital Imaging and Communications in Medicine – an international standard for the exchange of imaging and related information.
GSDF	Grayscale Standard Display Function, a mathematical function that adjusts pixel brightness in order to compensate for the nonlinearity of human visual perception. DICOM GSDF improves conspicuity of findings in the extremes of luminance and provides a mechanism to standardize the appearance of images on displays of different inherent brightness and with different response curves.
LCD	Liquid Crystal Display. The technology used for displays in notebook and other computers. Like light-emitting diode (LED) technology, LCDs allow displays to be much thinner than cathode ray tube (CRT) technology.
Luminance	Luminance is a photometric measure of the luminous intensity per unit area of light travelling in a given direction. It describes the amount of light that passes through or is emitted from a particular area and falls within a given solid angle. The International System of Units (SI) for luminance is candela per square meter (cd/m^2).
MQSA	Mammography Quality Standards Act. Created by the U.S. Food and Drug Administration (FDA) and approved by the U.S. Congress in 1994, MQSA establishes quality standards for mammography facilities. MQSA requires mammography facilities to be accredited by the FDA or an FDA-approved accreditation body, be certified by the FDA or the State, receive annual MQSA inspections, and display its FDA certification in a prominent area.
QA	Quality Assurance. Generally used to describe a program of policies, procedures, and practices intended to ensure that quality standards are developed, maintained, and adhered to.
QC	Quality Control. Refers to one or more procedures intended to ensure that a manufactured product or performed service complies with a defined set of quality criteria and meets the requirements of the client or customer.
USB	Universal Serial Bus. A specification to establish communication between devices and a host controller such as a computer. This interface can connect a computer and add-on devices, such as media players, keyboards, flash drives, and printers.

Chapter 2 QC Activities for the Medical Physicist (Barco)

Hologic provides QC software, QAWeb Enterprise Agent or MediCal QAWeb, that is used by Service Engineers and customers to establish and maintain the operating levels of the SecurView Barco displays. The software analyzes the results of display calibration and compliance testing and indicates whether the displays meet the preprogrammed QC limits established by the manufacturer. To determine the correct QC software for the installed display, refer to section *Testing the Displays (Barco)* on page 13.

Caution:
Connecting a MediCal QAWeb agent to a QAWeb server may overwrite the required Hologic Policy Map. When connecting to a QAWeb server, contact Technical Support at +1.800.760.8342 to obtain the correct version of QAWeb that will maintain the required Hologic Policy Map.

During SecurView system installation, a Service Engineer uses the software to calibrate and test the displays.

Radiologic Technologists use the software for the following two tests:

a. Diagnostic workstations using MediCal QAWeb:

- **Weekly:** The Hologic Compliance Test within MediCal QAWeb verifies that the displays are performing within the preprogrammed limits. The Technologist records the results in the SecurView Weekly QC Form (Barco).
- **Semi-Annual Auto-Calibration:** The MediCal QAWeb software automatically calibrates the displays twice per year to re-establish the operating levels. The Technologist records the results in the SecurView Semi-Annual QC Form (Barco).

b. Diagnostic workstations using QAWeb Enterprise:

- **Weekly:** The Barco Mammography constancy test within QAWeb Enterprise Agent verifies that the displays are performing within the preprogrammed limits. The Technologist records the results in the SecurView Weekly QC Form (Barco).
- **Semi-Annual Auto-Calibration:** The QAWeb Enterprise Agent software calibrates the displays twice per year to re-establish the operating levels and runs the SteadyColor response test (if applicable). The Technologist records the results in the SecurView Semi-Annual QC Form (Barco).

Note
For Barco Nio MDNG-6121 and MDNG-5121 displays, the Technologist must use a photometer and run the tests manually as explained in section *Manually Calibrating Displays* on page 31.

In addition, Hologic recommends using QAWeb Enterprise or MediCal QAWeb software for the following:

- **Annually:** The Medical Physicist checks the most recent results of the visual test and Hologic Compliance or Mammography Compliance report. The QAWeb Enterprise Agent Mammography acceptance test includes the TG18-OIQ visual test.
- **Medical Physicist**: Review and record the numerical results from the most recent Mammography Compliance report. If the Mammography Compliance report does not include a recent TG18-OIQ visual test, run the Mammography acceptance test.
- Record the results in the SecurView Annual QC Form (Barco). Refer to *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.

Note
When displays are replaced or relocated, the Medical Physicist needs to perform the visual test and Hologic Compliance or Barco Mammography acceptance test.

2.1 QC Procedures for the Medical Physicist

Hologic recommends that a Medical Physicist check the performance of each SecurView diagnostic workstation Barco display at least once per year, using the procedure given below. Use the display QC software (QAWeb Enterprise Agent or MediCal QAWeb) provided with each SecurView workstation. For detailed instructions on using the software, refer to section *Testing the Displays (Barco)* on page 13.

To perform the annual QC check, do the following:

1. **Check performance records.** For each diagnostic workstation, review the *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69, or alternative QC tracking documentation in use per local policy. Verify that the SecurView displays have been operating within the recommended tolerance limits.
2. Run the visual test.

Note
A visual evaluation shield mask is included with the Barco OneLook display. During the Mammography acceptance test, or TG18-OIQ visual test, masking (covering) bright areas of the pattern is recommended when looking for the “L” in the dark letters.

Note
Due to numerous variables at customer sites, it is possible the Barco OneLook visual test may not pass initially with the default QAWeb Enterprise Portal settings. Barco provides routine installation support to Hologic and its customers for the Onelook MDMC-32133 display. The customer and their medical physicist should work with Barco regarding any changes to the default settings for this display, verify that all QC tests pass, and communicate changes and test results back to Hologic.

3. **Review the visual test and Hologic Compliance or Barco Mammography Compliance report results.** Using the QC software, check the results of the most recent visual test and Hologic Compliance or Mammography Compliance report results.
4. **Verify results.** Ensure that the visual test and Hologic Compliance or Mammography Compliance results are within the recommended tolerance limits.
   a. For each display, check:
      - White level
      - DICOM GSDF compliance (Luminance Response).
      - Visual test results
   b. If the results do not meet specifications, refer to section *Corrective Action* on page 7.
5. **Record the results** in the following form(s):
   - *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.
   - *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.
6. For Selenia® Dimensions® Mammography systems:
   a. At the Acquisition Workstation, select **Admin > Quality Control > Physicist tab > Diagnostic Review Workstation Quality Control**.
   b. Select **Mark Completed** to label the status of this procedure as finished.
   c. To mark the QC procedure as completed, select **Yes.**

2.2 Corrective Action

If any display does not meet the performance criteria, adjust room lighting conditions and repeat the action that failed. If the action fails after the second attempt, correct the problem before performing mammographic image interpretation using the following instructions.

- If any performance criterion is not met, use the Auto-calibration procedure to recalibrate the display. Then rerun the Hologic Compliance or Barco Mammography constancy test and verify that the display performs within the recommended limits.
- A qualified Service Engineer may have to resolve any issues if display operating levels are not within recommended ranges.
- If the details of a test contain no results, the test shall be run manually after making sure the displays are correctly attached and turned on. A qualified Service Engineer may have to resolve any issues if the details of a test contain no results after the second attempt.
- While you resolve display calibration issues, SecurView systems can still receive images. Use an alternative diagnostic device (for example, a second diagnostic workstation or a DICOM printer) for mammography image interpretation until all issues are resolved and the displays perform within recommended ranges.

2.3 Reading Room Configuration Testing

A qualified in-person Medical Physicist performs testing when a reading room is initially configured and after each year of operation. If equipment is replaced between these scheduled tests without changing the reading room configuration, this replacement does not require in-person Medical Physicist testing and is subject to the Medical Physicist's oversight.

At the suggestion of the Lead Interpreting Physician, the Medical Physicist may set White Level to be other than the default shown in the Performance Criteria table in *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.

Chapter 3 QC Activities for the Radiologic Technologist (Barco)

Hologic provides QC software, QAWeb Enterprise Agent or MediCal QAWeb, that is used by the Radiologic Technologist to maintain the operating levels of the SecurView Barco displays. The software analyzes the results of display calibration and compliance testing and indicates whether the displays meet the preprogrammed QC limits established by the manufacturer. To determine the correct QC software for the installed display, refer to section *Testing the Displays (Barco)* on page 13.

Caution:
Connecting a MediCal QAWeb agent to a QAWeb server may overwrite the required Hologic Policy Map. When connecting to a QAWeb server, contact Technical Support at +1.800.760.8342 to obtain the correct version of QAWeb that will maintain the required Hologic Policy Map.

During SecurView system installation, a Service Engineer uses the software to calibrate and test the displays. Radiologic Technologists use the software for the following tests:

a. Diagnostic workstations using MediCal QAWeb:

- **Weekly:** The Hologic Compliance Test within MediCal QAWeb verifies that the displays are performing within the preprogrammed limits. The Technologist records the results in the SecurView Weekly QC Form (Barco).
- **Semi-Annual Auto-Calibration:** The MediCal QAWeb software automatically calibrates the displays twice per year to re-establish the operating levels. The Technologist records the results in the SecurView Semi-Annual QC Form (Barco).

b. Diagnostic workstations using QAWeb Enterprise Agent:

- **Weekly:** The Barco Mammography constancy test within QAWeb Enterprise Agent verifies that the displays are performing within the preprogrammed limits. The Technologist records the results in the SecurView Weekly QC Form (Barco).
- **Semi-Annual Auto-Calibration:** The QAWeb Enterprise Agent software automatically calibrates the displays twice per year to re-establish the operating levels and runs the SteadyColor response test (if applicable). The Technologist records the results in the SecurView Semi-Annual QC Form (Barco).

Note
For the Barco Nio MDNG-6121 and MDNG-5121 displays, the Technologist must use a photometer and run the tests manually as explained in section *Manually Calibrating Displays* on page 31.

3.1 QC Procedures for the Radiologic Technologist

Hologic recommends that a Radiologic Technologist check the performance of SecurView diagnostic workstation Barco displays using the following procedures. Use the QC software (QAWeb Enterprise Agent or MediCal QAWeb) provided with each workstation. For detailed instructions on using the software, refer to section *Testing the Displays (Barco)* on page 13.

To perform the weekly QC check:

1. Check the week's test results or run the **Hologic Compliance** or **Barco Mammography constancy test**, if needed.

Note
For displays that support scheduled tests, verify successful completion of the tests the morning after the scheduled tests occur. If the system fails one or more of the tests, the source of the problem must be identified, and corrective action taken before the system is used for clinical purposes. Refer to section *Corrective Action* on page 11.

- For the Barco OneLook, Uniti, High-Brightness, Coronis, and Barco Nio MDNG-5221 displays, MediCal QAWeb or QAWeb Enterprise Agent automatically runs the **Hologic Compliance** or **Barco Mammography constancy test** once per week. Verify that the test ran as scheduled, and the Status displayed is "OK."
- For Barco Nio MDNG-6121 and MDNG-5121 displays, MediCal QAWeb prompts you to run the Hologic Compliance Test once per week. Run the test with the photometer and, when done, verify that the Action Result displayed is "OK."
  - When the QC Check is done, verify that "Result: OK" displays.
  - If results are not "OK," refer to section *Corrective Action* on page 11.

2. Record the results in the *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69 or alternative QC tracking documentation in use per local policy.

Note
Hologic strongly recommends saving the MediCal QAWeb Action History monthly to prevent data loss in the event of a system failure. Hologic also recommends saving the Action History prior to a SecurView upgrade. Refer to section *Saving the MediCal QAWeb Action History* on page 37.

To run the semi-annual calibration:

1. If the displays have not been calibrated during the last six months, use the QC software's Auto-calibration or Calibration task to calibrate them.
2. Record the results in the *SecurView Semi-Annual QC Form for Radiologic Technologists (Barco)* on page 67.

After completing the QC procedure, do the following for Selenia Dimensions Mammography systems only:

1. At the Acquisition Workstation, select **Admin > Quality Control > Technologist tab > Diagnostic Review Workstation Quality Control**.
2. Select **Mark Completed** to label the status of this procedure as finished.
3. To mark the QC procedure as completed, select **Yes**.

3.2 Corrective Action

If any display does not meet the performance criteria, adjust room lighting conditions and repeat the action that failed. If the action fails after the second attempt, correct the problem before performing mammographic image interpretation using the instructions below.

If any performance criterion is not met, use the Auto-calibration procedure to recalibrate the display. Then rerun the Hologic Compliance Test and verify that the display performs within the recommended limits.

A qualified Service Engineer may have to resolve any issues if display operating levels are not within recommended ranges.

If the details of a test contain no results, the test shall be run manually after making sure the displays are correctly attached and turned on. A qualified Service Engineer may have to resolve any issues if the details of a test contain no results after the second attempt.

While you resolve display calibration issues, SecurView systems can still receive images. Use an alternative diagnostic device (for example, a second diagnostic workstation or DICOM printer) for mammography image interpretation until all issues are resolved and the displays perform within recommended ranges.

Chapter 4 Testing the Displays (Barco)

This section provides detailed QC procedures for various displays. There are two different QA software packages that can be used with Barco displays: QAWeb Enterprise Agent or MediCal QAWeb. QAWeb Enterprise Agent can be used with the displays indicated in the following table.

Display	Barco Model Number	Photometer	QC Software (QAWeb)	
			Enterprise	MediCal
Coronis OneLook	MDMC-32133	Internal	✓	X
Coronis Uniti	MDMC-12133	Internal	✓	✓
High-Brightness	MDMG-5221	Internal	✓	✓
Coronis	MDCG-10130	Internal	X	✓
	MDMG-5121	Internal	X	✓
	MFGD-5621 HD	Internal	X	✓
	MFGD-5421	Internal	X	✓
Nio 5.8 MP Color	MDNC-6121	Internal	✓	✓
Nio	MDNG-6121	External	X	✓
	MDNG-5121	External	X	✓
	MDNG-5221	Internal	✓	✓

4.1 Photometer Styles – Built-in vs. External

There are two types of display configurations:

- **Built-in photometer sensor displays - Barco OneLook, Uniti, High-Brightness, Coronis, and Barco Nio MDNG-5221:** The MediCal QAWeb or QAWeb Enterprise Agent software automatically runs the **Hologic Compliance** or **Mammography constancy test** and calibrates the Barco displays on a scheduled basis. The MediCal QAWeb or QAWeb Enterprise Agent software relies on a built-in photometer sensor. No user intervention is required; you only need to verify that the software ran the test as scheduled and that the results were within the tolerance ranges. The default scheduled time is between 12:00 midnight and 2:00 AM.
- **External photometer sensor displays - Barco Nio (MDNG-6121 and MDNG-5121):** The MediCal QAWeb software automatically alerts you to run the Hologic Compliance Test and calibrate these Barco Nio displays on a scheduled basis. You will use an external photometer to run the QC procedures. QAWeb Enterprise is not supported for these displays.

Important
When testing the displays, ensure that the room lighting conditions are similar to those used when reading studies.

4.2 Testing with Built-in Photometer Sensor Displays

For compatible displays with a built-in photometer sensor, MediCal QAWeb or QAWeb Enterprise Agent software automatically runs the **Hologic Compliance** or **Mammography constancy test** once per week and the Auto-calibration routine twice per year. Use this procedure as follows:

- **Radiologic Technologist**: Verify that the test(s) ran successfully.
- **Medical Physicist**: Review and record the numerical results from the most recent Hologic Compliance Test.

Note
Hologic recommends for displays older than five years that the Medical Physicist use an external photometer once per year for the luminance check to confirm that the internal photometer is still operating correctly. The luminance measured by the photometer must be within 15% of the calibrated luminance. The calibrated luminance for each display can be found in the configuration of MediCal QAWeb, QAWeb Enterprise, or in the most recent compliance check results in the status.

4.3 Testing with External Photometer Sensor Displays

For external photometer sensor displays, MediCal QAWeb alerts you to run the Hologic Compliance Test once per week and the Auto-calibration procedure (refer to section *Manually Calibrating Displays* on page 31) twice per year. Use the procedure in this section as follows:

- **Radiologic Technologist**: Run the QC tests and verify that they ran successfully.
- **Medical Physicist**: Review and record the numerical results from the most recent Hologic Compliance Test.

To run the tests and calibrate the displays, users must have an external photometer as shown in the following figures.

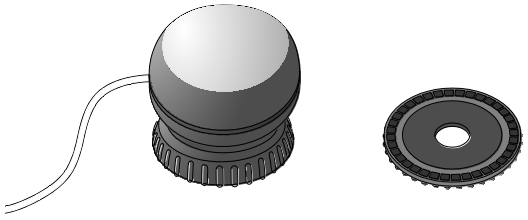

Figure 1: Barco Photometer Sensor and Felt Pad Attachment (previous model)

Figure 2: Barco Photometer Sensor (new model)

When performing test procedures, note the following:

- Verify that the Barco USB Photometer is plugged into the same USB port in which it was originally installed. If the sensor was removed for any reason, reconnect it as explained in section *Reconnecting the Photometer Sensor* on page 16 before continuing.
- Verify that the felt pad is attached to the photometer sensor. If the felt pad is not attached, reconnect it as explained in section *Attaching the Felt Pad to the Photometer Sensor* on page 16 before continuing.
- The new model of the sensor does not have a felt pad attachment. Verify that the photometer sensor is open by swiveling the unit up away from its cover.

Note
The only functional difference between the previous model and the new model of the Photometer Sensor is that the new model does not have the felt pad attachment. All other functions are similar.

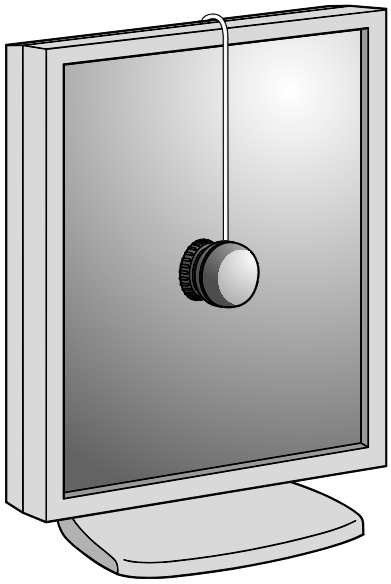

Figure 3: Using a Photometer to Calibrate the Display

4.3.1 Reconnecting the Photometer Sensor

The Barco photometer sensor is USB-port-specific and does not function if inserted into a different USB port than the one originally used when installed. After installation, there should be no need to remove the sensor from the original USB port. If the photometer is not connected to its USB port, then reconnect it as described here.

1. Log into Windows as Administrator.
2. Plug the Barco photometer sensor into an open USB port.
   - If a login prompt asks you to log into an account that is part of the Administrators group, select **Cancel**, then try a different USB port. When you plug into the correctly configured port, the system will not prompt you to log into another account.
   - If a *Found New Hardware Wizard* window opens after connecting the photometer sensor, select **Cancel**, then try a different USB port. When you plug into the correctly configured port, a *Found New Hardware Wizard* window should not open.
3. If you cannot find the correct USB port, contact Technical Support at +1.800.760.8342.

Note
The new model of the Photometer Sensor does not have a felt pad. The instructions to attach the felt pad to the Photometer Sensor apply only to the previous model.

4.3.2 Attaching the Felt Pad to the Photometer Sensor

The felt pad attachment is included with the display calibration kit. If you need to reconnect the felt pad, follow the instructions below.

1. If the suction cup attachment is installed, remove it by turning it approximately one-quarter turn counter-clockwise and then separating the attachment from the main portion of the photometer.

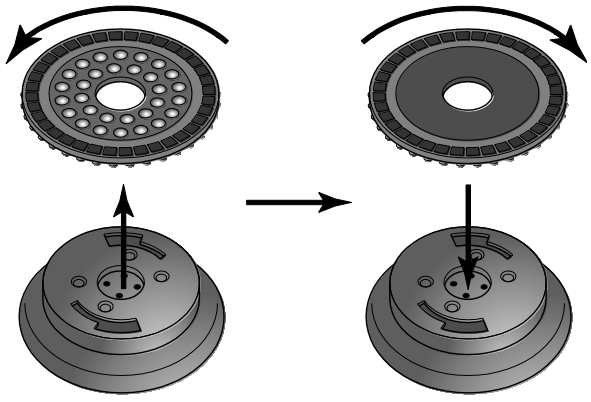

Figure 4: Removing the Suction Cup and Installing the Felt Pad

2. Install the felt pad by attaching it to the main portion of the photometer and turning it approximately one-quarter turn clockwise.

4.4 Testing Barco Display Performance using QAWeb Enterprise Agent

Displays compatible with QAWeb Enterprise all have built-in photometers. The QAWeb Enterprise Agent software automatically runs the Mammography constancy test and calibrates the Barco displays on a scheduled basis. No user intervention is required. You only need to verify that the software ran the test as scheduled and that the results were within the tolerance ranges. The default scheduled time is between 12:00 midnight and 2:00 AM.

QAWeb Enterprise Agent automatically runs the Mammography constancy test once per week and the Calibration routine twice per year. Use this procedure as follows:

- **Radiologic Technologist**: Verify that the test(s) ran successfully.
- **Medical Physicist**: Review and record the numerical results from the most recent Mammography Compliance report which includes the Mammography acceptance and Mammography constancy test results for the time interval of interest. The Mammography acceptance test includes the TG18-OIQ test.

Note
Hologic recommends for displays older than five years that the Medical Physicist use an external photometer once per year for the luminance check to confirm that the internal photometer is still operating correctly. The luminance measured by the photometer must be within 15% of the calibrated luminance. The calibrated luminance for each display can be found in the active policy of the Polices section of QAWeb Enterprise Portal or in the most recent Mammography constancy test results.

It is not necessary to log out of the SecurView DX application to check the performance of Barco displays:

1. To access the QC test results in the QAWeb Enterprise Portal software, use an internet browser to log in to *https://qaweb.healthcare.barco.com*.
2. Navigate to **Assets**, then select the workstation being evaluated.
3. Select the **Reports** tab, then on the lower right, select the + icon and the type of report to generate (Mammography Compliance report), then the date range of interest.
4. Wait for the report icon to turn green.
5. Select the green PDF next to the desired report to download and view the report.

Example below.

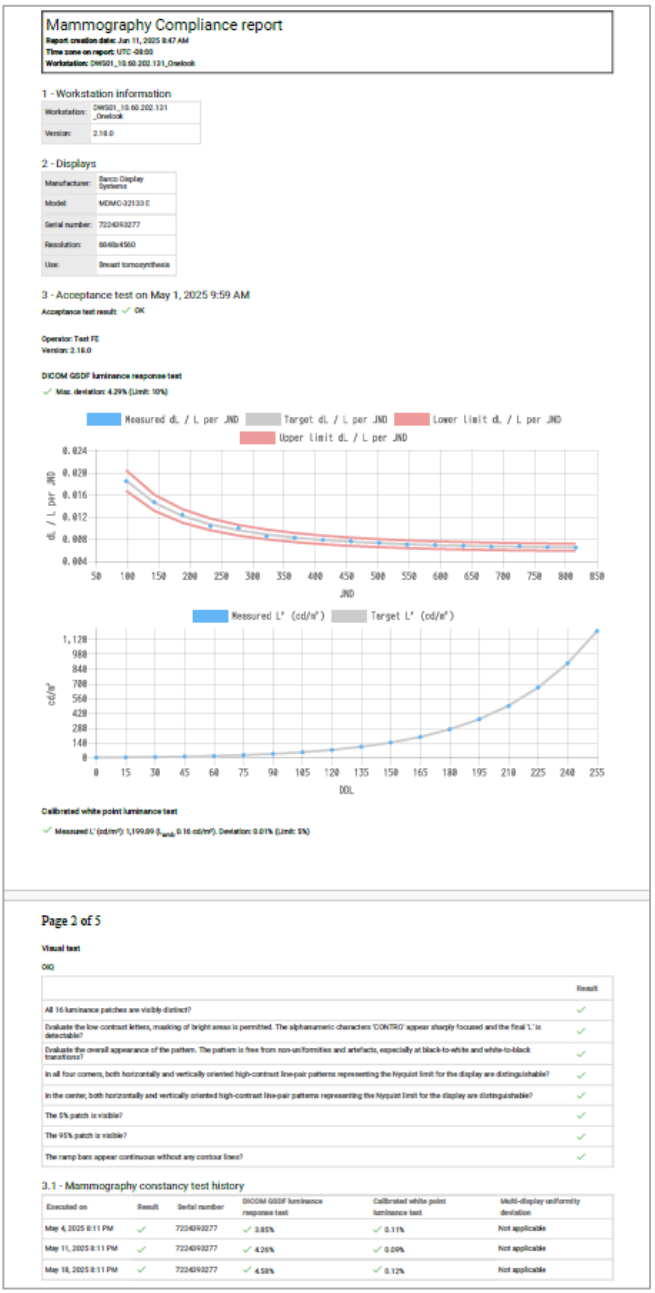

Figure 5: Sample Mammography Compliance Report

6. Check that the latest Mammography Acceptance and Mammography constancy tests have a result of "OK" or a green check mark. Check that details are present for these tests.
7. Record the value for **Action Result** in *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.

Important
If the details of a test contain no results, follow the instructions in section *Corrective Action* on page 7.

Note
You may **Print** the results or **Save as PDF** for a local copy.

8. Log out of the QAWeb Enterprise Portal or close the browser tab once finished.

Medical Physicist – To view the numerical results of the Mammography constancy test:

1. Using an internet browser, log in to *https://qaweb.healthcare.barco.com*.
2. Navigate to **Assets**, then select the workstation being evaluated.
3. In the *History* section, select the appropriate **Mammography constancy test** from the list.
4. The test results display the data graphically. Select the numerical icon above the graph to display the numerical data.

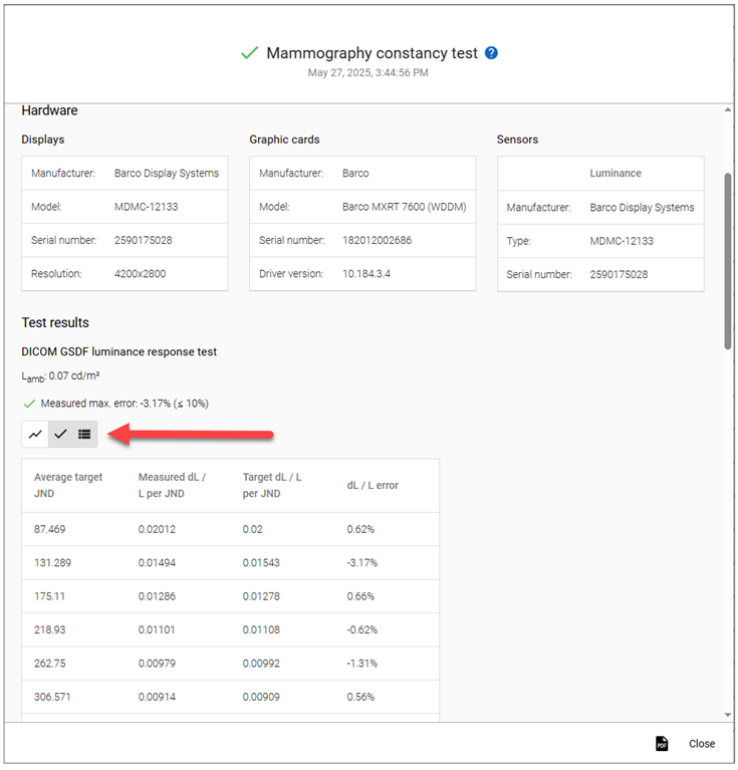

Figure 6: Sample Mammography Constancy Test

5. Verify that the results meet the performance criteria.
6. Record the results in *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.

7. Log out of the QAWeb Enterprise Portal or close the browser tab once finished.

4.5 Testing Barco Display Performance using MediCal QAWeb

This section requires a user to exit the SecurView application and access the Windows desktop as an administrative user.

1. Log out of the SecurView DX application.
2. Log into SecurView as an Administrator user.

Note
If not customized, the default SecurView Administrator credentials are:
Username: `admin`
Password: `admin`

3. Select the **Exit to Windows** tab. Wait until the application has fully closed.
4. Log into Windows as the customer administrator user.

Note
If not customized, the default Windows customer credentials are:
Username: `customer`
Password: `Simply-The-Best`

5. To start MediCal QAWeb, press the **Windows** key, then select **Menu > Barco > MediCal QAWeb Agent Version 1.xx.xx**.
6. The *MediCal QAWeb Agent* window opens. Select the **Status** icon.

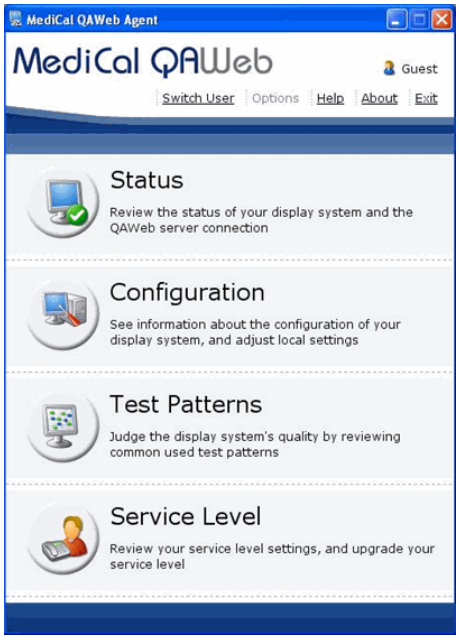

Figure 7: MediCal QAWeb Agent Window

7. The *Workstation > Status* window opens:

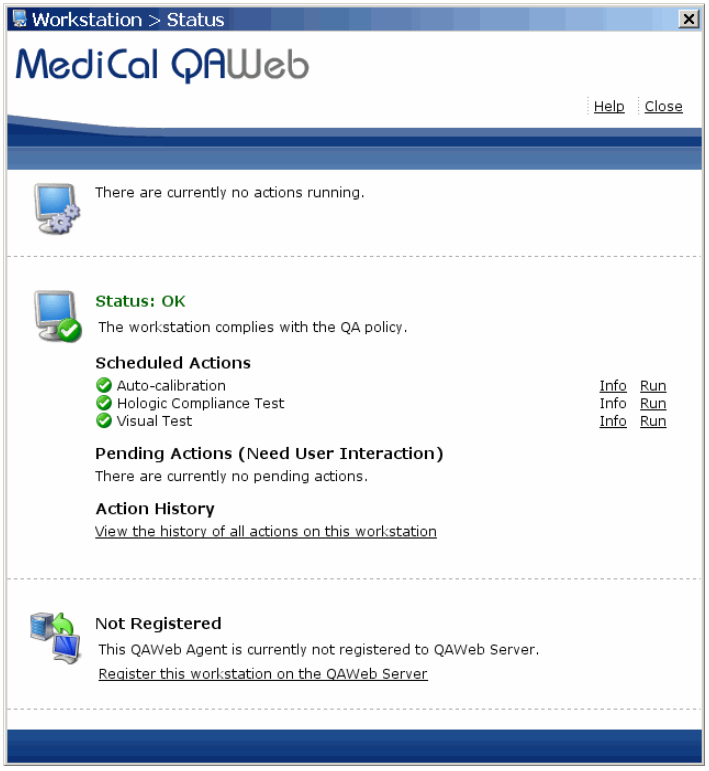

Figure 8: Workstation > Status Window

The *Workstation > Status* window indicates whether the workstation meets the recommended performance criteria. At any time, you can select **Run** to run a test manually (Auto-calibration, Hologic Compliance Test, or Visual Test).

Note
The Uniti display calibrates with SteadyColor Calibration by default. SteadyColor Calibration will show colors in the most optimum and consistent way, and it will show all grayscales with as little hue variation as possible. To manually calibrate the Uniti display without SteadyColor Calibration, navigate to **Configuration > Calibration**, select **Calibrate**, type the password `advanced` (case sensitive), select **Advanced**, then deselect **SteadyColor Calibration**. Select **Calibrate**.

Be sure to select **Run** next to the Auto-calibration after changing any calibration configuration settings.

Note
When you manually run the Auto-calibration, you may be prompted for a password. By default, the password is `advanced` (case sensitive).

8. **Radiologic Technologist** – To complete the tests and view results:
   a. Verify that "Status: OK" displays.
   b. Select **Info** next to 'Hologic Compliance Test'. The most recent results for the test display.
   c. Verify that "Action Result: OK" displays.

Figure 9: Hologic Compliance Test Window

d. Select **View Detailed Result**. A window opens with the detailed results.

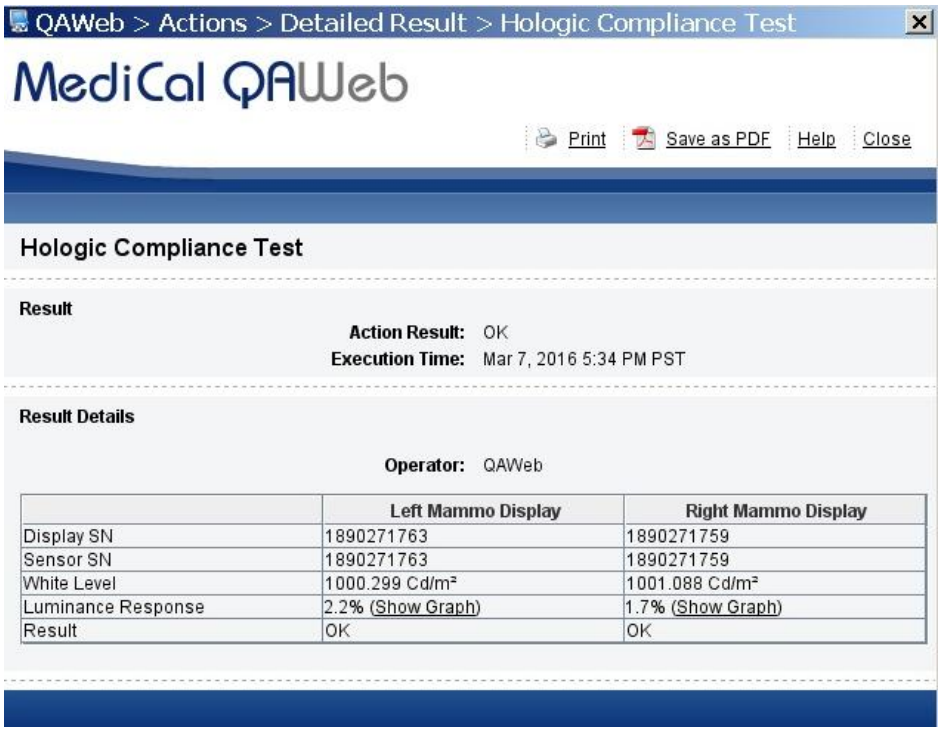

Figure 10: Hologic Compliance Test – View Detailed Result Window

e. Record the value for **Action Result** in *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.

Important
If the details of a test contain no results, follow the instructions in section *Corrective Action* on page 11.

Note
You may **Print** the results or **Save as PDF** for a local copy from this window. Select **Close** once you are finished.

f. Select **Close** to return to the *Hologic Compliance Test* window.

g. Close all open *MediCal QAWeb* windows.

h. Log out and log in as a SecurView user to restart the SecurView application.

9. **Medical Physicist** – To view the numerical results of the Hologic Compliance Test:
   a. On the *Workstation* > *Status* window, select **Info** next to 'Hologic Compliance Test'. The most recent results for the test display as shown in the following example.

Figure 11: Hologic Compliance Test Window

   b. Select **View Detailed Result**. A window opens with the detailed results.

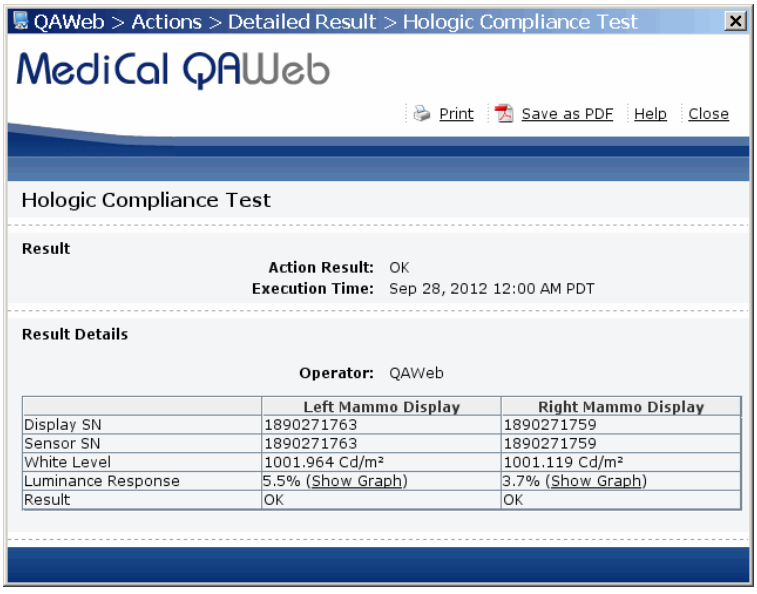

Figure 12: Hologic Compliance Test – View Detailed Result Window

c. Verify that the results meet the performance criteria.

d. Record the results in the *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.

e. Select **Close** twice to return to the *Workstation > Status* window.

f. Close all open *MediCal QAWeb* windows.

g. Log out and log in as a SecurView user to restart the SecurView application.

To test the displays:

1. Log out of the SecurView DX application.
2. Log into SecurView as an Administrator user.

Note
If not customized, the default SecurView Administrator credentials are:
Username: `admin`
Password: `admin`

3. Select the **Exit to Windows** tab. Wait until the application has fully closed.
4. Log into Windows as the customer administrator user.

Note
If not customized, the default Windows customer credentials are:
Username: `customer`
Password: `Simply-The-Best`

5. To start MediCal QAWeb, press the **Windows** key, then select **Menu > Barco > MediCal QAWeb Agent**.
6. The *MediCal QAWeb Agent* window opens. Select the **Status** icon.

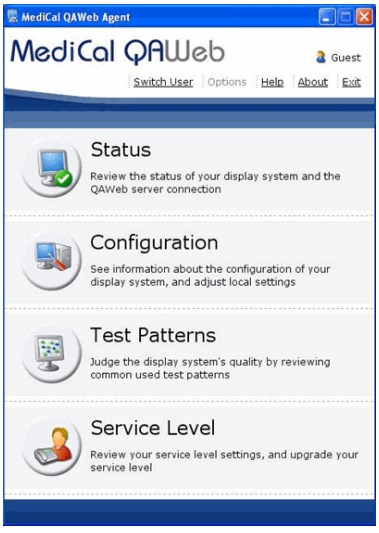

Figure 13: MediCal QAWeb Agent Window

7. The *Workstation > Status* window opens:

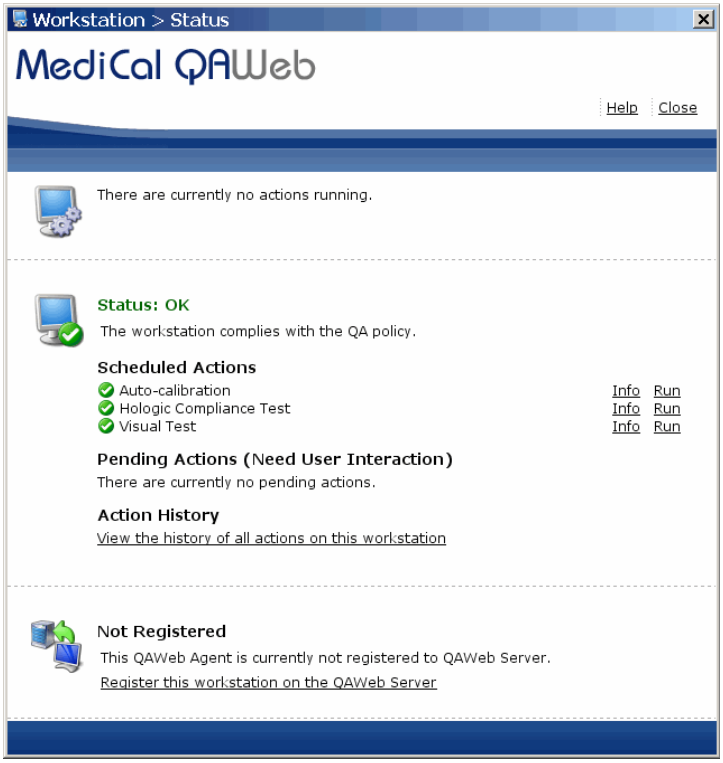

Figure 14: Workstation > Status Window

The *Workstation > Status* window indicates whether the displays meet the recommended performance criteria. At any time, you can select **Run** to run a test manually (Auto-calibration, Hologic Compliance Test, or Visual Test).

Note
When you manually run the Auto-calibration, you may be prompted for a password. By default, the password is `advanced` (case-sensitive).

8. **Radiologic Technologist** – To run the Hologic Compliance Test and view results:

Important
When testing the displays, ensure that the room lighting conditions are similar to those used when reading studies.

   a. Select **Run** next to 'Hologic Compliance Test'. Follow the on-screen instructions.
   b. After the test ends, verify that "Status: OK" displays.
   c. Select **Info** next to 'Hologic Compliance Test'. The most recent results for the test display.
   d. Verify that "Action Result: OK" displays.

Figure 15: Hologic Compliance Test Window

e. Select **View Detailed Result**. A window opens with the detailed results.

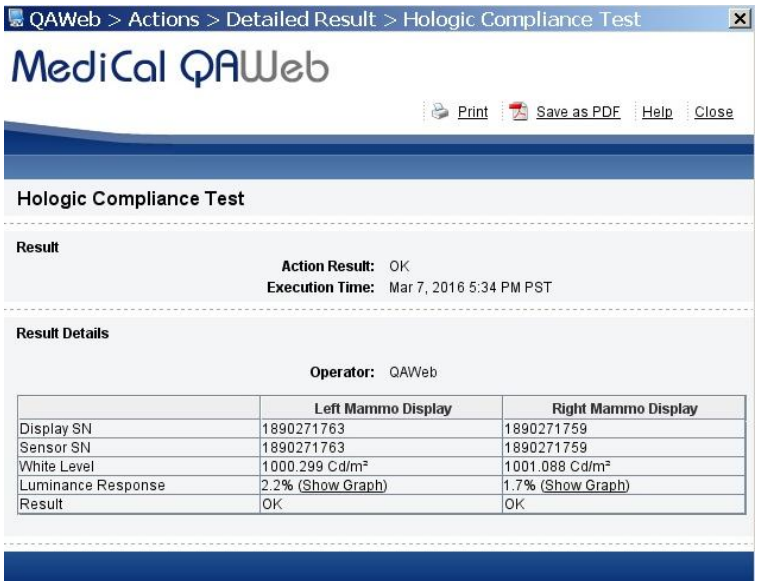

Figure 16: Hologic Compliance Test – View Detailed Result Window

f. Record the value for **Action Result** in *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.

Important
If the details of a test contain no results, follow the instructions in section *Corrective Action* on page 11.

Note
You may **Print** the results or **Save as PDF** for a local copy from this window. Select **Close** once you are finished.

g. Select **Close** to return to the *Hologic Compliance Test* window.

h. Close all open *MediCal QAWeb* windows.

i. Log out and log in as a SecurView user to restart the SecurView application.

9. **Medical Physicist** – To view the numerical results of the Hologic Compliance Test:

a. On the *Workstation* > *Status* window, select **Info** next to 'Hologic Compliance Test'. The most recent results for the test display as shown in the following example.

Figure 17: Hologic Compliance Test Window

b. Select **View Detailed Result**. A window opens with the detailed results.

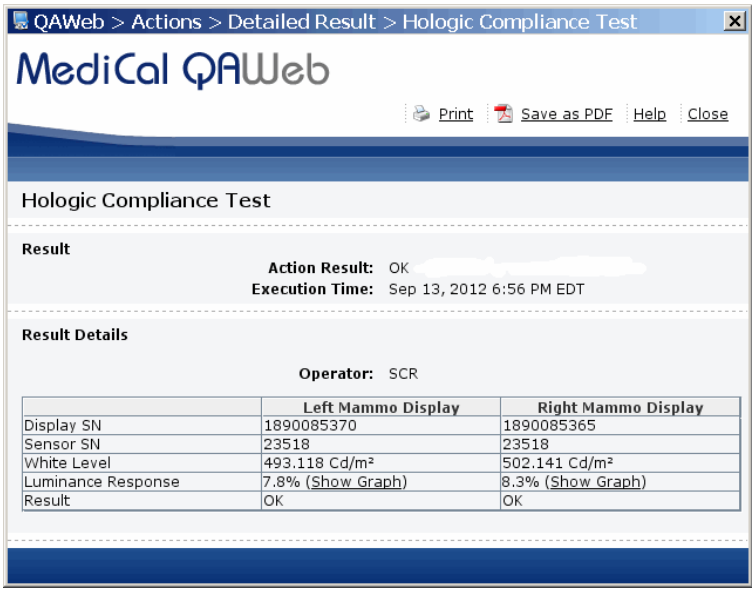

Figure 18: Hologic Compliance Test – View Detailed Result Window

c. Verify that the results meet the performance criteria.

d. Record the results in the *SecurView Annual QC Form for Medical Physicists (Barco)* on page 65.

e. Select **Close** twice to return to the *Workstation* > *Status* window.

f. Close all open *MediCal QAWeb* windows.

g. Log out and log in as a SecurView user to restart the SecurView application.

Chapter 5 Manually Calibrating Displays (Barco)

5.1 Manually Calibrating Displays using QAWeb Enterprise

This section requires a user to exit the SecurView application, then access the local QAWeb Enterprise Agent application from the QAWeb icon on the Windows taskbar.

5.1.1 Access Desktop from SecurView Application

1. Log out of the SecurView DX application.
2. Log into SecurView as an Administrator user.

Note
If not customized, the default SecurView Administrator credentials are:
Username: `admin`
Password: `admin`

3. Select the **Exit to Windows** tab. Wait until the application has fully closed.

5.1.2 Access the Local QAWeb Enterprise Agent Application

1. At the Windows taskbar, select **Start**, select the User icon, then select **Sign Off**.
2. Log into Windows as the customer administrator user.

Note
If not customized, the default Windows customer credentials are:
Username: `customer`
Password: `Simply-The-Best`

3. Select the QAWeb icon on the taskbar:

4. The *QAWeb Workstation details* window opens. Select **Tasks** on the left side menu. If there are no tasks required, you can select the **Gear** icon to see all available tasks.
5. Select the **Calibration** test, then select the arrow to view the Calibration details.

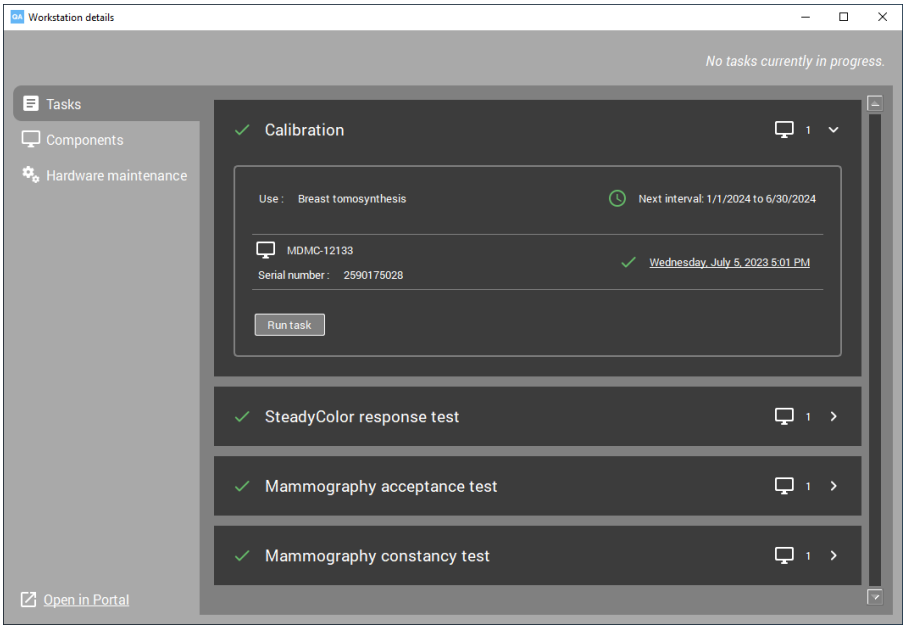

Figure 19: Workstation Details Window

6. Select **Run task** to start the Calibration process. **Calibration** will be displayed in the upper left-hand side of the window.
7. When the calibration procedure ends, the results are displayed as shown in the following example. The check mark next to each display icon indicates that the calibration ran successfully.

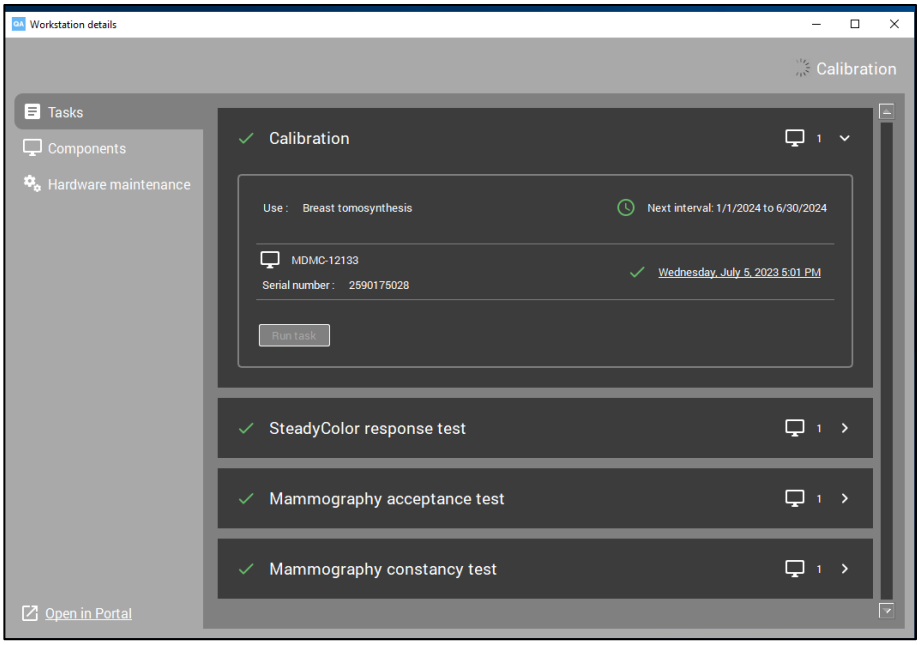

Figure 20: Calibration Test Results

8. To view the calibration details, select the date and time next to the green check mark to display the calibration report. See the following example.

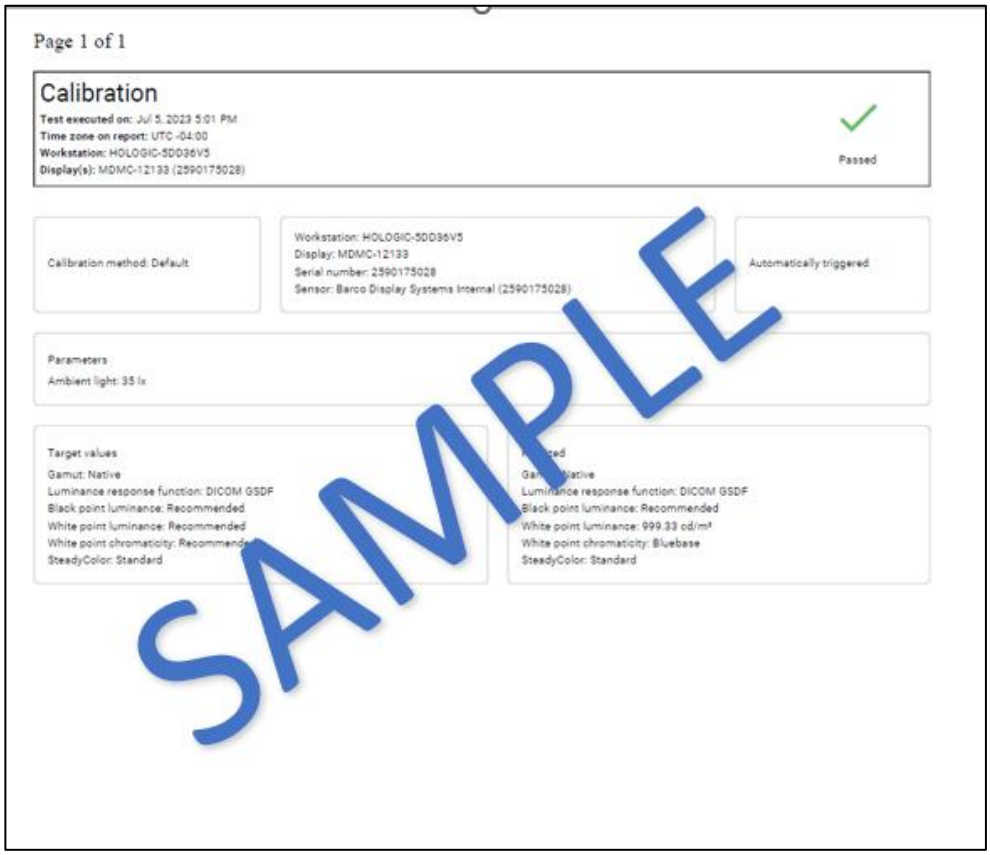

Figure 21: Sample Calibration Report

9. To run the additional tests (SteadyColor response, Mammography acceptance, and Mammography constancy) select the arrow to view the details, then select **Run task** to start the test.

Note
A visual evaluation shield mask is included with the Barco OneLook display. During the Mammography acceptance test, or TG18-OIQ visual test, masking (covering) bright areas of the pattern is recommended when looking for the "L" in the dark letters.

Note
Due to numerous variables at customer sites, it is possible the Barco OneLook visual test may not pass initially with the default QAWeb Enterprise Portal settings. Barco provides routine installation support to Hologic and its customers for the Onelook MDMC-32133 display. The customer and their medical physicist should work with Barco regarding any changes to the default settings for this display, verify that all QC tests pass, and communicate changes and test results back to Hologic.

10. When the test procedure ends, the results are displayed. The check mark next to each test's display icon indicates that the test ran successfully.
11. For two-monitor systems, repeat for the second display.
12. Record the results in the *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.
13. Close all open *QAWeb* windows.
14. Log out and log in as a SecurView user to restart the SecurView Application.

5.2 Manually Calibrating Displays using MediCal QAWeb

This section requires a user to exit the SecurView application, then access the Windows desktop as an administrative user.

1. Log out of the SecurView DX application.
2. Log into SecurView as an Administrator user.

Note
If not customized, the default SecurView Administrator credentials are:
Username: `admin`
Password: `admin`

3. Select the **Exit to Windows** tab. Wait until the application has fully closed.
4. At the Windows taskbar, select **Start**, select the User icon, then select **Sign Off.**
5. Log into Windows as the customer administrator user.

Note
If not customized, the default Windows customer credentials are:
Username: `customer`
Password: `Simply-The-Best`

6. Set up the displays and start MediCal QAWeb as described in section *Testing Barco Display Performance using QAWeb EnterpriseWeb Enterprise* on page 17.

Note
If you are calibrating external photometer sensor displays, attach the photometer sensor as described in section *Testing with External Photometer Sensor Displays* on page 14.

7. From the *MediCal QAWeb Agent* window, select the **Status** icon. The *Workstation > Status* window opens.

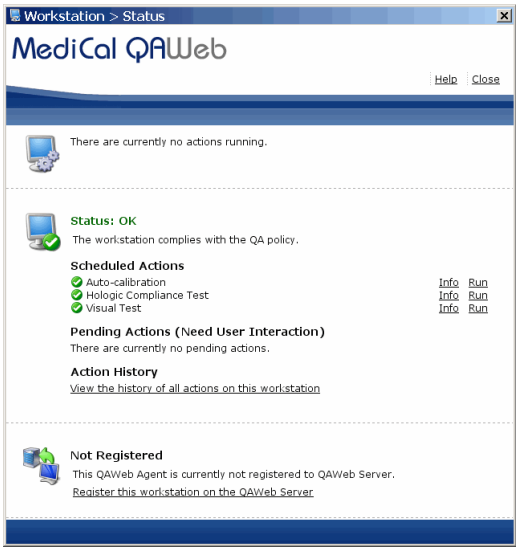

Figure 22: Workstation > Status Window

8. On the *Workstation > Status* window, select **Run** next to 'Auto-calibration'.

Note
When you manually run the Auto-calibration, you may be prompted for a password. By default, the password is `advanced`.

9. Follow the on-screen instructions. Repeat for the second display. When the calibration procedure ends, the results are displayed as shown in the following example. The check mark next to each display icon indicates that the calibration ran successfully.

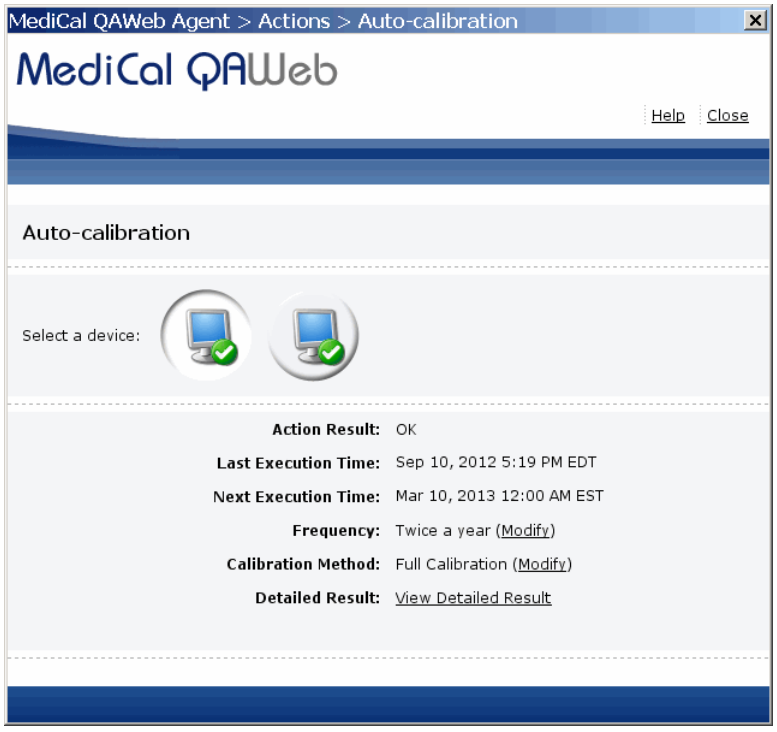

Figure 23: Auto-Calibration Window

10. Record the results in the *SecurView Weekly QC Form for Radiologic Technologists (Barco)* on page 69.
11. Close all open *MediCal QAWeb* windows.
12. Log out and log in as a SecurView user to restart the SecurView application.

Note
The Next Execution Time for the Auto-calibration will be six months after the last day the test was manually run. It is important to continue monitoring the dates the tests are due for semi-annual documentation. The monitors may require calibration in between the six-month time frames if the Hologic Compliance Test fails.

Chapter 6 Additional MediCal QAWeb Procedures (Barco)

6.1 Saving the MediCal QAWeb Action History

Caution:
Connecting a MediCal QAWeb agent to a QAWeb server may overwrite the required Hologic Policy Map. When connecting to a QAWeb server, contact Technical Support at +1.800.760.8342 to obtain the correct version of QAWeb that will maintain the required Hologic Policy Map.

Hologic strongly recommends saving the MediCal QAWeb Action History monthly to prevent data loss in the event of a system failure. Hologic also recommends saving the Action History prior to a SecurView upgrade.

Printing the Action History provides a hardcopy record of all of the actions run on the SecurView workstation during a given month. Hologic recommends retaining the printed Action History as proof of compliance. Use the following procedure to save the Action History to a USB drive and then transfer it to a different computer for printing.

1. Log out of the SecurView DX application.
2. Insert a USB drive into the SecurView workstation.
3. To start MediCal QAWeb, press the **Windows** key, then select **Menu > Barco > MediCal QAWeb Agent**.
4. The *MediCal QAWeb Agent* window opens. Select the **Status** icon.
5. The *Workstation > Status* window opens. In the 'Action History' section, select the **View the history of all actions on this workstation** link. The *Action History* window opens. This window displays all of the actions run on the workstation during one month.

Note
Use the **From** and **To** calendar menu to specify a date range for the Action History results.

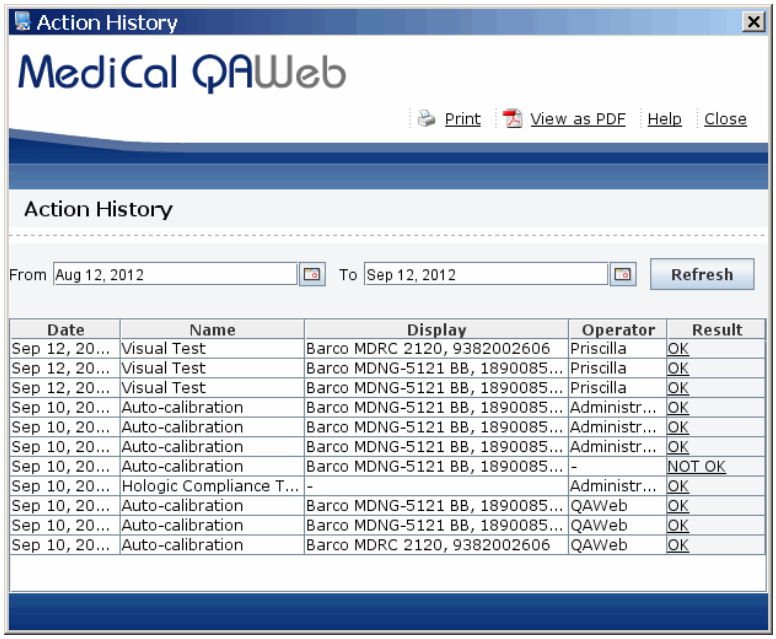

Figure 24: Action History Window

6. Select **View as PDF**.

Note
The SecurView workstation must have Adobe Acrobat Reader installed in order to view the Action History as a .pdf file.

7. The *QAWeb Action History .pdf* file opens. Select **File > Save As**…
8. Navigate to the USB drive where you want to save the QAWeb Action History .pdf file. Select **Save**.
9. Select **Close** twice to return to the *Workstation > Status* window.
10. Close all open *MediCal QAWeb* windows.
11. Remove the USB drive from the SecurView workstation.
12. Insert the USB drive into a computer with Adobe Acrobat Reader installed and printer capabilities.
13. Open the QAWeb Action History .pdf file, then select **File > Print**.
14. The *Print* dialog box opens. Specify the printing options, then select **Print**.

6.2 Scheduling the MediCal QAWeb Hologic Compliance Test

By default, the Hologic Compliance Test automatically runs weekly (except on systems using external photometer sensor displays). Use this procedure to change the time/day of the scheduled Hologic Compliance Test.

1. Log out of the SecurView DX application.

2. To start MediCal QAWeb, press the **Windows** key, then select **Menu > Barco > MediCal QAWeb Agent**.
3. The *MediCal QAWeb Agent* window opens. Select the **Status** icon.
4. The *Workstation > Status* window opens. Select **Info** next to 'Hologic Compliance Test'.
5. The *Hologic Compliance Test* window opens. Select **Modify** next to 'Frequency'.
6. The *MediCal QAWeb login* window opens. By default, the User is 'Advanced'. Type `advanced` (case sensitive) in the 'Password' field, then select **OK**.
7. The *Modify Hologic Compliance Test Frequency* window opens. Select **Custom** from the Frequency: drop-down menu, then select **Properties**.
8. The *Modify Custom Frequency of Hologic Compliance Test* window opens. In the 'Timing' section, select the test start time, then select the day(s) you want the test to run. Select **OK**.
9. At the *Modify Hologic Compliance Test Frequency* window, select **OK**.
10. Close all open windows.

Chapter 7 Double Black Imaging (DBI) Displays

MQSA Recommended Testing:

Note
CFS™ Software Installation and Configuration is required prior to testing.

For installation or configuration assistance, contact Double Black Imaging at

303-404-2222 or service@doubleblackimaging.com.

For additional details on the CFS software, please reference the following DBI documentation located in the DBI folder on the Windows desktop:

CFS Calibration Suite User Manual Local and CFS WebManager

Double Black Imaging MQSA Quality Control Procedures Manual

Weekly Test
Performed by Field Engineer, Radiologic Technologist, PACS Admin, IT, or trained personnel

1. Clean Display
2. Visual Test (TG18-OIQ or similar)

Annual Test
Performed by Medical Physicist or trained personnel

1. Clean Display
2. TG-18 Visual Test
3. Front Sensor Automatically Checks/Corrects
   a. Luminance
   b. DICOM Calibration/Conformance
4. *Optional* Tests with Hand-held Photometer
   a. Front Sensor Re-Calibration
   b. Luminance Assessment Verification for Displays installed longer than 5 years with Hand-held Photometer and TG-18-OIQ Test Pattern

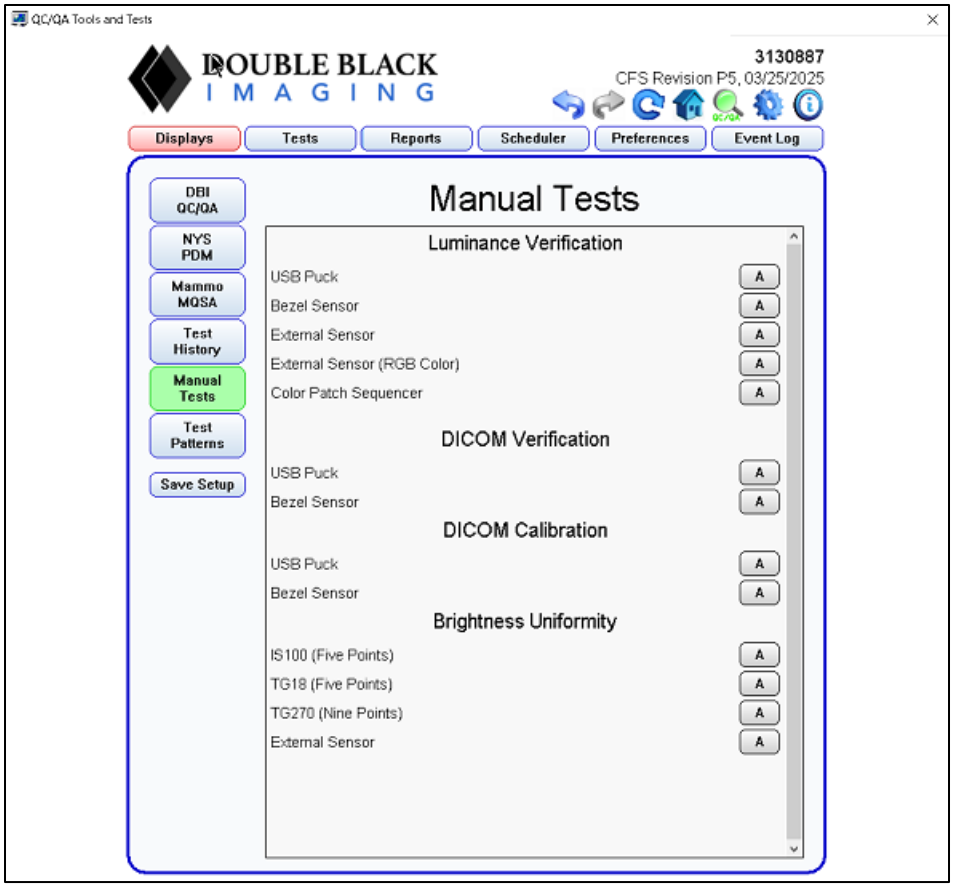

Figure 25: DBI Manual Tests Options

Chapter 8 QC Activities for the Medical Physicist (DBI)

Hologic provides the CFS (Calibration Feedback System Calibration Suite™) QC software that is used by Service Engineers and customers to establish and maintain the operating levels of the SecurView DBI displays. The software analyzes the results of display calibration and compliance testing and indicates whether the display(s) meet the preprogrammed QC limits established by the manufacturer.

During the SecurView system installation, a Service Engineer uses the software to set up and confirm calibration of the displays. After installation, Radiologic Technologists use the software for the following two tests:

- **Weekly:** Visual Acceptance Test within CFS assists the person running the test with confirming visually that the displays look suitable to the human eye. The Radiologic Technologist records the results in the SecurView Weekly QC Form (DBI).
- **Monthly:** Scheduled within CFS, the White Level Luminance and DICOM Compliance tests run automatically to check compliance and auto-adjust the operating levels, if required. The Technologist records the results in the SecurView Monthly QC Form (DBI).
- **Annually:** The Medical Physicist checks the most recent results of the monthly test and records them in the SecurView Annual QC Form (DBI). Refer to *SecurView Annual QC Form for Medical Physicists (DBI)* on page 71.

Notes:
When displays are replaced or relocated, the Medical Physicist needs to perform the Luminance and DICOM tests.

Confirm the display is clean prior to performing any QC measurements – refer to the Double Black Imaging MQSA manual, located in the DBI folder on the Windows desktop, for proper cleaning instructions.

The display must be turned ON for a minimum of 15 minutes prior to performing quality control tests.

When testing the displays, ensure that the room lighting conditions are similar to those used when reading studies.

All QC procedures performed must be documented.

If utilized, CFS WebManager users must be physically in front of each display being tested.

Caution:
To prevent potential damage to the display, it is important to follow the manufacturer cleaning instructions outlined in the DBI MQSA manual.

8.1 QC Procedures for the Medical Physicist

Hologic recommends that a Medical Physicist check the performance of each SecurView diagnostic workstation DBI display at least once per year using the procedure outlined below. Use the display QC software (CFS) provided with each SecurView workstation. For detailed instructions on using the software, refer to section *Testing the Displays (DBI)* on page 51.

To run the annual QC check, do the following:

1. **Check performance records.** For each diagnostic workstation, review the *SecurView Weekly QC Form for Radiologic Technologists (DBI*) on page 75 or alternative QC tracking documentation in use per local policy. Verify that the SecurView displays have been operating within the recommended tolerance limits.
2. **Review the compliance test results.** If any performance criterion is not met, using the QC software, check the test results in the monthly CFS DICOM Report.
3. **Verify results.** Ensure that the compliance test results are within the recommended tolerance limits.
   a. For each display, check:
      - White level
      - DICOM GSDF compliance (Luminance Response).
   b. If the results do not meet specifications, refer to section *Corrective Action* on page 44.
4. **Record the results** in the following form(s):
   - *SecurView Annual QC Form for Medical Physicists (DBI)* on page 71.
   - *SecurView Weekly QC Form for Radiologic Technologists (DBI)* on page 75.

8.2 Corrective Action

If any display does not meet the performance criteria, adjust room lighting conditions and repeat the action that failed. If the action fails after the second attempt, correct the problem before performing mammographic image interpretation using the following instructions.

- If any performance criterion is not met, on the CFS Home page, run the Calibrate All Displays To full Compliance procedure to recalibrate the display.
- A qualified Service Engineer may have to resolve any issues if display operating levels are not within recommended ranges.
- If the details of a test contain no results, the test shall be run manually after making sure the displays are correctly attached and turned on. A qualified Service Engineer may have to resolve any issues if the details of a test contain no results after the second attempt.
- While you resolve display calibration issues, SecurView systems can still receive images. Use an alternative diagnostic device (for example, a second diagnostic

workstation or a DICOM printer) for mammography image interpretation until all issues are resolved and the displays perform within recommended ranges.

8.3 Reading Room Configuration Testing

A qualified in-person Medical Physicist performs testing when a reading room is initially configured and after each year of operation. If equipment is replaced between these scheduled tests without changing the reading room configuration, this replacement does not require in-person Medical Physicist testing and is subject to the Medical Physicist's oversight.

Chapter 9 QC Activities for the Radiologic Technologist (DBI)

Hologic provides the CFS (Calibration Feedback System Calibration Suite™) QC software that is used by the Radiologic Technologist to maintain the operating levels of the SecurView DBI displays. The software analyzes the results of display calibration and compliance testing and indicates whether the displays meet the preprogrammed QC limits established by the manufacturer.

During SecurView system installation, a Service Engineer uses the software to calibrate the displays. After installation, Radiologic Technologists use the software for the following two tests:

- **Weekly:** The weekly visual test within CFS assists the Technologist running the test by confirming the displays are performing within the preprogrammed limits. The Technologist records the results in the SecurView Weekly QC Form (DBI).
- **Monthly:** Scheduled within CFS, the White Level Luminance and DICOM Compliance tests run automatically to check compliance and auto-adjust the operating levels, if required.

Notes:
When displays are replaced or relocated, the Medical Physicist needs to perform the Luminance and DICOM test results check.

Confirm the display is clean prior to performing any QC measurements – refer to the Double Black Imaging MQSA manual, located in the DBI folder on the Windows desktop, for proper cleaning instructions.

The display must be turned ON for a minimum of 15 minutes prior to performing quality control tests.

When testing the displays, ensure that the room lighting conditions are similar to those used when reading studies.

All QC procedures performed must be documented.

If utilized, CFS WebManager users must be physically in front of each display being tested.

Caution:
To prevent potential damage to the display, it is important to follow the manufacturer cleaning instructions outlined in the DBI MQSA manual.

9.1 QC Procedures for the Radiologic Technologist

Hologic recommends that a Radiologic Technologist check the performance of SecurView diagnostic workstation DBI displays using the following procedures. Use the display QC software (CFS) provided with each workstation. For detailed instructions on using the software, refer to section *Testing the Displays (DBI)* on page 51.

Note
Verify the most recent monthly automated testing was successful by reviewing the test results following that test. If the system failed one or more of the tests, the source of the problem must be identified, and corrective action taken, before the system is used for clinical purposes. Refer to section *Corrective Action* on page 49.

CFS Mammography (MQSA) Weekly Visual Acceptance Test:

1. If CFS is set up to automatically run the scheduled Visual Acceptance Test once per week at a specific time, a qualified person must be present during that scheduled time to perform the procedure. If no one was present during the scheduled time, a reminder message is posted to the screen to alert the next user that the Weekly QC Check must be completed.
2. If CFS is not set up to automatically start the weekly visual test, the Radiologic Technologist must initiate this test manually using the steps outlined in section *Testing the Displays (DBI)*.
   - Verify the visual test passed.
   - If the results are not acceptable, refer to section *Corrective Action* on page 49.
3. Record the results in the *SecurView Weekly QC Form for Radiologic Technologists (DBI)* on page 75 or alternative QC tracking documentation in use per local policy.
4. Once a month, check the monthly CFS DICOM Report and verify the Device Status is In Full Compliance.

Note
Hologic strongly recommends saving the CFS History (database files) monthly to prevent data loss in the event of a system failure. Hologic also recommends saving the CFS History prior to a SecurView upgrade. Refer to section *Additional CFS Procedures (DBI)* on page 61.

9.2 Corrective Action

If any display does not meet the performance criteria, adjust room lighting conditions and repeat the action that failed. If the action fails after the second attempt, correct the problem before performing mammographic image interpretation using the instructions below.

- If any performance criterion is not met, on the CFS Home page, run the Calibrate All Displays To full Compliance procedure to recalibrate the display.
- A qualified Service Engineer may have to resolve any issues if display operating levels are not within recommended ranges.
- If the details of a test contain no results, the test shall be run manually after making sure the displays are correctly attached and turned on. A qualified Service Engineer may have to resolve any issues if the details of a test contain no results after the second attempt.
- While you resolve display calibration issues, SecurView systems can still receive images. Use an alternative diagnostic device (for example, a second diagnostic workstation or DICOM printer) for mammography image interpretation until all issues are resolved and the displays perform within recommended ranges.

Chapter 10 Testing the Displays (DBI)

This section provides detailed QC procedures for DBI displays. CFS is the QC software package that can be used with the DBI display as indicated in the following table.

Display	Display Model Number	Photometer	CFS Calibration Suite Software
DBI – Double Black Imaging	31HN713D	Internal	✓

10.1 Photometer Styles – Integrated vs. External

The DBI display contains an integrated (built-in) Photometer.

- **Integrated (Built-in) Photometer:** The CFS software automatically runs monthly Luminance and DICOM tests – the default schedule is set for the first Friday of the month at 8PM. The CFS software relies on the integrated photometer for these tests. No user intervention is required; you only need to verify that the software ran the test as scheduled and that the results were within the tolerance ranges. In addition to the monthly automated tests, there is a weekly visual test. The visual test requires that someone be present in front of the display so this test should be scheduled when radiologists are not using the workstations.
- **External Photometer:** The external photometer can be used during the annual Medical Physicist testing if the optional brightness uniformity test is required. The external photometer would also be utilized when recalibrating the integrated photometer.

Notes:
When displays are replaced or relocated, the Medical Physicist needs to perform the Luminance and DICOM test results check.

Confirm the display is clean prior to performing any QC measurements – refer to the Double Black Imaging MQSA manual, located in the DBI folder on the Windows desktop, for proper cleaning instructions.

The display must be turned ON for a minimum of 15 minutes prior to performing quality control tests.

When testing the displays, ensure that the room lighting conditions are similar to those used when reading studies.

All QC procedures performed must be documented.

If utilized, CFS WebManager users must be physically in front of each display being tested.

Caution:
To prevent potential damage to the display, it is important to follow the manufacturer cleaning instructions outlined in the DBI MQSA manual.

10.2 Testing with External Photometer

- **Radiologic Technologist**: In the event of a compliance test failure, the external photometer can be used to recalibrate the internal photometer.
- **Medical Physicist**: During annual testing, the external photometer can be used for the brightness uniformity testing.

To run tests such as brightness uniformity, you must have one of the two external photometers shown in the following figure.

Figure 26: DBI (X-Rite i1D3 or Spyder X) Photometer Sensor

- Verify that the DBI USB Photometer is plugged into any available USB port (it is not USB port specific).

Note
The X-Rite and Spyder photometers function similarly in that either can be plugged into any available USB port and used for all CFS tests requiring an external photometer.

Figure 27: Using an External Photometer During Annual Physicists Testing

10.3 Testing DBI Display Performance using CFS (Local)

Note

The CFS System Tray Icon (

) referenced below may change color based on the display calibration status. When the display is in full calibration, the icon color is green. However, if the icon color changes to red, immediate attention is required and the user should double-click the icon to view details on the appropriate action required to correct the issue.

The CFS software automatically runs monthly Luminance and DICOM tests on a scheduled basis using the display built-in photometer. No user intervention is required. You only need to verify that the software ran the test as scheduled and that the results were within the tolerance ranges. The default scheduled time is set for the first Friday of the month at 8PM.

The CFS software is also used to perform a Weekly and Annually tests.

- **Radiologic Technologist**: Verify that the test(s) ran successfully.
- **Medical Physicist**: Review and record the numerical results from the most recent Weekly and Annually tests.

Note

Hologic recommends for displays older than five years that the Medical Physicist use an external photometer once per year for the luminance check to confirm that the internal photometer is still operating correctly. The luminance measured by the photometer must be within 10% of the calibrated luminance. The calibrated luminance for each display can be found in the QC/QA option under Test History or in the most recent Mammography constancy test results.

10.3.1 Perform the MQSA Weekly Visual Test

1. If the SecurView application is running, log out of the SecurView application and then login into the SecurView application as **admin**.
2. Select **Exit to Windows** on the right side of the application, then select **OK** in the confirmation dialog box.
3. Clean the display using the display manufacturer cleaning procedures found in the **Double Black Imaging MQSA Quality Control Procedures manual**, located in the DBI folder on the Windows desktop.
4. From the Windows taskbar, double-click the CFS icon in the system tray.

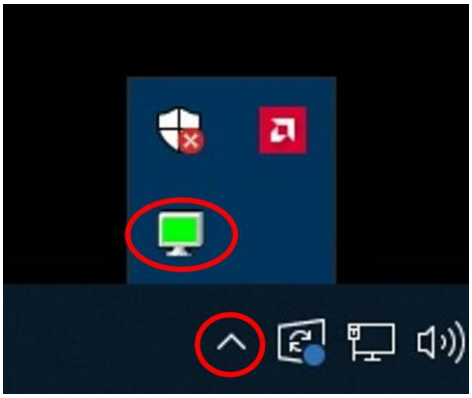

Figure 28: CFS Icon in System Tray

5. At the top of the CFS Home page select the **QC/QA** icon, then select **Mammo MQSA**.

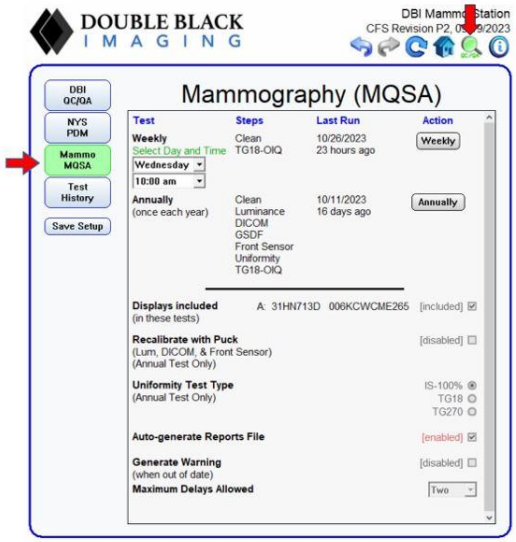

Figure 29: CFS QC/QA – Mammo MQSA Selected

6. Under the Action column select **Weekly**.

7. Type your name or initials (three-character minimum) to verify that display cleaning was completed per manufacturer cleaning guidelines. Select **Confirm**.

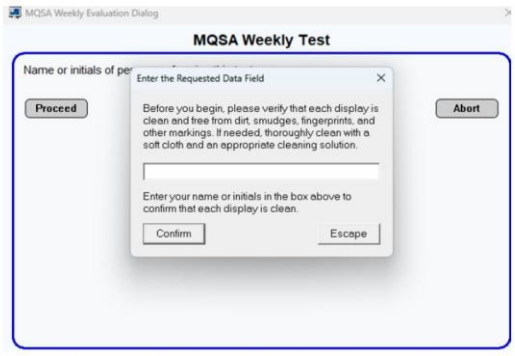

Figure 30: CFS MQSA Weekly Test Cleaning Confirmation

8. Evaluate the on-screen test patterns as prompted by the MQSA Visual Wizard and select **Yes** or **No** as appropriate. A **No** selection will result in a failed test.

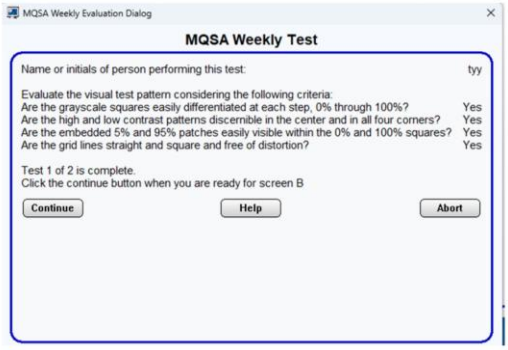

Figure 31: CFS MQSA Weekly Test Questions

10.3.2 Perform the MQSA Annually Tests

1. If the SecurView application is running, log out of the SecurView application and then login as **admin**.
2. Select **Exit to Windows** on the right side of the application, then select **OK** in the confirmation dialog box.
3. Clean the display using the display manufacturer cleaning procedures found in the **Double Black Imaging MQSA Quality Control Procedures manual**, located in the DBI folder on the Windows desktop.

4. From the Windows taskbar, double-click the CFS icon in the system tray.

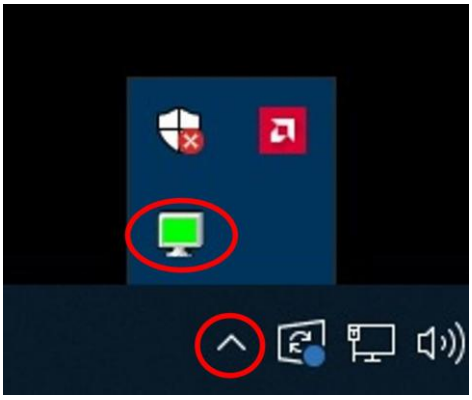

Figure 32: CFS Icon in System Tray

5. At the top of the CFS Home page select the **QC/QA** icon, then select **Mammo MQSA**.

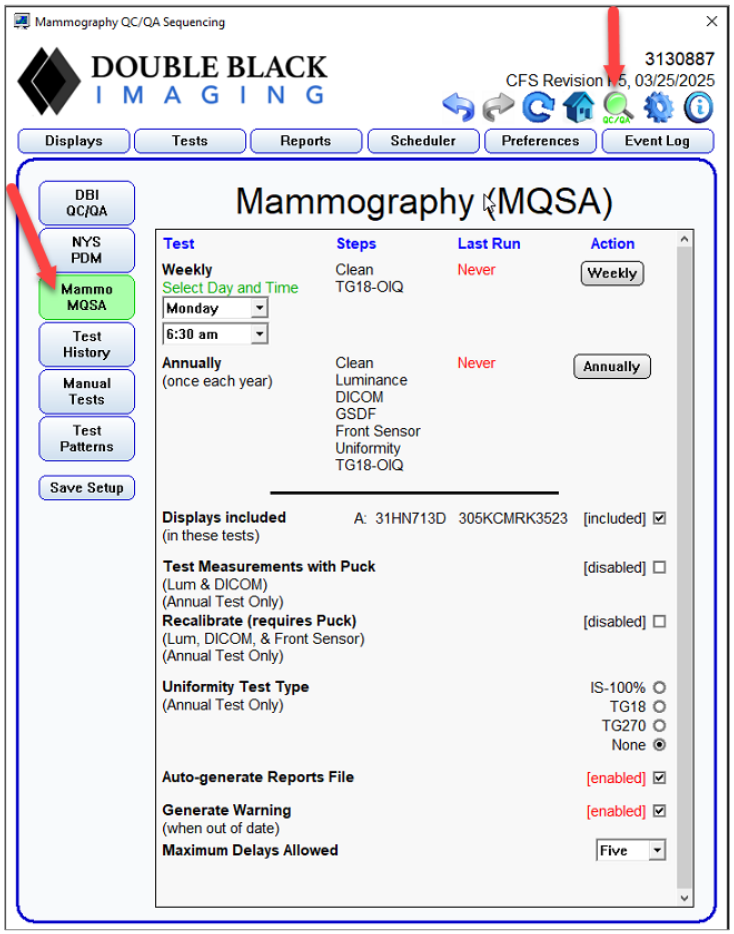

Figure 33: CFS QC/QA – Mammo MQSA Selected

6. Under the Action column select **Annually**, then follow the on-screen prompts.

7. Type your name or initials (three-character minimum) to verify that display cleaning was completed per manufacturer cleaning guidelines. Select **Confirm**.

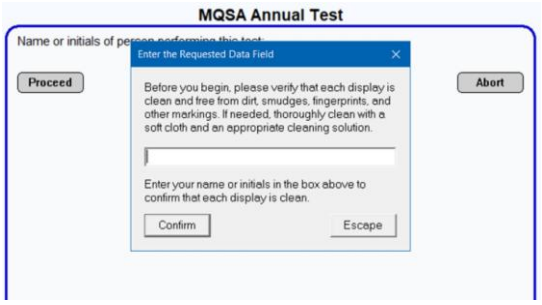

Figure 34: CFS MQSA Annual Test Cleaning Confirmation

8. The Front sensor will automatically perform the following tasks:
   a. Check Luminance and adjust if necessary.
   b. Check DICOM Conformance and recalibrate/verify conformance if necessary.
9. Evaluate the on-screen test patterns as prompted by the MQSA Visual Wizard and select **Yes** or **No** as appropriate. A **No** selection will result in a failed test.
10. You may decide to include the following optional tests in your quality control schedule:
    a. **Front sensor calibration** – This recalibrates the front sensor to the middle of the screen using a hand-held photometer (puck). This is a useful tool in extending the lifetime of your DBI Display system.
    b. **Uniformity testing** – This test utilizes a hand-held photometer (puck) to check uniformity of the display from the center of the screen and across various quadrants.

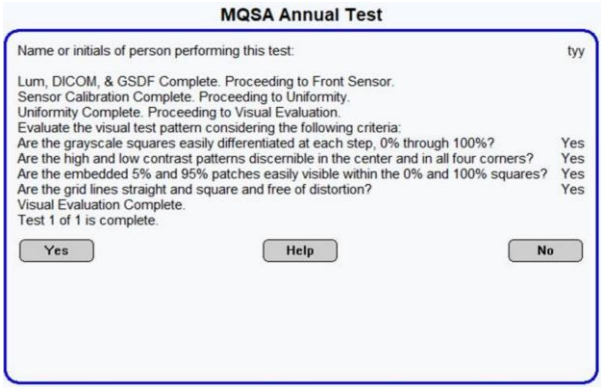

Figure 35: CFS MQSA Annual Test Questions

10.3.3 Viewing MQSA Weekly or Annually Test Results

1. At the top of the CFS Home page select the **QC/QA** icon, then select **Mammo MQSA**.
2. Select **Test History**.
3. From the Test History page select **MQSA Weekly** or **MQSA Annually** from the Test Type drop-down list. Pass/Fail for each completed test is listed in the rightmost P/F column.

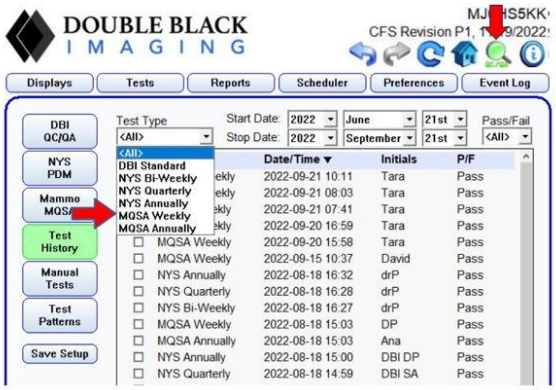

Figure 36: CFS MQSA Test History

4. Select the check box for each test result you want to view, then select **Show Data**.
5. A report is displayed as shown in the sample figure below. Select **Export to PDF** to save the report.

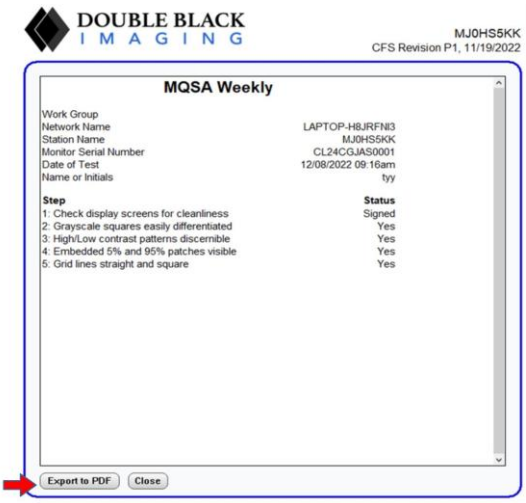

Figure 37: CFS MQSA Test History – Export to PDF

10.3.4 System Report Access

It is not necessary to log out of the SecurView DX application to check the performance of DBI displays.

Standalone System Report access:

1. Press the Windows key to display the Windows taskbar.
2. From the Windows taskbar, right-click the 

in the system tray, then select **CFS Login**.
3. Select **Administrative**, type the default password `admin`, then select **Confirm**.

Figure 38: CFS User Login Window

4. From the CFS Home page, select the **Reports** tab.

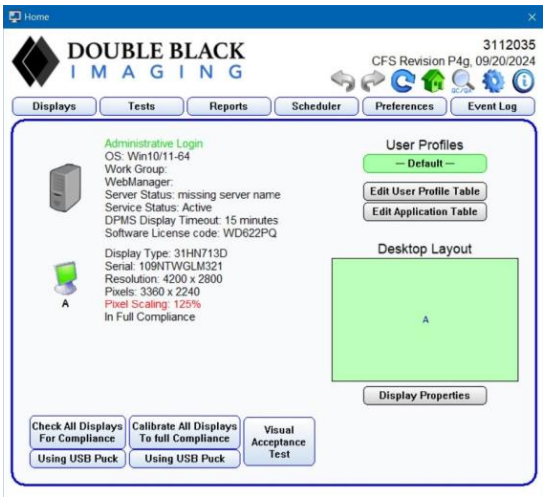

Figure 39: CFS Home Page

5. On the left-hand side of the Reports page, select one of the tests to view the report list. As an example, the figure below shows a report list for DICOM Conformance.

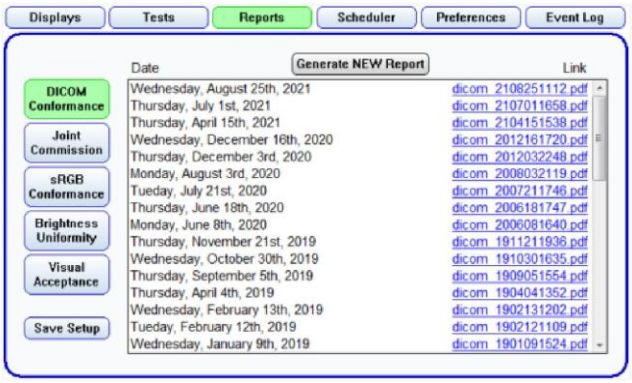

Figure 40: CFS DICOM Conformance Reports Page

6. The Reports page displays a historic list of all past verification reports for the following:
   a. DICOM Compliance (graphs with curves and data points)
   b. Joint Commission (JCAHO – Same data set as the DICOM report but instead of a pair of conformance graphs, it simply lists the sample data points numerically)
   c. sRGB Conformance (sRGB graphs with curves and data points)
   d. Brightness Uniformity
   e. Visual Acceptance
7. All reports are stored in the PDF format. The figure below shows a sample DICOM Conformance Report (which includes White Luminance).

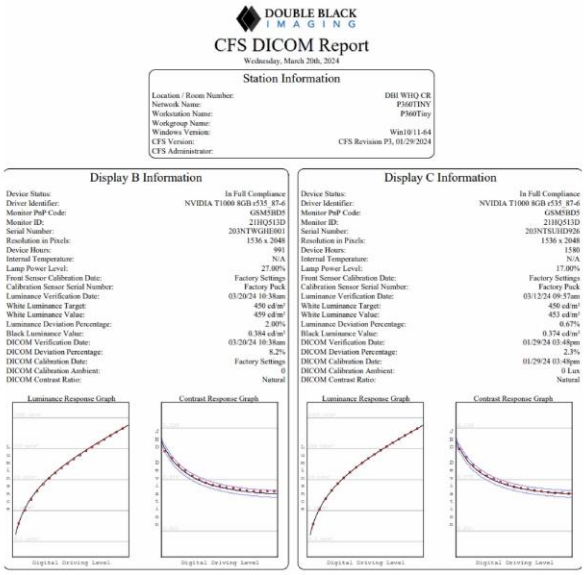

Figure 41: CFS Sample DICOM Conformance Report

Chapter 11 Additional CFS Procedures (DBI)

11.1 Saving the CFS Calibration History - Introduction

Hologic strongly recommends saving the CFS Calibration (database files) History to secure media monthly to prevent data loss in the event of a system failure. Hologic also recommends saving the CFS Calibration History prior to a SecurView upgrade.

Depending on the system configuration (CFS Standalone or CFS WebManager), the methods to backup/save the calibration history vary slightly and are covered in detail below.

Optional – Printing the CFS Calibration History provides a hardcopy record of all the actions run on the SecurView workstation during a given month. If utilizing this method, Hologic recommends retaining the printed CFS Calibration History as proof of compliance. In the following procedures, the CFS Calibration History can either be stored to a local USB drive (for saving to or printing from a different computer), or if using CFS WebManager, sent directly to a different computer for printing.

11.2 Saving the CFS Calibration History – CFS Standalone

1. Log out of the SecurView DX application.
2. Connect a USB drive to the SecurView workstation.
3. From the Windows taskbar, right-click the CFS icon in the system tray, then select **CFS Login**.

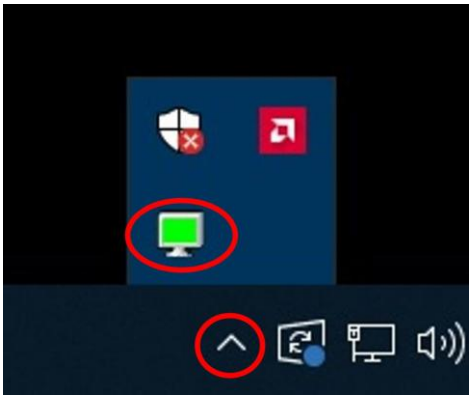

Figure 42: CFS Icon in System Tray

4. Select **Administrative**, type the default password `admin`, then select **Confirm**.

5. The CFS Home page is displayed.

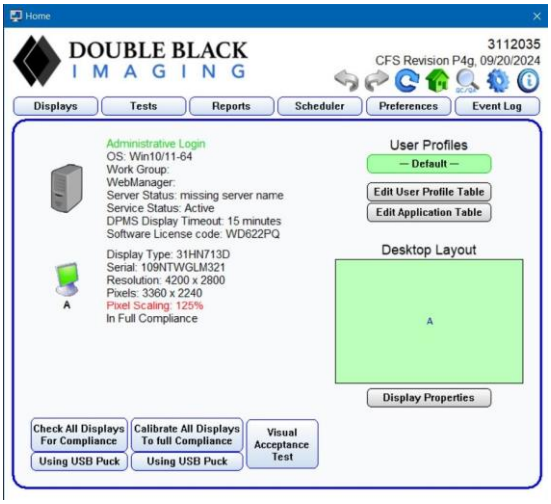

Figure 43: CFS Home Page

From the CFS Home page, select the **Preferences** tab.

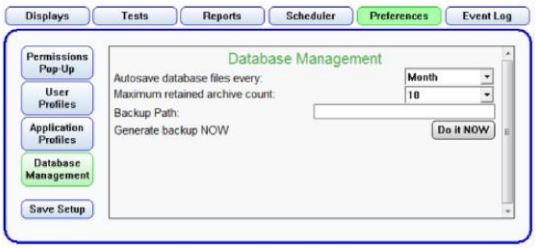

Figure 44: CFS Home Page

6. If Database Management had not been previously set up, do the following on the Database Management page:
   a. **Autosave database files every**: Select Day, Week, Month, Quarter, or Year.
   b. **Maximum retained archive count**: Set the number of backup files to retain before they are automatically purged from the archive. Default is 10.
   c. **Backup Path**: Text entry field - Default is C:/ImageSystems/CFS/Backup but it is strongly suggested to copy the backup files to external media. Files are named Dbase_yymmdd.zip where “yymmdd” represents the two-digit year, month, and day of the backup operation.
   d. **Generate Backup Now**: Select **Do It Now** to perform an immediate backup operation. (This will not replace scheduled backup procedures.)

11.3 Saving the CFS Calibration History – CFS WebManager

1. Open a web browser and navigate to the IP Address of the CFS WebManager server. For example, http://192.168.0.0. If the port was changed from its default setting, include the non-standard port number. For example, http://192.168.0.0:6060.
2. The CFS Web Manager Login page displays.

Figure 45: CFS Web Manager Login Page

3. After successful login, on the CFS WebManager page, select the **File** tab, then select **ZIP Backup/Restore**.

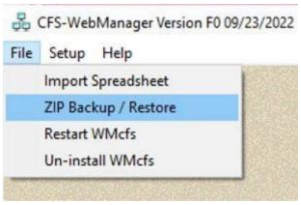

Figure 46: CFS WebManager File Tab

4. The *ZIP Backup* window displays.

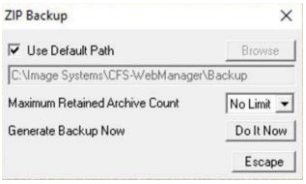

Figure 47: CFS WebManager ZIP Backup Window

Set the ZIP Backup options:

a. **Use Default Path:** If checked, the default path of C:\ImageSystems\CFS\WebManager\Backup is used. It is strongly suggested to copy the backup files to external media. If a different path is desired, deselect **Use Default Path**, then select **Browse** to select a different folder path.

b. **Maximum Retained Archive Count**: Select the drop-down arrow to change from the default "No Limit" setting.

c. **Generate Backup Now**: Select **Do It Now** to perform an immediate backup operation. (This will not replace scheduled backup procedures.)

11.4 Scheduling Automated Tests

ACR recommends that the Luminance and DICOM compliance tests be run quarterly but CFS defaults to once a month with its schedule set by default to the first Friday of the month at 8PM. Use this procedure to change the time/day of the scheduled compliance test.

1. Log out of the SecurView DX application.
2. From the Windows taskbar, right-click the CFS icon in the system tray.
3. Select **CFS Login**.
4. Select **Administrative**, type the default password `admin`, then select **Confirm**.
5. From the CFS Home page, select the **Scheduler** tab.
6. On the Scheduler page, select the day, time, and frequency for the White Level Luminance and DICOM Compliance tests.

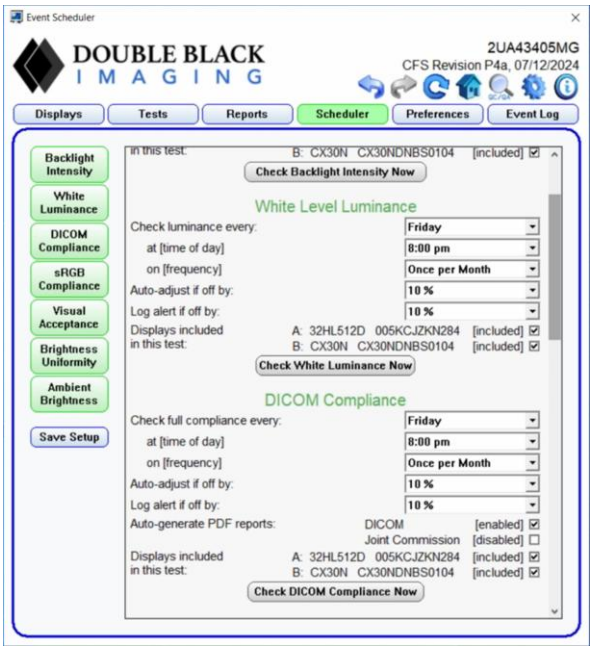

Figure 48: CFS Scheduler Page

7. Select **Check White Luminance Now** or select **Check DICOM Compliance Now** to run either test manually.
8. Close all open windows.

Appendix A SecurView Annual QC Form for Medical Physicists (Barco)

Complete this form once per year for each SecurView diagnostic workstation.

Table 2: Annual QC Form for Medical Physicists (Barco)

System Information				
SecurView SN				
Photometer SN				
Barco Display	**Left Display**	**Pass/Fail**	**Right Display**	**Pass/Fail**
Serial Number				
White Level Performance	cd/m^2		cd/m^2	
Luminance Response	%		%	
Barco Display	**Single Display**		**Pass/Fail**	
Serial Number				
White Level Performance	cd/m^2			
Luminance Response	%			
Comments:				
Signature:		Date:		

Table 3: Performance Criteria (Barco)

Barco Display	White Level Luminance	White Level Performance	DICOM GSDF Performance
Coronis OneLook MDMC-32133	600 - 1200 cd/m^2	± 6%	± 10%
Coronis Uniti MDMC-12133	600 - 1000 cd/m^2	± 6%	± 10%
High-Brightness MDMG-5221	600 - 1000 cd/m^2	± 6%	± 10%
Coronis Fusion 10MP MDCG-10130	500 cd/m^2	± 6%	± 10%
Coronis 5MP MDMG-5121	600 cd/m^2	± 6%	± 10%
Coronis 5MP MFGD-5621 HD	600 cd/m^2	± 6%	± 10%
Coronis 5MP MFGD-5421	500 cd/m^2	± 6%	± 10%
Nio 5.8MP Color MDNC-6121	500 - 600 cd/m^2	± 6%	± 10%
Nio 5MP MDNG-6121	500 cd/m^2	± 6%	± 10%
Nio 5MP MDNG-5121	500 cd/m^2	± 6%	± 10%
Nio 5MP MDNG-5221	500 cd/m^2	± 6%	± 10%

Appendix B SecurView Semi-Annual QC Form for Radiologic Technologists (Barco)

Table 4: Semi-Annual QC Form for Radiologic Technologists (Barco)

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

Date	**Comments**	**Initials**

Appendix C SecurView Weekly QC Form for Radiologic Technologists (Barco)

Table 5: Weekly QC Form for Radiologic Technologists (Barco)

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

Appendix D SecurView Annual QC Form for Medical Physicists (DBI)

Complete this form once per year for each SecurView diagnostic workstation.

Table 6: Annual QC Form for Medical Physicists (DBI)

System Information				
SecurView SN				
Photometer SN				
DBI Display	**Left Display**	**Pass/Fail**	**Right Display**	**Pass/Fail**
Serial Number				
White Level Performance	cd/m^2		cd/m^2	
Luminance Response	%		%	
DBI Display	**Single Display**		**Pass/Fail**	
Serial Number				
White Level Performance	cd/m^2			
Luminance Response	%			
Comments:				
Signature:		Date:		

Table 7: Performance Criteria (DBI)

DBI Display	White Level Luminance	White Level Performance	DICOM GSDF Performance
31HN713D	420 - 700 cd/m^2	± 10%	± 10%

Appendix E SecurView Monthly QC Form for Radiologic Technologists (DBI)

Table 8: Monthly QC Form for Radiologic Technologists (DBI)

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

Date	Comments	Initials

Appendix F SecurView Weekly QC Form for Radiologic Technologists (DBI)

Table 9: Weekly QC Form for Radiologic Technologists (DBI)

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

SecurView SN:			
Date	**Time**	**Pass/Fail**	**Initials**

HOLOGIC®

Hologic, Inc.
600 Technology Drive
Newark, DE 19702 USA
1.800.447.1856

Australian Sponsor **Hologic (Australia & New Zealand) Pty Ltd.**
Level 3, Suite 302
2 Lyon Park Road
Macquarie Park NSW 2113
Australia
1.800.264.073

Asian Pacific Sponsor **Hologic Asia Pacific Ltd.**
Unit Nos. 01-03A, 13/F
909 Cheung Sha Wan Road, Cheung Sha Wan
Kowloon, Hong Kong

EC REP **Hologic BV**
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80
Fax: +32 2 725 20 87

CE
2797

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