Barco Mammography Display Systems

Recommended Quality Assurance

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This memo outlines quality checks for Barco mammography display systems. These quality checks are not preconditions for warranty service, but rather are recommended to ensure equipment is tested and properly functioning when using these display systems for reading mammography, including breast tomosynthesis. The instructions and forms below can be incorporated into the overall quality program for a site that aims to comply with MQSA or similar requirements.

This manufacturer's recommendation is for the following products; for products not listed here please contact Barco to request the correct recommendations.

Coronis OneLook® Coronis Uniti®, Mammo Tomosynthesis 5MP, Nio Color 5MP, Nio Gray 5.8MP, Nio Fusion 12MP, MDMC-32133, MDMC-12133, MDMG-5221, MDNC-6121, MDNG-6221, MDNC-12130

The tasks below can be performed with QAWeb Enterprise[1], a quality assurance software package from Barco included with the above display models.

Barco's QAWeb Enterprise should be set up to perform following tasks[2]:

Task or Test		**Recommended Frequency**	**Reasoning**
Calibration		TWICE A YEAR (<8 months)	Re-calibration with the I-Guard® is applied automatically, ensuring DICOM GSDF compliance.
Mammography Compliance	Mammography acceptance	ONCE (Upon display installation)	Verifies the display system is compliant to the desired display function & target white luminance. Verifies absence of possible artifacts
	Mammography constancy	WEEKLY (<13 days)	Automatically measures compliance to the desired display function and common white luminance.
Visual Check of the Temporal Response[3]		YEARLY	Verify a test pattern (e.g. RapidFrame Pattern) to make sure RapidFrame™ feature is enabled
Visual Check of test pattern AAPM OIQ		YEARLY	Verifies absence of possible artifacts
Ambient Light		DAILY	Sensor automatically monitors viewing conditions provides real-time alerts
Luminance Check		On equipment >five years old, YEARLY	Older systems calibration system should be checked periodically

[1] It may also still possible to use the older *MediCal QAWeb*, although this product is no longer being developed and may become incompatible with newer operating system and product model updates, e.g. MDMC-32133; please follow detailed instructions found in K5905277 version 14 when using MediCal QAWeb. For support in updating to QAWeb Enterprise, see p2.

[2] Additional tasks may be enabled, e.g. SteadyColor response test, these are not part of these recommendations.

[3] Visual test -Temporal Response is not required on Coronis OneLook, Nio Color 5MP, Nio Gray 5.8MP, MDMC-32133, MDNC-6121, MDNG-6221.

Notes :

1) Role of the Medical Physicist
   a) When a reading room is initially configured, medical physicist involvement is required; the medical physicist must be in-person to evaluate the reading room configuration.
   b) For subsequent yearly evaluations, whether performed by the Radiologic Technologist, Interpreting Physician, or the Medical Physicist, the results of all QC tests as well as written documentation of any corrective actions taken and their results, must be evaluated for adequacy by the medical physicist during a facility's annual survey.
   c) Between these scheduled tests, if display (monitor) equipment is replaced without replacing the workstation and without changing the reading room configuration, this replacement is subject to medical physicist oversight and may not require in-person medical physicist testing. This applies when both the equipment being replaced and the replacement are covered by this document.
2) Display cleaning instructions have been removed from the QC Manual, as cleaning is commonly performed on healthcare equipment and detailed instructions can be found in the User Guide for each display model.
3) Pixel Formats of each display system
   a) 6848x4560 - Coronis OneLook® and MDMC-32133
   b) 4200x2800 - Coronis Uniti®, Nio Fusion 12MP, MDMC-12133, and MDNC-12130
   c) 2100x2800 - Nio Color 5MP, Nio Gray 5.8MP, MDNC-6121, and MDNG-6221
   d) 2048x2560 - Mammo Tomosynthesis 5MP and MDMG-5221
4) FDA Authorizations covering each display system
   a) K242008 - Coronis OneLook®, MDMC-32133
   b) K151505 - Coronis Uniti®, MDMC-12133
   c) K203106 - Nio Fusion 12MP, MDNC-12130
   d) K170476 - Nio Color 5MP, Nio Gray 5.8MP, MDNC-6121, and MDNG-6221
   e) K103792 - Mammo Tomosynthesis 5MP and MDMG-5221

An example of a Display QC Manual for a mammography facility can be found on the following pages. While other forms may be used, these instructions and forms conform to the above manufacturer's QC recommendations.

For updates to this document, sign-up at my.barco.com, search for your product, e.g. MDMG-5221, and "Subscribe to this product.", or reach out to us as follows :

For support in using Barco products like QAWeb or Barco display systems, please feel free to contact Barco's helpdesk:
Our helpdesk provides you with prompt phone support. A team of experienced support engineers is at your service for any professional assistance.
Healthcare USA/Canada Hours: 8 am to 8 pm EST

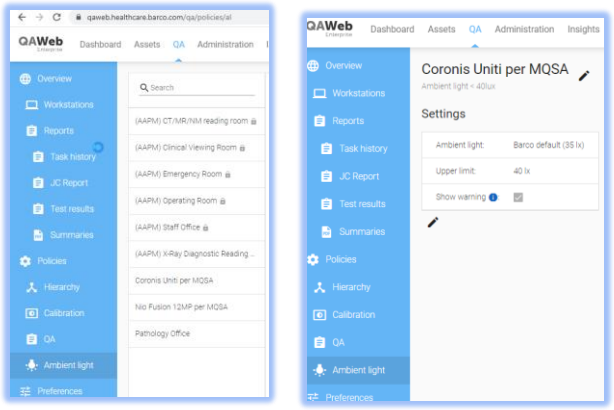
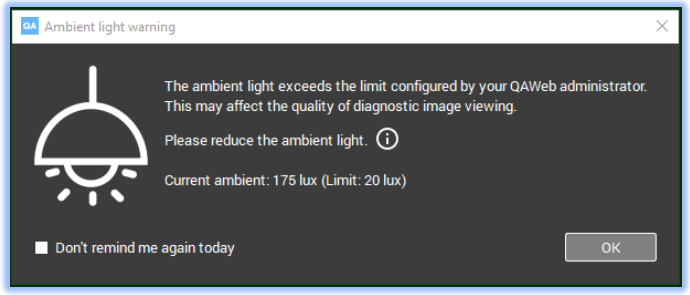
Free phone: +1 866 99BARCO
Email: **Service.Medical.USA@Barco.com**

For questions or comments about these quality recommendations, please feel free to contact the product manager:
+1 503 748 6060
albert.xthona@barco.com

QUALITY CONTROL MANUAL

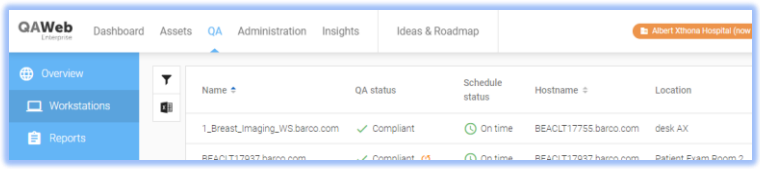
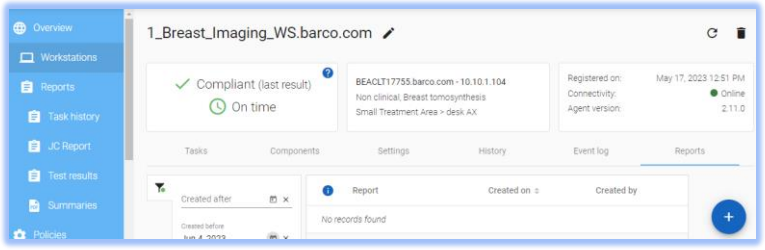
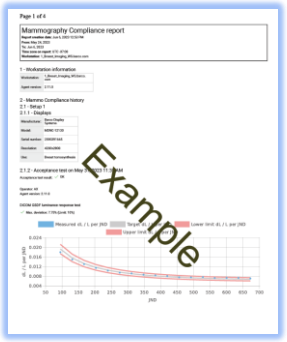
1 ONGOING QC TASKS FOR THE USER

1.2 Ambient Light

1.1.1	Frequency	Occurs automatically at least Daily when system is in use.
1.1.2	Objective	To ensure optimal viewing conditions.
1.1.3	Equipment	Built-in ambient-light sensor.
1.1.4	Procedure	The acceptable ambient light is configured in the QAWeb Enterprise web portal. To review policies in QAWeb Enterprise, using an internet browser, log in to https://qaweb.healthcare.barco.com, then navigate to Policies/Ambient light.  When the built-in ambient-light sensor on the display detects a higher level of room light than the limit allowed by the policy, it prompts with a pop-up on the workstation :  1. This pop-up shows the current ambient-light level and the limit level. Adapt the local conditions to reduce the ambient-light level whereupon the pop-up will automatically close. 2. The option "Don't remind me again today" is provided for when the display system is used for purposes that do not include mammography interpretation. 3. For additional information on maintaining the appropriate illuminance level, you may contact your Medical Physicist.
1.1.5	Action limit	The current ambient light level should not exceed the limit level.
1.1.6	Use of test results	If the reading room ambient light has increased above the limit, it shall be reduced so as not to exceed the Ambient light Policy level or the changes must be approved by the Physicist before any further mammographic images are reviewed or interpreted using this specific display. As the pop-up warning is immediately addressed, no routine record of this task is recorded.

2 QC TASKS FOR RADIOLOGIC TECHNOLOGIST[4]

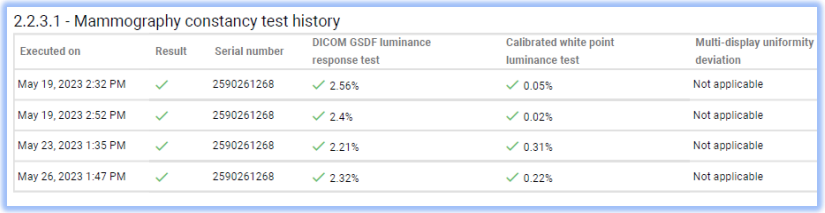
2.1 IMAGE QUALITY CHECK

2.1.1	Frequency	Weekly.
2.1.2	Objective	Review to verify that QAWeb software is reporting that the display is compliant with the recommended tests.
2.1.3	Equipment	None.
2.1.4	Procedure	All required General QC task and tests will run automatically. The frequency of the QC tests will be set up when the QAWeb software is installed[5]. To access QC test results in QAWeb Enterprise[6], using an internet browser, log in to https://qaweb.healthcare.barco.com A. Navigate to the workstation a.  B. Click on the Reports Tab, a.  b. click on the + icon, select the type of report to generate, Mammography Compliance Report and the date range of interest. C. Press "Generate" and wait for the report icon to turn green PDF D. Open the Mammography Compliance Report by clicking on the icon  E.

[4] Tasks can be performed by others with appropriate training, e.g. radiologists, medical physicists

[5] To review policies in QAWeb Enterprise, using an internet browser, log in to https://qaweb.healthcare.barco.com, then navigate to Policies.

[6] It is also possible to similarly access the most recent acceptance test and constancy test at the workstation by opening the QAWeb agent.

<table>
<tr>
<td></td>
<td></td>
<td>F. Check that the latest Acceptance test for the current display[7] has a result of "OK" and observe that details {DICOM GSDF luminance response test, Calibrated white point test, Visual test} are present in the report for this test.
G. Check that the latest Constancy tests have a result of "OK" and observe that details are present in the report for these tests.
a.

2.2.3.1 - Mammography constancy test history
<table>
<tr><th>Executed on</th><th>Result</th><th>Serial number</th><th>DICOM GSDF luminance response test</th><th>Calibrated white point luminance test</th><th>Multi-display uniformity deviation</th></tr>
<tr><td>May 19, 2023 2:32 PM</td><td>✓</td><td>2590261268</td><td>✓ 2.56%</td><td>✓ 0.05%</td><td>Not applicable</td></tr>
<tr><td>May 19, 2023 2:52 PM</td><td>✓</td><td>2590261268</td><td>✓ 2.4%</td><td>✓ 0.02%</td><td>Not applicable</td></tr>
<tr><td>May 23, 2023 1:35 PM</td><td>✓</td><td>2590261268</td><td>✓ 2.21%</td><td>✓ 0.31%</td><td>Not applicable</td></tr>
<tr><td>May 26, 2023 1:47 PM</td><td>✓</td><td>2590261268</td><td>✓ 2.32%</td><td>✓ 0.22%</td><td>Not applicable</td></tr>
</table>

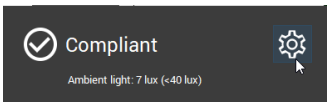
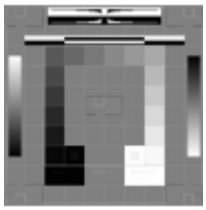
H. Check that the Calibration history shows a result of "OK" executed in the past eight months.
a.

3 - Calibration history
<table>
<tr><th>Executed on</th><th>Result</th><th>Display</th><th>Luminance response function</th><th>Luminance target</th></tr>
<tr><td>May 30, 2023 2:25 PM</td><td>✓</td><td>MDNC-12130 (SN: 2590391645)</td><td>dicom-gsdf</td><td>451</td></tr>
<tr><td>May 19, 2023 3:30 PM</td><td>✓</td><td>MDNC-12130 (SN: 2590261268)</td><td>dicom-gsdf</td><td>600</td></tr>
</table>

I. If a posted record is desired, record completion of review on the "Weekly Checks Form".</td>
</tr>
<tr>
<td>2.1.5</td>
<td>Action limit</td>
<td>Current results of each of the QC Tests {Acceptance, Constancy, and Calibration} must be "OK" and Details must be present.</td>
</tr>
<tr>
<td>2.1.6</td>
<td>Use of test results</td>
<td>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.
If the system failed one or more of the tests, the source of the problem must be identified, and corrective action taken. The system with failures is subject to medical physicist oversight before any further mammographic images are reviewed or interpreted using this specific display. All failures must be corrected within 30 days.</td>
</tr>
</table>

[7] Sometimes multiple displays are used sequentially on a workstation; if there is more than one "Setup" in the report, examine the one that corresponds to the diagnostic display(s) currently present.

2.2 VISUAL CHECK OF AAPM OIQ

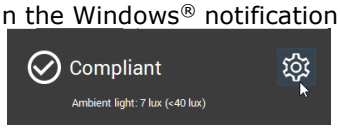
2.2.1	Frequency	Annually
2.2.2	Objectives	To assure the display (monitor) is calibrated and the brightness and contrast settings are at an appropriate level for the reading of mammographic images on the Workstation.
2.2.3	Equipment	None.
2.2.4	Procedure	1. Quit the Workstation viewer application, if it is running. 2. Using QAWeb Enterprise Agent locally on the workstation: A. Open the local agent in the Windows® notification area (systray)  B. Click the "gear" icon.  C. In Tasks/Visual test[8], press "Run task" D. Enter your name or callsign as Operator, then press "Next" button or Tab+Enter. E. This will display the TG18-OIQ on all diagnostic screens  3. There is a single summary question "Does the image on the display meet the required image quality criteria?"; the criteria are elaborated if you press the angle bracket in the upper right corner. 4.  5. Examine the image on each monitor carefully to ensure image quality meets the following recommended criteria: • General image quality and artifacts: Evaluate the overall appearance of the pattern. Note any non-uniformities or artifacts, especially at black-to-white and white-to-black transitions. Verify that the ramp bars appear continuous without any contour lines. • Luminance, reflection, noise, and glare: Verify that all 16 luminance patches are distinctly visible. Verify that the 5% and 95% patches are visible. Evaluate the appearance of low contrast letters and the targets at the corners of all luminance patches. • Resolution: Verify the visibility of the high-contrast line-pair patterns at the Nyquist frequency at the center and corners of the pattern. 6. Answer the single question and then press "Save" in the lower right corner. 7. The overall Visual test result will appear in future generated Mammography Compliance Reports covering this time period. 8. If a posted record is desired, record the results of the Image Quality Test on "Image Quality View TG18 Test Pattern Form"

[8] If a task is missing from the local agent, this task needs to be added to the Calibration or QA policy governing this workstation. To review, edit, or assign policies in QAWeb Enterprise, using an internet browser, log in to https://qaweb.healthcare.barco.com, then navigate to Policies.

2.2.5	Action limit	0%-5% contrast and 95%-100% contrast must be visible, each gray step represented in 16 luminance patches from 0% to 100% must be distinguishable from the adjacent ones. The alphanumeric characters "CONTRO" must appear sharply focused. The final "L" must be detectable. Masking (covering) bright areas of the pattern is recommended when looking for the "L" in the dark letters. The high-contrast line-pair patterns representing the Nyquist limit for the display must be distinguishable[9] at the center and the corners of the display for both the horizontal and vertical orientations of the line-pair patterns.
2.2.6	Use of test results	If the system failed one or more of the tests, the source of the problem must be identified, and corrective action taken. The system with failures is subject to medical physicist oversight before any further mammographic images are reviewed or interpreted using this specific display. All failures *must* be corrected within 30 days.

2.3 VISUAL CHECK OF TEMPORAL RESPONSE

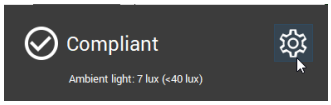
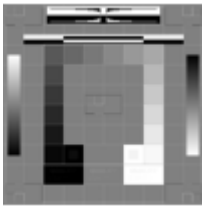
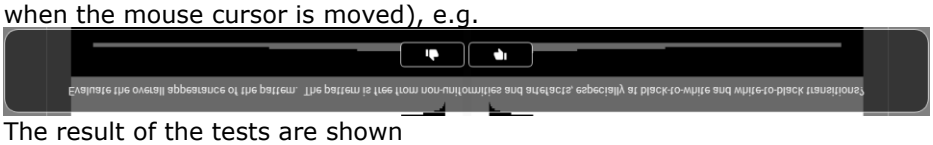
VISUAL CHECK OF TEMPORAL RESPONSE

2.3.1	Frequency	Yearly
2.3.2	Objectives	To assure the monitor's response time is at an appropriate level for the reading of mammographic images on the Workstation.
2.3.3	Equipment	None.
2.3.4	Procedure	A. Quit the Workstation application, if it is running. B. Using QAWeb Enterprise Agent locally on the workstation : C. Open the local agent in the Windows® notification area (systray)  D. Click the "gear" icon.  E. In Tasks/Visual test[10], press "Run task" F. Enter your name or callsign as Operator, then press "Next" button or Tab+Enter. G. The test pattern appears on all diagnostic screens. H. One half of the display remains corrected by the RapidFrame function, while the other half is uncorrected during this test. I. Observe that the corrected half is brighter, showing that the RapidFrame feature is working properly. J. Answer the question and press "Finish" K. The overall Visual test result will appear in future generated Mammography Compliance Reports covering this time period. L. If a posted record is desired, record the results of the Visual Test of Response Time on "Yearly Checks Form"
2.3.5	Action limit	The RapidFrame-corrected half of the display must be brighter than the uncorrected half during the test. Flicker and some blinking are normal, depending on WS CPU load.
2.3.6	Use of test results	If the system fails the test, the source of the problem must be identified, and corrective action taken. The system with failures is subject to medical physicist oversight before any further mammographic images are reviewed or interpreted using this specific display. All failures *must* be corrected within 30 days.

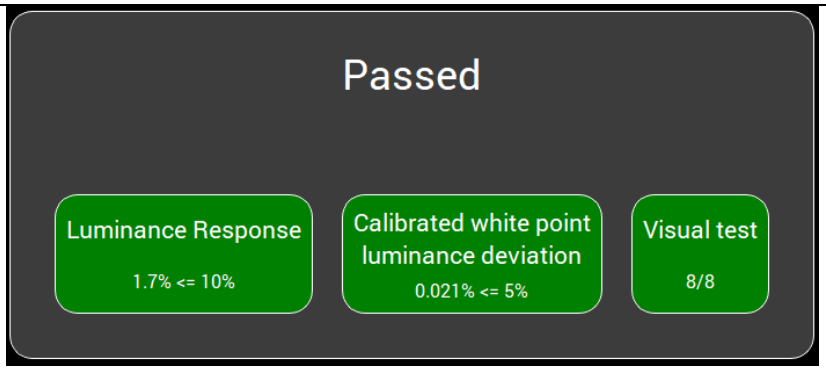
[9] Tint of high-contrast line pairs may not match the overall tint of the display, this is a normal phenomenon.
[10] If a task is missing from the local agent, this task needs to be added to the Calibration or QA policy governing this workstation. To review, edit, or assign policies in QAWeb Enterprise, using an internet browser, log in to https://qaweb.healthcare.barco.com, then navigate to Policies.

3 QC TESTS FOR THE MEDICAL PHYSICIST

3.1 MAMMOGRAPHY ACCEPTANCE TEST

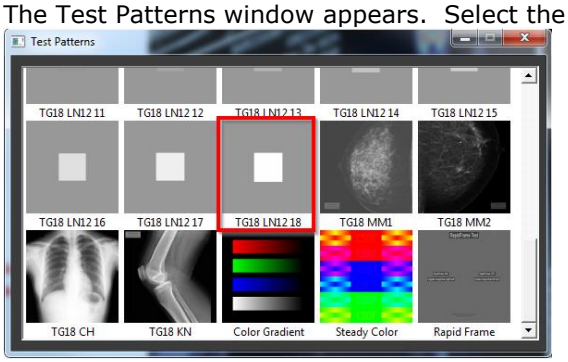
3.1.1	Frequency	ONCE (Upon display installation)
3.1.2	Objectives	Evaluate the settings, automatic measurements, and test pattern to ensure the display system is ready for mammographic images to be reviewed or interpreted.
3.1.3	Equipment required	Lux meter and photometer, optionally
3.1.4	Procedure	The QAWeb agent receives the calibration- and QA policies as they are defined in the QAWeb Enterprise Portal. The settings cannot be modified locally[11]. To review or set policies in QAWeb Enterprise, using an internet browser, log in to https://qaweb.healthcare.barco.com, choose an organization, then navigate to Policies. 1) Measure the ambient light, using either a) The internal illuminance meter of a display (see details in section 1.1 above) b) A standalone lux meter. To measure the ambient light, hold the illuminance meter against the center of each display, facing outwards. 2) In situations where the ambient light can be easily adjusted, typical preferred levels are between two and ten lux. Record the highest of the values measured. 3) Quit the Workstation viewer application, if it is running. 4) Using QAWeb Enterprise locally on the workstation: 5) Open the local agent in the Windows® notification area (systray)  6) Click the "gear" icon.  7) In Tasks/Mammography acceptance test, press "Run task" 8) Enter your name or callsign as Operator, then press "Next" button or Tab+Enter. 9) The acceptance test then automatically confirms the display luminance is stable and measures the luminance response to be compared with the DICOM GSDF curve. 10) It will then display the TG18-OIQ on all diagnostic screens 11)  12) Answer the prompted questions (they vanish after 3-4 seconds and return when the mouse cursor is moved), e.g. 13)  14) The result of the tests are shown

[11] Most installations operate in online mode, however, in stand-alone mode, the calibration and QA policies can be modified using the agent user interface.

		15)  16) Press "Save" to finish. 17) If a posted record of the room evaluation is desired record the room arrangement and ambient light on VIEWING CONDITIONS CHECK AND SETTING form. 18) If a posted record is desired, record the results of the Calibration, Luminance Response, Multi-display uniformity, and Visual Test on "MAMMOGRAPHY ACCEPTANCE TEST" form.
3.1.5	Action limit	The ambient light must be <20 lux for Nio Color 5MP (MDNC-6121), Nio Gray 5.8MP (MDNG-6221) <20 lux for Mammo Tomosynthesis 5MP (MDMG-5221) <40 lux for Nio Fusion 12MP (MDNC-12130) <40 lux for Coronis Uniti (MDMC-12133). <40 lux for Coronis OneLook (MDMC-32133). White point luminance shall be within 5% of target values. Luminance response shall be within 10% of target values. Multi-display uniformity shall be within 10% when multiple diagnostic displays are used simultaneously on the same workstation. The 0%-5% contrast and the 95%-100% contrast must be visible, and each gray step represented in the 16 luminance patches from 0% to 100% must be distinguishable from the adjacent ones. The alphanumeric characters "CONTRO" must appear sharply focused. The final "L" must be detectable. Masking (covering) bright areas of the pattern is recommended when looking for the "L" in the dark letters. The high-contrast line-pair patterns representing the Nyquist limit for the display must be distinguishable[12] at the center and the corners of the display for both the horizontal and vertical orientations of the line-pair patterns.
3.1.6	Use of test results	If the system fails the tests, the source of the problem must be identified and corrective action taken, before any further mammographic images are reviewed or interpreted using this specific display.

[12] Tint of high-contrast line pairs may not match the overall tint of the display, this is a normal phenomenon.

3.2 LUMINANCE CHECK

3.2.1	Frequency	On displays that are greater than five years old, Annually
3.2.2	Objectives	To assure that internal calibration systems are operating
3.2.3	Equipment required	Photometer. To successfully measure the display luminance, it is recommended that the photometer be designed for LCD displays that employ LED or CCFL backlights, have a narrow acceptance angle, and have a current calibration sticker.
3.2.4	Procedure	1. Check the manufacture date printed on the rear of each display. 2. If no display is older than five years, record "None" on the "LUMINANCE CHECK FOR DISPLAYS OLDER THAN FIVE YEARS" form and skip the remainder of this procedure. 3. Quit the Workstation application, if it is running. 4. Using QAWeb Enterprise locally on the workstation : A. Open local agent in the Windows® notification area (systray)  B. Click the "Test patterns" icon.  C. The Test Patterns window appears. Select the TG18-LN12-18  D. The test pattern appears on all screens. Note : The pixel value of the central region varies from 0 to 4080 for the 12-bit version (TG18-LN12) patterns, and thus the center of TG18-LN12-18 is not full white. This ~1.5% difference was considered in setting the action limit below. 5. Use the photometer to measure the luminance emitted normal to the screen surface. 6. Record the results of the Luminance Check on "LUMINANCE CHECK FOR DISPLAYS OLDER THAN FIVE YEARS".
3.2.5	Action limit	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 most recent calibration results.
3.2.6	Use of test results	If the system fails the tests, the source of the problem must be identified and corrective action taken, before any further mammographic images are reviewed or interpreted using this specific display.

Forms

1 WEEKLY CHECKS FORM

Year		Month				
Week		1	2	3	4	5
Initials						
Image Quality Check						
Date						

2 YEARLY CHECKS FORM

Year				
Initials				
Date				
	Left Display	Right Display	Left Display	Right Display
	Pass	Fail	Pass	Fail
Visual Test – Temporal Response[13]				
Visual Test - TG18 OIQ	Pass	Fail	Pass	Fail
Artifacts, non-uniformities				
Grayscale continuity				
0% - 5% contrast				
95% - 100% contrast				
Gray steps				
Alphanumerics				
Line-pairs (center)				
Line-pairs (corner)				

[13] Visual Test of Temporal Response is not required on Coronis OneLook, Nio Color 5MP, Nio Gray 5.8MP, MDMC-32133, MDNC-6121, MDNG-6221.

3 VIEWING CONDITIONS CHECK AND SETTING

Facility: _____

Room: _____ Date: _____

Room description

Display positions: _____
_____

Room lights: _____
_____

Desk lights: _____
_____

Others: _____

Ambient illuminance: _____

Note—Confirmation of this value is not part of the daily check by the Radiological Technologist.

Display Type	Ambient Illuminance measured on surface of displays	Pass	Fail
Nio Color 5MP (MDNC-6121)	<20lux		
Mammo Tomosynthesis 5MP MDMG-5221	<20lux		
Coronis OneLook (MDMC-32133)	<40lux		
Coronis Uniti (MDMC-12133)	<40lux		
Nio Fusion 12MP MDNC-12130	<40lux		
Nio Gray 5.8MP MDNC-6221	<20lux		

Room Layout

4 MAMMOGRAPHY ACCEPTANCE TEST

Multi-display Uniformity	Pass	Fail	Not Applicable

	Left Display		Right Display	
	Pass	Fail	Pass	Fail
Calibration				
Luminance Response				

Visual Test - TG18 OIQ	Pass	Fail	Pass	Fail
Artifacts, non-uniformities				
Grayscale continuity				
0% - 5% contrast				
95% - 100% contrast				
Gray steps				
Alphanumerics				
Line-pairs (center)				
Line-pairs (corner)				

5 LUMINANCE CHECK FOR DISPLAYS OLDER THAN FIVE YEARS

Display Serial Number	Display Manufacture Date	Luminance Measured	Date Measured	Pass	Fail