Radiation Physics
CONSULTANTS

July 18, 2023

MQSA PHYSICIST CONTINUING EXPERIENCE

This document expires on May 8, 2025.

This letter is in reference to the Continuing Experience requirement set forth by the MQSA regarding the number of at least 6 mammography surveys completed at least 2 sites within a 24-month period.

Steven T. Nicholas, M.S., a Radiation Physics Consultants, Inc. physicist, has met the Continuing Experience requirements of MQSA. Surveys at the following facilities have been completed within the required time frame:

Site	City	Unit	Date
St. Luke's Hospital	Duluth, MN	Selenia Dimensions DBT	May 8, 2023
Lakewood Health Center	Baudette, MN	Siemens Revelations DBT	May 24, 2023
DMS Health Technologies	Mobile Truck	Selenia Dimensions DBT	June 2, 2023
Mariner Medical Clinic	Superior, WI	Selenia Dimensions DBT	June 27, 2023
Osceola Medical Center	Osceola, WI	Selenia Dimensions DBT	June 13, 2023
North Shore Health	Grand Marais, MN	Selenia Dimensions DBT	July 6, 2023

Please do not hesitate to contact me if you have any additional questions.

Sincerely,

Steven T. Nicholas, M.S., DABMP
President, RPC

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Lorad/Hologic

Site Name	North Shore Health	**Report Date**	7/6/2023
Address	515 5th Ave West, Grand Marais, MN 55604	**Survey Date**	7/6/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	Steven T. Nicholas
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	6/21/2019	**Room ID**	Mammo
		SN	SDM131900754

QC Manual Version # **MAN-03706, Rev. 010 (Aug 2020)** (*use any version applicable to model; contact mfr if questions*)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	☐ On-site ☑ Off-site	MAN-04959, Rev. 002
Film Printer*	NA	NA	**NA**	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System (www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm).*

Survey Type- **MEE following AEC recalibration and Annual Survey**

Features- **2D** and **Digital Breast Tomosynthesis (DBT)**

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

		PASS/FAIL
1.	**Mammographic Unit Assembly Evaluation**	**Pass**
2.	**Collimation Assessment**	**Pass**
3.	**Artifact Evaluation**	**Pass**
4.	**kVp Accuracy and Reproducibility**	**Pass**
5.	**Beam Quality Assessment - HVL Measurement**	**Pass**
6.	**Evaluation of System Resolution**	**Pass**
7.	**Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*	**Pass**
8.	**Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**	
	Average glandular dose for average breast is ≤3 mGy (300 mrad) *(conventional)* — 118 mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)*** — 148 mrad	**Pass**
9.	**Radiation Output Rate**	**Pass**

10. Phantom Image Quality Evaluation

	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	6.0	4.0	4.5	**Pass**
Phantom image scores ***(DBT)***	6.0	4.0	4.5	**Pass**

11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements *(values required for all tests)*

SNR *(value)*	56.7		**Pass**
CNR *(value)*	11.16	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			**Pass**
12.	**Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*		**Pass**
13.	**DICOM Printer QC** *(if applicable, MEE only)*		**NA**
14.	**Detector Flat Field Calibration** *(MEE only)*		**Pass**
15.	**Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***		**Pass**
16.	**Compression Thickness Indicator** *(MEE only)*		**Pass**
17.	**Compression** *(MEE only)*		**Pass**
18.	**Detector Ghosting** *(troubleshooting only)*		**NA**

****** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON <u>THIS</u> FORM ******

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

		Frequency	PASS/FAIL
1.	DICOM Printer Quality Control *(if applicable)*	Weekly	NA
2.	Viewboxes and Viewing Conditions	Weekly	Pass
3.	Artifact Evaluation	Weekly	Pass
4.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
5.	Phantom Image Quality Evaluation	Weekly	Pass
6.	Detector Flat-Field Calibration	Weekly	Pass
7.	Compression Thickness Indicator	Bi-weekly	Pass
8.	Visual Checklist	Monthly	Pass
9.	Repeat/Reject Analysis	Quarterly	Pass
10.	Compression	Semi-annually	Pass
11.	Geometry Calibration (Tomosynthsis Option) ***(DBT)***	Semi-annually	Pass
12.	Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	Pass
13.	Mobile Unit Quality Control *(if applicable)*	After every move	NA

Medical Physicist's Recommendations for Quality Improvement

This is an annual Medical Physicist's survey on a DBT unit.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

There are no discrepancies.

Site does not print.

Important: The FDA's MQSA regulations require that the facility's quality assurance program for digital mammography be "substantially the same as the quality assurance program recommended by the image receptor manufacturer." The medical physicist should follow the QC manual version provided by the manufacturer for the unit surveyed. See the attached FDA Approved Alternative Requirement for the Lorad Selenia for the allowed correction periods on taking corrective action for test failures. (If these tests are performed as part of an Equipment Evaluation, corrective action must be taken before mammographic images are acquired.)

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Lorad/Hologic

Site Name	Mariner Medical Clinic	**Report Date**	7/18/2023
Address	109 North 28th St, Superior, WI 54880	**Survey Date**	6/27/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	Steven T. Nicholas
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	9/11/2020	**Room ID**	Mammo
		SN	SDM131901270

QC Manual Version # **MAN-03706, Rev. 009 (Sept. 2019)** (*use any version applicable to model; contact mfr if questions*)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	☐ On-site ☑ Off-site	MAN-04959, Rev. 002
Film Printer*	NA	NA	**NA**	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System (www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm).*

Survey Type- **MEE for new detector**

Features- **2D** and **Digital Breast Tomosynthesis (DBT)**

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

		PASS/FAIL
1.	**Mammographic Unit Assembly Evaluation**	**Pass**
2.	**Collimation Assessment**	**Pass**
3.	**Artifact Evaluation**	**Pass**
4.	**kVp Accuracy and Reproducibility**	**Pass**
5.	**Beam Quality Assessment - HVL Measurement**	**Pass**
6.	**Evaluation of System Resolution**	**Pass**
7.	**Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*	**Pass**
8.	**Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**	
	Average glandular dose for average breast is ≤3 mGy (300 mrad) *(conventional)* — 133 mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)*** — 156 mrad	**Pass**
9.	**Radiation Output Rate**	**Pass**

10. Phantom Image Quality Evaluation

	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	6.0	4.0	5.0	**Pass**
Phantom image scores ***(DBT)***	6.0	4.0	4.0	**Pass**

11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements *(values required for all tests)*

SNR *(value)*	57.8	**Pass**
CNR *(value)*	11.35 *(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*		**Pass**

12.	**Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*	**Pass**
13.	**DICOM Printer QC** *(if applicable, MEE only)*	**NA**
14.	**Detector Flat Field Calibration** *(MEE only)*	**Pass**
15.	**Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***	**Pass**
16.	**Compression Thickness Indicator** *(MEE only)*	**Pass**
17.	**Compression** *(MEE only)*	**Pass**
18.	**Detector Ghosting** *(troubleshooting only)*	**NA**

****** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON <u>THIS</u> FORM ******

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

*(Required for Annual Surveys; not required for Mammography Equipment Evaluations of new units. However, medical physicists **must** review the site's technologist QC program within 45 days and complete this section so that the facility may submit this form along with the entire Mammography Equipment Evaluation report with their phantom and clinical images to the ACR.)*

		Frequency	PASS/FAIL
1.	DICOM Printer Quality Control *(if applicable)*	Weekly	NA
2.	Viewboxes and Viewing Conditions	Weekly	NA
3.	Artifact Evaluation 	Weekly	NA
4.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	NA
5.	Phantom Image Quality Evaluation	Weekly	NA
6.	Detector Flat-Field Calibration	Weekly	NA
7.	Compression Thickness Indicator	Bi-weekly	NA
8.	Visual Checklist	Monthly	NA
9.	Repeat/Reject Analysis	Quarterly	NA
10.	Compression	Semi-annually	NA
11.	Geometry Calibration (Tomosynthsis Option) ***(DBT)***	Semi-annually	NA
12.	Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	NA
13.	Mobile Unit Quality Control *(if applicable)*	After every move	NA

Medical Physicist's Recommendations for Quality Improvement

This is Medical Physicist's MEE following replacement of the detector array.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

Not performed. Keep your current baselines.

Important: The FDA's MQSA regulations require that the facility's quality assurance program for digital mammography be "substantially the same as the quality assurance program recommended by the image receptor manufacturer." The medical physicist should follow the QC manual version provided by the manufacturer for the unit surveyed. See the attached FDA Approved Alternative Requirement for the Lorad Selenia for the allowed correction periods on taking corrective action for test failures. (If these tests are performed as part of an Equipment Evaluation, corrective action must be taken before mammographic images are acquired.)

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Lorad/Hologic

Site Name	Osceola Medical Center	**Report Date**	6/14/2023
Address	2600 65th Ave, Osceola, WI 54020	**Survey Date**	6/13/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	Steven T. Nicholas
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	9/20/2018	**Room ID**	Mammo Rm 1
		SN	SDM131500755

QC Manual Version # **MAN-03706, Rev. 009 (Sept 2019)** (*use any version applicable to model; contact mfr if questions*)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	MDMG-5221	**On-Site**	MAN-03706, Rev. 009 (Sept 2019)
Film Printer*	NA	NA	NA	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System (www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm).*

Survey Type- **Annual Survey**

Features- **2D** and **Digital Breast Tomosynthesis (DBT)**

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

		PASS/FAIL
1.	**Mammographic Unit Assembly Evaluation**	**Pass**
2.	**Collimation Assessment**	**Pass**
3.	**Artifact Evaluation**	**Pass**
4.	**kVp Accuracy and Reproducibility**	**Pass**
5.	**Beam Quality Assessment - HVL Measurement**	**Pass**
6.	**Evaluation of System Resolution**	**Pass**
7.	**Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*	**Pass**
8.	**Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**	
	Average glandular dose for average breast is ≤3 mGy (300 mrad) *(conventional)* — 124 mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)*** — 144 mrad	**Pass**
9.	**Radiation Output Rate**	**Pass**

10. Phantom Image Quality Evaluation

	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	6.0	4.0	4.5	**Pass**
Phantom image scores ***(DBT)***	6.0	4.0	4.5	**Pass**

11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements *(values required for all tests)*

SNR *(value)*	56.9		**Pass**
CNR *(value)*	10.73	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			**Pass**
12.	**Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*		**Pass**
13.	**DICOM Printer QC** *(if applicable, MEE only)*		**NA**
14.	**Detector Flat Field Calibration** *(MEE only)*		**Pass**
15.	**Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***		**Pass**
16.	**Compression Thickness Indicator** *(MEE only)*		**Pass**
17.	**Compression** *(MEE only)*		**Pass**
18.	**Detector Ghosting** *(troubleshooting only)*		**NA**

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MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

		Frequency	PASS/FAIL
1.	DICOM Printer Quality Control *(if applicable)*	Weekly	NA
2.	Viewboxes and Viewing Conditions	Weekly	Pass
3.	Artifact Evaluation	Weekly	Pass
4.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
5.	Phantom Image Quality Evaluation	Weekly	Pass
6.	Detector Flat-Field Calibration	Weekly	Pass
7.	Compression Thickness Indicator	Bi-weekly	Pass
8.	Visual Checklist	Monthly	Pass
9.	Repeat/Reject Analysis	Quarterly	Pass
10.	Compression	Semi-annually	Pass
11.	Geometry Calibration (Tomosynthsis Option) ***(DBT)*** TOMO	Semi-annually	Pass
12.	Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	Pass
13.	Mobile Unit Quality Control *(if applicable)*	After every move	NA

Medical Physicist's Recommendations for Quality Improvement

This is an annual Medical Physicist's survey.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

No discrepancies.

Site does not print.

Important: The FDA's MQSA regulations require that the facility's quality assurance program for digital mammography be "substantially the same as the quality assurance program recommended by the image receptor manufacturer." The medical physicist should follow the QC manual version provided by the manufacturer for the unit surveyed. See the attached FDA Approved Alternative Requirement for the Lorad Selenia for the allowed correction periods on taking corrective action for test failures. (If these tests are performed as part of an Equipment Evaluation, corrective action must be taken before mammographic images are acquired.)

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Lorad/Hologic

Site Name	DMS Health Technologies	**Report Date**	6/7/2023
Address	728 Benton Drive, Suite 101, West Fargo, ND 58078	**Survey Date**	6/2/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	Steven T. Nicholas
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	5/24/2022	**Room ID**	MM28
		SN	SDM131901781
QC Manual Version #	**MAN-03706, Rev. 011**	(*use any version applicable to model; contact mfr if questions*)	

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Hologic	SecurView	**Off-Site**	MAN-03706, Rev. 011
Film Printer*	NA	NA	**NA**	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System (www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm).*

Survey Type- **MEE following an upgrade and AEC recalibration. A full annual was also performed.**

Features- **2D** and **Digital Breast Tomosynthesis (DBT)**

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

		PASS/FAIL
1.	**Mammographic Unit Assembly Evaluation**	**Pass**
2.	**Collimation Assessment**	**Pass**
3.	**Artifact Evaluation**	**Pass**
4.	**kVp Accuracy and Reproducibility**	**Pass**
5.	**Beam Quality Assessment - HVL Measurement**	**Pass**
6.	**Evaluation of System Resolution**	**Pass**
7.	**Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*	**Pass**
8.	**Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**	
	Average glandular dose for average breast is ≤3 mGy (300 mrad) *(conventional)* — 31 mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)*** — 52 mrad	**Pass**
9.	**Radiation Output Rate**	**Pass**

10. Phantom Image Quality Evaluation

	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	5.5	5.0	4.5	**Pass**
Phantom image scores ***(DBT)***	5.5	4.0	4.5	**Pass**

11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements *(values required for all tests)*

SNR *(value)*	59.2	**Pass**
CNR *(value)*	10.70 *(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*		**Pass**

12.	**Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*	**Pass**
13.	**DICOM Printer QC** *(if applicable, MEE only)*	**NA**
14.	**Detector Flat Field Calibration** *(MEE only)*	**NA**
15.	**Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***	**NA**
16.	**Compression Thickness Indicator** *(MEE only)*	**Pass**
17.	**Compression** *(MEE only)*	**NA**
18.	**Detector Ghosting** *(troubleshooting only)*	**NA**

****** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON <u>THIS</u> FORM ******

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

		Frequency	PASS/FAIL
1.	DICOM Printer Quality Control *(if applicable)*	Weekly	NA
2.	Viewboxes and Viewing Conditions	Weekly	Pass
3.	Artifact Evaluation	Weekly	Pass
4.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
5.	Phantom Image Quality Evaluation	Weekly	Pass
6.	Detector Flat-Field Calibration	Weekly	Pass
7.	Compression Thickness Indicator	Bi-weekly	Pass
8.	Visual Checklist	Monthly	Pass
9.	Repeat/Reject Analysis	Quarterly	Pass
10.	Compression	Semi-annually	Pass
11.	Geometry Calibration (Tomosynthsis Option) ***(DBT)***	Semi-annually	Pass
12.	Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	Pass
13.	Mobile Unit Quality Control *(if applicable)*	After every move	Pass

Medical Physicist's Recommendations for Quality Improvement

This is an Annual survey of a mobile DBT unit.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

No discrepancies.

Important: The FDA's MQSA regulations require that the facility's quality assurance program for digital mammography be "substantially the same as the quality assurance program recommended by the image receptor manufacturer." The medical physicist should follow the QC manual version provided by the manufacturer for the unit surveyed. See the attached FDA Approved Alternative Requirement for the Lorad Selenia for the allowed correction periods on taking corrective action for test failures. (If these tests are performed as part of an Equipment Evaluation, corrective action must be taken before mammographic images are acquired.)

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Lorad

Site Name	St. Luke's Hospital	**Report Date**	7/18/2023
Address	915 E 1st St, Duluth, MN 55805	**Survey Date**	5/8/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	
X-Ray Unit Manufacturer	Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	3/10/2017	**Room ID**	Mammo Room 1
		SN	81002177895

QC Manual Version # **MAN-03706, Rev. 006 (June 2017)** (*use any version applicable to model; contact mfr if questions*)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	**On-site**	MAN-04959, Rev. 002
Film Printer*	NA	NA	NA	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM.*

Survey Type **Annual Survey of 2D and Tomo**

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

	PASS/FAIL
1. Mammographic Unit Assembly Evaluation	**Pass**
2. Collimation Assessment	
Deviation between X-ray field and light field ≤ 2% of SID	**Pass**
X-ray field does not extend beyond any side of the IR by >2% of SID	**Pass**
X-ray field covers all of the IR on the chest wall side	**Pass**
Paddle chest wall edge does not extend beyond IR by >1% of SID or appear on mammogram	**Pass**
3. Artifact Evaluation *(no significant artifacts visible)*	**Pass**
4. kVp Accuracy and Reproducibility	
Measured average kVp within ±5% of indicated kVp	**Pass**
kVp coefficient of variation ≤ 0.02	**Pass**
5. Beam Quality Assessment - HVL Measurement	**Pass**
6. Evaluation of System Resolution *(system limiting spatial resolution >7 cycles/mm (lp/mm))*	**Pass**
7. Automatic Exposure Control (AEC) Function Performance *(NA for systems without AEC)*	
Each pixel value (2-8 cm; all operating modes) within ±10% of mean	**Pass**
Exposure compensation steps performance within acceptable limits	**Pass**
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose	
Average glandular dose for average breast is ≤3 mGy (300 mrad)	**Pass**
Average glandular to a 4.2 cm breast on your unit is — mrad: 117 Conventional	
TOMO — mrad: 132 Tomosynthesis Option	
Coefficient of variation for either R or mAs ≤ 0.05 (NA for systems without AEC)	**Pass**
9. Radiation Output Rate *(> 230 mR/sec)* — mR/sec: 700	**Pass**
10. Phantom Image Quality Evaluation	
Phantom image quality scores (Conventional) — Fibers: 6.0 Specks: 4.0 Masses: 4.5	**Pass**
TOMO Phantom image quality scores (Tomosynthesis Option) — Fibers: 6.0 Specks: 4.0 Masses: 4.5	**Pass**
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements *(values required for all tests)*	
SNR *(value)*: 52.0	**Pass**
CNR *(value)*: 10.5 *(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*	
CNR should not vary by more than ±15% *(NA for Equipment Evaluation)*	**Pass**
12. Diagnostic Review Workstation (RWS) QC *(for all RWS, even if located offsite; NA if only hardcopy read)*	**Pass**
13. DICOM Printer QC *(Mammography Equipment Evaluations only)*	**NA**
14. Detector Flat Field Calibration *(Mammography Equipment Evaluations only)*	**NA**
15. Compression Thickness Indicator *(Mammography Equipment Evaluations only)*	**Pass**
16. Compression *(Mammography Equipment Evaluations only)*	**NA**
17. Geometry Calibration TOMO	**NA**

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

*(Required for Annual Surveys; not required for Mammography Equipment Evaluations of new units. However, medical physicists **must** review the site's technologist QC program within 45 days and complete this section so that the facility may submit this form along with the entire Mammography Equipment Evaluation report with their phantom and clinical images to the ACR.)*

		Frequency	PASS/FAIL
1.	DICOM Laser Printer Quality Control	Weekly	NA
2.	Detector Flat-Field Calibration	Weekly	Pass
3.	Geometry Calibration (Tomosynthesis Option)	Weekly	Pass
4.	Artifact Evaluation	Weekly	Pass
5.	Phantom Image Quality Evaluation	Weekly	Pass
6.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
7.	Compression Thickness Indicator	Bi-weekly	Pass
8.	Review Workstation QC-Overall	See FDA guidance	Pass
9.	Viewboxes and Viewing Conditions	Weekly	Pass
10.	Visual Checklist	Monthly	Pass
11.	Repeat Analysis	Quarterly	Pass
12.	Compression	Semi-annually	Pass

Medical Physicist's Recommendations for Quality Improvement

This is an annual survey.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

No discrepancies. (QC for both rooms was reviewed at this time. Will likely review both again in June. I intend to move everything to June for 2024).

This facility does not print hard copy.

Important: The FDA's MQSA regulations require that the facility's quality assurance program for digital mammography be "substantially the same as the quality assurance program recommended by the image receptor manufacturer." The medical physicist should follow the QC manual version provided by the manufacturer for the unit surveyed. See the attached FDA Approved Alternative Requirement for the Lorad Selenia for the allowed correction periods on taking corrective action for test failures. (If these tests are performed as part of an Equipment Evaluation, corrective action must be taken before mammographic images are acquired.)

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – Siemens

Site Name	LakeWood Health Center	**Report Date**	5/31/2023
Address	600 Main Ave S., Baudette, MN 56623	**Survey Date**	5/24/2023
Medical Physicist's Name	Steven T. Nicholas	**Signature**	
X-Ray Unit Manufacturer	Siemens	**Model**	Mammomat Revelation Tomosynthesis
Date of Installation	6/10/2021	**Room ID**	DBT Mammo

QC Manual Version # Tomo QC VC20, 2D QC VC20 (*use version applicable to unit tested; contact mfr if questions*)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Double Black	Wide 5MP	☐ On-site ☑ Off-site	X-Cal Software 5.2.0.5
Film Printer*	NA	NA	NA	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System (www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm).*

Survey Type ☐ Mammo Eqpt Evaluation (MEE) of new unit (include MQSA Rqmts for Mammo Eqpt checklist) ☑ Annual Survey

Features ☑ 2D ☑ Digital Breast Tomosynthesis (DBT)

Medical Physicist's QC Tests

("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.)

		PASS/FAIL
1.	**Image Quality** Largest 5 fibers, 4 speck groups and 4 masses visible* *(*largest 4 fibers, 3 speck groups and 3 masses acceptable if spatial resolution and CNR pass)* Phantom image scores: Fibers 6.0 Specks 4.0 Masses 4.5	**Pass**
2.	**Artifact Detection**	**Pass**
3.	**Printer Check** *(if applicable)*	**NA**
4.	**SNR, CNR and AEC Repeatability** Measured values: SNR 63.1 CNR 2.65	**Pass**
	CV for mAs and entrance air kerma ≤5%	**Pass**
	Max deviation of mean pixel values and SNR within ±15% of mean for measurements	**Pass**
5.	**Radiation Dose** Average glandular dose for average breast is ≤3 mGy (300 mrad) **2D** 0.80 mGy; **3D** 1.70 mGy; **2D + 3D** 2.50 mGy	**Pass**
6.	**Spatial Resolution**	**Pass**
7.	**AEC Test**	**Pass**
8.	**Detector Uniformity**	**Pass**
9.	**Mechanical Tests**	**Pass**
10.	**Acquisition Workstation Monitor Check**	**Pass**
11.	**Site Audit/Evaluation of Technologist QC Program**	**Pass**
12.	**Collimation, Dead Space & Compression Paddle Position**	**Pass**
13.	**HVL and Radiation Output**	**Pass**
14.	**Tube Voltage Measurement & Repeatability**	**Pass**
15.	**Average Glandular Dose** ***(DBT)*** **3D** 1.70 mGy	**Pass**
16.	**Geometric Accuracy in X and Y Direction and Z-Resolution** ***(DBT)***	**Pass**
17.	**Radiation Field** ***(DBT)***	**Pass**
18.	**System Imaging Quality** ***(DBT)*** ≥ 4 fibers, ≥ 3 speck groups and ≥ 3 masses must be visible Phantom image scores: Fibers 6.0 Specks 4.0 Masses 4.0	**Pass**
19.	**Artifact Detection** ***(DBT)***	**Pass**
20.	**Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*	**Pass**

****** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS FORM ******

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(Siemens, continued)

Evaluation of Technologist QC Program

New units: Medical physicists ***must*** review the technologist QC ***within 45 days of installation*** and complete this section. The facility is required to submit the entire Mammography Equipment Evaluation report (including this form) along with their testing materials for accreditation.

Existing units: Medical physicists ***must*** complete this section as part of the unit's annual survey.

Relocating units: This section is ***not*** required if the medical physicist does ***not*** conduct a complete annual survey after relocation.

		FREQUENCY	PASS/FAIL
1.	Phantom Image Quality	Novation & Fusion-Daily; Inspiration-Weekly	**Pass**
2.	Artifact Detection	Weekly	**Pass**
3.	SNR and CNR Measurements	Weekly	**Pass**
4.	Detector Calibration	Novation-Weekly; Inspiration & Fusion-Quarterly	**Pass**
5.	Repeat/Reject Analysis	Quarterly	**Pass**
6.	Compression Force	Semi-annually	**Pass**
7.	System Imaging Quality ***(DBT)***	Daily when DBT performed	**Pass**
8.	Printer Check *(if applicable)*	Daily, when images printed	**NA**
9.	Review Workstation QC-Overall *(NA if only hardcopy read)*	See FDA guidance	**Pass**
10.	Mobile Unit Quality Control *(if applicable)*	After every move	**NA**

Medical Physicist's Recommendations for Quality Improvement

This is an annual survey.There are no discrepancies with the machine or QC program.

Important:
1. The facility's "quality assurance program shall be ***substantially the same*** as the quality assurance program recommended by the ***image receptor [digital detector] manufacturer*** ." This is required by the FDA.
2. Use the QC manual version provided by the manufacturer ***for the digital system surveyed*** .
3. If the RWS or printer is FDA-cleared for FFDM, their ***QC manual*** is considered to be ***"substantially the same"*** and may be followed. (Check with the RWS or printer manufacturers for their clearance status and QC manual.)
4. If the RWS or printer is not cleared by the FDA for FFDM, ***follow the QC manual provided by the image receptor manufacturer*** . (Check with the image receptor manufacturer for their required tests.)
5. All tests must be evaluated for the facility's ***on and off-site*** equipment. If the evaluation was done on a different day than the survey date, note the date above.
6. See the FDA-approved alternative standard for Siemens FFDM regarding corrective action periods when components fail QC. However, if these tests are performed as part of a Mammography Equipment Evaluation (e.g., for a new system), corrective action must be taken before mammographic images are acquired.