

March 11, 2025

Shane McCotter

████████████████████
SUPERIOR, WI 54880

Dear Shane McCotter,

This letter is to verify that you have met *all MQSA initial qualification requirements as stated in the final regulations, 900.12(a)(3)(i)* and all Iowa registration requirements for a medical physicist in:

Mammography: Digital
Mammography: Tomosynthesis

Therefore, you are permitted to perform all those procedures required under Iowa Radiation Machines Rules for the above categories. Your **registration number MPHY10075** expires on April 30, 2026.

Each Iowa facility where you provide medical physics services must have a copy of this Medical Physics Approval letter.

Thank you for your cooperation. Please call 515-285-3246 if you have any questions.

Sincerely,



Patty Riesberg, Bureau Chief
Bureau of Radiological Health
Office Phone: 515-371-2255
Email: patty.riesberg@hhs.iowa.gov



December 9, 2021

**ATTESTATION REGARDING INITIAL REQUIREMENTS OF
THE MAMMOGRAPHY QUALITY STANDARDS ACT AND/OR ACR REQUIREMENTS FOR DIGITAL AND DBT
BREAST IMAGING**

This document is intended to provide proof of medical physicist's initial qualification in Digital and Tomosynthesis (DBT) Mammography.

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance, reading/interpreting, or other activity dates; and the supervising/responsible person (where applicable) for the institution/facility.

I, Steven Nicholas, attest that, to the best of my knowledge and my belief, the following information provided in this declaration is true and correct. Under my direct supervision, Shane McCotter, MS, a Radiation Physics Consultants, Inc. physicist, has met the Initial Qualifications requirements of MQSA and the FDA with 8 hours of Digital Mammography training and 28 hours of DBT Mammography training.

"Have a master's degree or higher in a physical science with at least 20 semester hours (30 quarter hours) of graduate or undergraduate physics, and, have the experience of conducting surveys of at least one mammography facility with a total of at least 10 mammography units, and at least 20 hours of mammography facility survey training."

Please see the addition details on the following pages.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Steven T. Nicholas', is written over a light blue circular background.

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

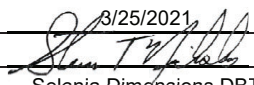
Facility	Type of Unit	Description of Tests	Time (hrs)	Date
St. Luke's Clinic (Ashland, WI)	DBT	Annual Physics Survey	3.00	3/25/2021
Essentia Health Clinic (Ashland, WI)	Digital	Annual Physics Survey	3.00	3/25/2021
Essentia Health Hospital (Moose Lake, MN)	DBT	Annual Physics Survey	3.00	4/26/2021
Lake View Hospital (Two Harbors, MN)	DBT	Annual Physics Survey	3.00	6/17/2021
Welia Clinic (Pine City, MN)	DBT	Annual Physics Survey	3.00	7/6/2021
North Shore Hospital (Grand Marais, MN)	DBT	Annual Physics Survey	3.00	7/13/2021
Memorial Hospital (Ashland, WI)	DBT	Annual Physics Survey	3.50	7/22/2021
Rainy Lake Medical Center (I'Falls, MN)	DBT	Annual Physics Survey	3.50	7/27/2021
Essentia Health Clinic (I'Falls, MN)	Digital	Annual Physics Survey	2.50	7/27/2021
St. Lukes Mariner Clinic (Superior, WI)	Digital	Annual Physics Survey	2.50	9/13/2021
Riverwood Hospital (Aitkin, MN)	DBT	Annual Physics Survey	3.00	9/14/2021
St. Francis Hospital (Shakopee, MN)	DBT	Annual Physics Survey	3.00	10/13/2021

Total DBT (hrs): 28

Total Digital (hrs): 8

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

Full-Field Digital – Lorad

Site Name	St Luke's - Chequamegon Clinic	Report Date	3/25/2021
Address	2201 Lakeshore Drive E, Ashland, WI 54806	Survey Date	3/25/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)	Signature	
X-Ray Unit Manufacturer	Hologic	Model	Selenia Dimensions DBT
Date of Installation	3/14/2018	Room ID	Mammography/DEXA Room #129
		SN	SDM131900240

QC Manual Version # MAN-03706, Rev. 007 (March 2018) (use any version applicable to model; contact mfr if questions)




Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	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.fda.gov/CDRH/MAMMOGRAPHY/robhelp/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 $\leq 2\%$ 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 <small>(no significant artifacts visible)</small>	Pass
4. kVp Accuracy and Reproducibility	
Measured average kVp within $\pm 5\%$ of indicated kVp	Pass
kVp coefficient of variation ≤ 0.02	Pass
5. Beam Quality Assessment - HVL Measurement	Pass
6. Evaluation of System Resolution <small>(system limiting spatial resolution >7 cycles/mm (lp/mm))</small>	Pass
7. Automatic Exposure Control (AEC) Function Performance <small>(NA for systems without AEC)</small>	
Each pixel value (2-8 cm; all operating modes) within $\pm 10\%$ 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 109 Conventional	
mrad 138 Tomosynthesis Option	
Coefficient of variation for either R or mAs ≤ 0.05 (NA for systems without AEC)	Pass
9. Radiation Output Rate <small>(> 230 mR/sec)</small>	
mR/sec 620	Pass
10. Phantom Image Quality Evaluation	
Phantom image quality scores (Conventional)	
 Fibers 5.5 Specks 4.0 Masses 4.0	Pass
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 <small>(values required for all tests)</small>	
SNR (value) 53.3	Pass
CNR (value) 10.4 <small>(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)</small>	
CNR should not vary by more than $\pm 15\%$ (NA for Equipment Evaluation)	Pass
12. Diagnostic Review Workstation (RWS) QC <small>(for all RWS, even if located offsite; NA if only hardcopy read)</small>	Pass
13. DICOM Printer QC <small>(Mammography Equipment Evaluations only)</small>	NA
14. Detector Flat Field Calibration <small>(Mammography Equipment Evaluations only)</small>	NA
15. Compression Thickness Indicator <small>(Mammography Equipment Evaluations only)</small>	Pass
16. Compression <small>(Mammography Equipment Evaluations only)</small>	NA
17. Geometry Calibration 	Pass

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

Steven T. Nicholas and Shane McCotter (training)

	Frequency	PASS/FAIL
1. DICOM Laser Printer Quality Control	Weekly	NA
2. Detector Flat-Field Calibration	Weekly	PASS
3. Geometry Calibration (Tomosynthesis Option) 	Semi-annually	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 a Medical Physicist's annual survey.

Medical Physicist's QC Tests

No Discrepancies.

Note: Your 2D dose is starting to get low. The next time service is on site, have a service engineer adjust the dose scale back up to 1.2 mGy dose to the ACR phantom.

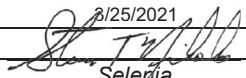
Evaluation of Site's Technologist QC Program

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	Essentia Health - Ashland Clinic	Report Date	4/22/2021
Address	1625 Maple Lane, Ashland, WI 54806	Survey Date	3/25/2021
Medical Physicist's Name	Steven T. Nicholas (Shane McCotter, trainee)	Signature	
X-Ray Unit Manufacturer	Lorad	Model	Selenia
Date of Installation	11/18/2010, moved 4/28/2016	Room ID	Mammo

QC Manual Version: (check one; **must** use version applicable to unit tested; contact mfr if questions)

☐ MAN-00093, Rev. 008

☐ OTHER (write in):

MAN-01476 Rev. 001 June 2009

Accessory Equipment:

Manufacturer	Model	Location	QC Manual Version
Review Workstation*	Barco/Hologic	<input type="checkbox"/> On-site <input type="checkbox"/> Off-site	MAN-01476 Rev. 001 June 2009
Laser Film Printer*	NA	<input type="checkbox"/> On-site <input type="checkbox"/> Off-site	NA

**FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used, but the use of others is also legal. See FDA's Policy Guidance Help System Modification Document #9 (page 27).*

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

Medical Physicist's QC Tests

1. Mammographic Unit Assembly Evaluation

- Performs according to 1999 ACR Mammography Quality Control Manual
- Autodecompression can be overridden to maintain compression (& status displayed)
- Manual emergency compression release can be activated in the event of power failure

PASS/FAIL

Pass

Pass

Pass

2. Collimation Assessment

- Deviation between X-ray field and light field $\leq 2\%$ of SID
- X-ray field does not extend beyond any side of the IR by $>2\%$ of SID
- X-ray field covers all of the IR on the chest wall side
- Paddle chest wall edge does not extend beyond IR by $>1\%$ of SID or appear on mammogram

Pass

Pass

Pass

Pass

Pass

3. Artifact Evaluation (no significant artifacts visible)

Pass

4. kVp Accuracy and Reproducibility

- Measured average kVp within $\pm 5\%$ of indicated kVp
- kVp coefficient of variation ≤ 0.02

Pass

Pass

5. Beam Quality Assessment - HVL Measurement

Pass

Pass

7. Automatic Exposure Control (AEC) Function Performance (NA for systems without AEC)

- Each pixel value (2-8 cm; all operating modes) within $\pm 10\%$ of mean
- Exposure compensation steps performance within acceptable limits

Pass

Pass

8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose

- Average glandular dose for average breast is ≤ 3 mGy (300 mrad)
- Coefficient of variation for either R or mAs ≤ 0.05 (NA for systems without AEC)

124 mrad

Pass

Pass

9. Radiation Output Rate (>7.0 mGy air kerma/sec (800 mR/sec) @ 28 kVp, Mo/Mo)

Pass

10. Phantom Image Quality Evaluation

- 5 largest fibers, 4 largest speck groups and 4 largest masses are visible*
- (*4.5 fibers, 4.0 speck groups and 3.5 masses may be acceptable under certain circumstances)
- Phantom image quality scores: Fibers Specks Masses
- Hard copy background density must be ≥ 1.20 (with operating level ≥ 1.40)
- Hard copy density difference (DD) over acrylic disk must be within acceptable limits
- Optical densities: Background Disk DD

Pass

NA

NA

11. Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR) Measurement (values required for all tests)

- SNR is ≥ 40
- CNR should not vary by more than $\pm 15\%$ (NA for Equipment Evaluation)

SNR

CNR

Pass

Pass

12. Viewbox Luminance and Room Illuminance

- Mammographic viewbox is capable of a luminance of at least 3000 cd/sq m (nit)
- Room illuminance (viewbox surface as seen by observer) is ≤ 50 lux
- Room illuminance (monitor surface) is ≤ 20 lux for softcopy reading

Pass

Pass

Pass

13. Review Workstation (RWS) Tests* (for all RWS, even if located offsite)

- Overall Results ("Pass" means all tests pass; indicate "Fail" if any test fails)

Pass

****FDA requires that all RWS comply with a QC program that is substantially the same as that recommended by the image receptor manufacturer.**
 If the RWS is FDA-approved, the RWS's QC manual is considered to be "substantially the same" and you may follow it. (Check with the RWS manufacturer for their FDA clearance status and QC manual.) If the RWS is **not** FDA-approved for FFDM, you **must** follow the QC manual provided by the image receptor manufacturer. (Check with the image receptor manufacturer for their required tests.)

***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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 MQSA Regs
1. Darkroom Cleanliness (if applicable)	Daily	NA
2. Processor Quality Control (if applicable)	Daily	NA
3. Laser Printer Quality Control	Weekly*	NA
4. Viewboxes and Viewing Conditions	Weekly	Pass
5. Artifact Evaluation	Weekly	Pass
6. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
7. Phantom Image	Weekly	Pass
8. Detector Flat-Field Calibration	Weekly	Pass
9. Compression Thickness Indicator	Bi-weekly	Pass
10. Visual Checklist	Monthly	Pass
11. Analysis of Fixer Retention in Film (if applicable)	Quarterly	NA
12. Repeat Analysis	Quarterly	Pass
13. Darkroom Fog (if applicable)	Semi-annually	NA
14. Compression	Semi-annually	Pass
15. Review Workstation QC-Overall	See FDA guidance	Pass

* Dry laser printer (daily if wet processor used)

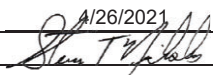
Medical Physicist's Recommendations for Quality Improvement

This is an annual medical physics survey.
Medical Physicist's QC Tests No Discrepancies
Note: Site does not print hard copy. The RWS is off-site at the Breast Center in Duluth, MN.
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/Hologic

Site Name	Essentia Health Moose Lake	Report Date	4/30/2021
Address	4572 Co. Rd. 61, Moose Lake, MN 55767	Survey Date	4/26/2021
Medical Physicist's Name	Steven T. Nicholas (w/ Shane McCotter (trainee))	Signature	
X-Ray Unit Manufacturer	Lorad/Hologic	Model	Selenia Dimensions DBT
Date of Installation	1/20/2017	Room ID	Mammo Rm 1
		SN	81012167628
QC Manual Version #	MAN-03706, Rev. 006 (June 2017) <i>(use any version applicable to model; contact mfr if questions)</i>		

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	SecureView	Off-Site	MAN-03706, Rev. 009 (June 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 <i>(NA for systems without AEC)</i>	Pass
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose	
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(conventional)</i>	Pass
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(DBT)</i>	Pass
9. Radiation Output Rate	Pass
10. Phantom Image Quality Evaluation	
Phantom image scores <i>(conventional)</i>	Pass
Phantom image scores <i>(DBT)</i>	Pass
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <i>(values required for all tests)</i>	
SNR <i>(value)</i>	Pass
CNR <i>(value)</i>	
50.8	
10.71 <i>(required for new unit MEE and Annual Survey)</i>	
CNR should not vary by more than $\pm 15\%$ <i>(NA for MEE)</i>	Pass
12. Diagnostic Review Workstation (RWS) QC <i>(for all RWS, even if located offsite; NA if only hardcopy read)</i>	Pass
13. DICOM Printer QC <i>(if applicable, MEE only)</i>	NA
14. Detector Flat Field Calibration <i>(MEE only)</i>	NA
15. Geometry Calibration For Tomosynthesis <i>(DBT MEE only)</i>	Pass
16. Compression Thickness Indicator <i>(MEE only)</i>	Pass
17. Compression <i>(MEE only)</i>	NA
18. Detector Ghosting <i>(troubleshooting only)</i>	NA


***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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 Laser Printer Quality Control	Weekly	NA
2. Detector Flat-Field Calibration	Weekly	PASS
3. Geometry Calibration (Tomosynthesis Option) 	Semi-annually	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 an annual survey.

Medical Physicist's QC Tests

No Discrepancies.

Note: A deep AEC recalibration was performed after this testing (on 4/30/2021). Results from that MEE are in a separate report.

Evaluation of Site's Technologist QC Program

No Discrepancies.

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.)


***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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	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 (Tomosynthesis 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 a Medical Physicist's annual survey.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

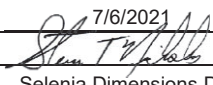
No Discrepancies. Make sure the compression force test is performed in "Full" rather than "Dual".

Facility does not print hard copy. The St. Luke's RWS results are included. A different physics group performs the RWS testing for CRL.

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	CMDI at FirstLight Health System	Report Date	8/5/2021
Address	1425 N Main Street, Pine City, MN 55063	Survey Date	7/6/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)	Signature	
X-Ray Unit Manufacturer	Lorad/Hologic	Model	Selenia Dimensions DBT
Date of Installation	7/10/2019	Room ID	Mammo
		SN	SDM131900771
QC Manual Version #	MAN-03706, Rev. 008 (Dec 2018) <i>(use any version applicable to model; contact mfr if questions)</i>		

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	<input type="checkbox"/> On-site <input type="checkbox"/> 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/Polis_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 <i>(NA for systems without AEC)</i>		Pass
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose		
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(conventional)</i>	116	mrad
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(DBT)</i>	143	mrad
9. Radiation Output Rate		Pass
10. Phantom Image Quality Evaluation		
Phantom image scores <i>(conventional)</i>	6.0	4.0
Phantom image scores <i>(DBT)</i>	4.5	4.0
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <i>(values required for all tests)</i>		
SNR <i>(value)</i>	56.9	
CNR <i>(value)</i>	11.43	
CNR should not vary by more than $\pm 15\%$ <i>(NA for MEE)</i>		
12. Diagnostic Review Workstation (RWS) QC <i>(for all RWS, even if located offsite; NA if only hardcopy read)</i>		PASS
13. DICOM Printer QC <i>(if applicable, MEE only)</i>		Pass
14. Detector Flat Field Calibration <i>(MEE only)</i>		NA
15. Geometry Calibration For Tomosynthesis <i>(DBT MEE only)</i>		NA
16. Compression Thickness Indicator <i>(MEE only)</i>		Pass
17. Compression <i>(MEE only)</i>		Pass
18. Detector Ghosting <i>(troubleshooting only)</i>		NA


***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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 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 a Medical Physicist's Annual Survey

Medical Physicist's QC Tests

No Discrepancies.

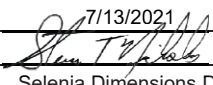
Evaluation of Site's Technologist QC Program

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/Hologic

Site Name	North Shore Health	Report Date	7/26/2021
Address	515 5th Ave West, Grand Marais, MN 55604	Survey Date	7/13/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)	Signature	
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. 008 (Dec 2018) <small>(use any version applicable to model; contact mfr if questions)</small>		

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	<input type="checkbox"/> On-site <input type="checkbox"/> 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/Polis_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 <small>(NA for systems without AEC)</small>		Pass
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose		
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <small>(conventional)</small>	119 mrad	Pass
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) (DBT)	143 mrad	Pass
9. Radiation Output Rate		Pass
10. Phantom Image Quality Evaluation		
Phantom image scores <small>(conventional)</small>	5.5 4.0 5.0	Pass
Phantom image scores (DBT)	5.0 4.0 4.5	Pass
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <small>(values required for all tests)</small>		
SNR <small>(value)</small>	54.0	Pass
CNR <small>(value)</small>	10.60	
<small>(required for new unit MEE and Annual Survey)</small>		
CNR should not vary by more than $\pm 15\%$ <small>(NA for MEE)</small>		Pass
12. Diagnostic Review Workstation (RWS) QC <small>(for all RWS, even if located offsite; NA if only hardcopy read)</small>		Pass
13. DICOM Printer QC <small>(if applicable, MEE only)</small>		NA
14. Detector Flat Field Calibration <small>(MEE only)</small>		NA
15. Geometry Calibration For Tomosynthesis (DBT MEE only)		Pass
16. Compression Thickness Indicator <small>(MEE only)</small>		Pass
17. Compression <small>(MEE only)</small>		NA
18. Detector Ghosting <small>(troubleshooting only)</small>		NA

***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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 <i>(if applicable)</i>	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 (Tomosynthesis Option) <i>(DBT)</i>	Semi-annually	Pass
12. Diagnostic Review Workstation QC <i>(NA if only hardcopy read)</i>	See Hologic QC Manual	Pass
13. Mobile Unit Quality Control <i>(if applicable)</i>	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 – Siemens

Site Name	Memorial Medical Center	Report Date	8/11/2021
Address	1615 Maple Ln, Ashland, WI 54806	Survey Date	7/22/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter	Signature	
X-Ray Unit Manufacturer	Siemens	Model	Mammomat Revelation Tomosynthesis
Date of Installation	6/14/2018	Room ID	DBT Mammo

QC Manual Version # Tomo QC 56.01.24, 2D QC 51.01.24 (use version applicable to unit tested; contact mfr if questions)

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	MDMG-5121	<input checked="" type="checkbox"/> On-site <input type="checkbox"/> Off-site	Hologic Man-01478
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	<input type="checkbox"/> Mammo Eqpt Evaluation (MEE) of new unit (include MQSA Rqmts for Mammo Eqpt checklist)	<input checked="" type="checkbox"/> Annual Survey
Features	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> 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)		Pass
	Phantom image scores:	Fibers <input type="text" value="5.5"/> Specks <input type="text" value="4.0"/> Masses <input type="text" value="4.5"/>	
2. Artifact Detection			Pass
3. Printer Check (if applicable)			NA
4. SNR, CNR and AEC Repeatability	Measured values: SNR <input type="text" value="57.3"/> CNR <input type="text" value="2.28"/> CV for mAs and entrance air kerma $\leq 5\%$ Max deviation of mean pixel values and SNR within $\pm 15\%$ of mean for measurements		Pass
5. Radiation Dose	2D Average glandular dose for average breast is ≤ 3 mGy (300 mrad)	<input type="text" value="63"/> mrad	Pass
	3D Average glandular dose for average breast is ≤ 3 mGy (300 mrad)	<input type="text" value="130"/> mrad	Pass
	2D+3D Average glandular dose for average breast is ≤ 3 mGy (300 mrad) TOTAL	<input type="text" value="193"/> mrad	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)			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 <input type="text" value="6.0"/> Specks <input type="text" value="4.0"/> Masses <input type="text" value="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 *****

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(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	NA
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

* For Mammomat Revelation, indicate NA-calibration required before QC but does not need to be documented

Medical Physicist's Recommendations for Quality Improvement

This is an annual survey.

Medical Physicist's QC Tests

There are no discrepancies.

Note: At the time of testing we noted that there was 6.5mm of "Chest Wall Missing Tissue" (also known as "Detector Dead Space"). A service engineer corrected the issue on 7/29/2021 and I received the images to review on 8/11/2021. The service images appear to show that the problem was corrected.

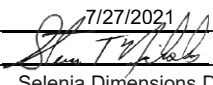
Evaluation of Technologist QC Program

There are no discrepancies.

Average glandular dose for average breast is <3 mGy (300 mrad) TOTAL of 2D and 3D

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

Full-Field Digital – Lorad/Hologic

Site Name	Rainy Lake Medical Center	Report Date	8/4/2021
Address	1400 Highway 71, International Falls, MN 56649	Survey Date	7/27/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)	Signature	
X-Ray Unit Manufacturer	Lorad/Hologic	Model	Selenia Dimensions DBT
Date of Installation	10/15/2020	Room ID	Mammo
		SN	SDM131901306
QC Manual Version #	MAN-03706, Rev. 010 (Aug 2020) <small>(use any version applicable to model; contact mfr if questions)</small>		

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	<input checked="" type="checkbox"/> On-site <input type="checkbox"/> Off-site	MAN-04959, Rev. 006
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/Polis_Guidance_Help_System.htm).

Survey Type- Annual Mammography Equipment 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 <i>(NA for systems without AEC)</i>	Pass
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose	
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(conventional)</i>	123 mrad
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(DBT)</i>	150 mrad
9. Radiation Output Rate	Pass
10. Phantom Image Quality Evaluation	
Phantom image scores <i>(conventional)</i>	Pass
Phantom image scores <i>(DBT)</i>	Pass
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <i>(values required for all tests)</i>	
SNR <i>(value)</i>	56.6
CNR <i>(value)</i>	11.04
<i>(required for new unit MEE and Annual Survey)</i>	
CNR should not vary by more than $\pm 15\%$ <i>(NA for MEE)</i>	Pass
12. Diagnostic Review Workstation (RWS) QC <i>(for all RWS, even if located offsite; NA if only hardcopy read)</i>	Pass
13. DICOM Printer QC <i>(if applicable, MEE only)</i>	NA
14. Detector Flat Field Calibration <i>(MEE only)</i>	NA
15. Geometry Calibration For Tomosynthesis <i>(DBT MEE only)</i>	Pass
16. Compression Thickness Indicator <i>(MEE only)</i>	Pass
17. Compression <i>(MEE only)</i>	NA
18. Detector Ghosting <i>(troubleshooting only)</i>	NA


***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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	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 (Tomosynthesis 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 Equipment Evaluation.

Medical Physicist's QC Tests

No Discrepancies.


Evaluation of Site's Technologist QC Program

There are 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	Essentia Health International Falls		Report Date	8/24/2021
Address	2501 Keenan Dr, International Falls, MN 56649		Survey Date	7/27/2021
Medical Physicist's Name	Steven Nicholas and Shane McCotter(training)		Signature	
X-Ray Unit Manufacturer	Lorad/Hologic		Model	Selenia
Date of Installation	1/16/15		Room ID	Mammo

QC Manual Version # **MAN-01476 Rev. 002 Sept 2014** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Hologic	SecurView	<input checked="" type="checkbox"/> On-site <input type="checkbox"/> Off-site	Man-01476 Rev001
Film Printer*	NA	NA	<input type="checkbox"/> On-site <input type="checkbox"/> Off-site	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	<input type="checkbox"/> Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist)	<input checked="" type="checkbox"/> Annual Survey
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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		Pass
	Average glandular dose for average breast is ≤ 3 mGy (300 mrad)	120	mrads
9.	Radiation Output Rate		Pass
10.	Phantom Image Quality Evaluation		Pass
	Phantom image scores:	Fibers 5.0 Specks 4.0 Masses 4.5	
11.	Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements	(values required for all tests)	
	SNR (value)	54.4	Pass
	CNR (value)	11.07	(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)
	CNR should not vary by more than $\pm 15\%$	(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)	Pass

***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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 MQSA Regs
1. Darkroom Cleanliness (if applicable)	Daily	NA
2. Processor Quality Control (if applicable)	Daily	NA
3. Laser Printer Quality Control	Weekly*	NA
4. Viewboxes and Viewing Conditions	Weekly	Pass
5. Artifact Evaluation	Weekly	Pass
6. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
7. Phantom Image	Weekly	Pass
8. Detector Flat-Field Calibration	Weekly	Pass
9. Compression Thickness Indicator	Bi-weekly	Pass
10. Visual Checklist	Monthly	Pass
11. Analysis of Fixer Retention in Film (if applicable)	Quarterly	NA
12. Repeat Analysis	Quarterly	Pass
13. Darkroom Fog (if applicable)	Semi-annually	NA
14. Compression	Semi-annually	Pass
15. Review Workstation QC-Overall	See FDA guidance	Pass

* Dry laser printer (daily if wet processor used)

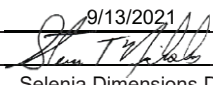
Medical Physicist's Recommendations for Quality Improvement

<p>This is an Annual Evaluation on a mammo unit.</p> <p>Medical Physicist's QC Tests</p> <p>No Discrepancies</p>
<p>This site does not print hard copy films.</p> <p>Evaluation of Site's Technologist QC Program</p> <p>No Discrepancies.</p>

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	9/20/2021
Address	109 North 28th St, Superior, WI 54880	Survey Date	9/13/2021
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)	Signature	
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) <i>(use any version applicable to model; contact mfr if questions)</i>		

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMG-5221	<input type="checkbox"/> On-site <input type="checkbox"/> 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/Polis_Guidance_Help_System.htm).

Survey Type- Mammography Equipment Evaluation following tube replacement. Annual survey 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 <i>(NA for systems without AEC)</i>		Pass						
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose								
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) <i>(conventional)</i>	121	Pass						
Average glandular dose for average breast is ≤ 3 mGy (300 mrad) (DBT)	150	Pass						
9. Radiation Output Rate		Pass						
10. Phantom Image Quality Evaluation								
Phantom image scores <i>(conventional)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 33%;">Fibers</th> <th style="width: 33%;">Specks</th> <th style="width: 33%;">Masses</th> </tr> <tr> <td style="text-align: center;">6.0</td> <td style="text-align: center;">4.0</td> <td style="text-align: center;">4.5</td> </tr> </table>	Fibers	Specks	Masses	6.0	4.0	4.5	Pass
Fibers	Specks	Masses						
6.0	4.0	4.5						
Phantom image scores (DBT)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 33%;">Fibers</th> <th style="width: 33%;">Specks</th> <th style="width: 33%;">Masses</th> </tr> <tr> <td style="text-align: center;">6.0</td> <td style="text-align: center;">4.0</td> <td style="text-align: center;">4.5</td> </tr> </table>	Fibers	Specks	Masses	6.0	4.0	4.5	Pass
Fibers	Specks	Masses						
6.0	4.0	4.5						
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <i>(values required for all tests)</i>								
SNR (value)	56.1	Pass						
CNR (value)	10.79							
CNR should not vary by more than $\pm 15\%$ <i>(NA for MEE)</i>		Pass						
12. Diagnostic Review Workstation (RWS) QC <i>(for all RWS, even if located offsite; NA if only hardcopy read)</i>		Pass						
13. DICOM Printer QC <i>(if applicable, MEE only)</i>		NA						
14. Detector Flat Field Calibration <i>(MEE only)</i>		Pass						
15. Geometry Calibration For Tomosynthesis (DBT MEE only)		Pass						
16. Compression Thickness Indicator <i>(MEE only)</i>		Pass						
17. Compression <i>(MEE only)</i>		Pass						
18. Detector Ghosting <i>(troubleshooting only)</i>		NA						


***** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS 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	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 (Tomosynthesis 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 Medical Physicist's Equipment Evaluation on a DBT unit following tube replacement. A full annual survey was also performed because it was due.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

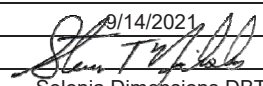
No discrepancies.

Note: I recommend not using a pad under the bathroom scale when performing the semi-annual compression test as it gives incorrectly high readings as shown in your QC records. When we repeated the tests together to troubleshoot your high QC results, using a pad was shown to erroneously increase the measured result by about 5 lbs. It is probable that your prior results would have been well within the 25-45 lb range.

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	Riverwood Health Care Center			Report Date	10/15/2021
Address	200 Bunker Hill Drive, Aitkin, MN 56431			Survey Date	9/14/2021
Medical Physicist's Name	Steven T. Nicholas & Shane McCotter (Training)			Signature	
X-Ray Unit Manufacturer	Lorad/Hologic			Model	Selenia Dimensions DBT
Date of Installation	3/14/2018			Room ID	Mamm Rm #230
				SN	SDM131500537
QC Manual Version #	MAN-03706 Rev. 007 (March 2018)			(use any version applicable to model; contact mfr if questions)	
Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #	
Review Workstation*	Barco/Hologic	MDMG-5221	<input checked="" type="checkbox"/> On-site <input type="checkbox"/> 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 ☒ 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. 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)	125 mrad
 Average glandular dose for average breast is ≤3 mGy (300 mrad) (DBT)	149 mrad
9. Radiation Output Rate	Pass
10. Phantom Image Quality Evaluation	
 Phantom image scores (conventional)	Pass
 Phantom image scores (DBT)	Pass
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements (values required for all tests)	
SNR (value)	54.7
CNR (value)	10.80 (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 Tomosynthesis (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 THIS FORM ***

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Lorad, continued)

Evaluation of Site's Technologist QC Program

Steven T. Nicholas & Shane McCotter (Training)

	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 a Medical Physicist's equipment evaluation followin a deep AEC recalibration and collimator repair. A full annual survey was also completed for timing purposes.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program


There are 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

(Lorad, continued)

Evaluation of Site's Technologist QC Program

	Frequency	PASS/FAIL
1. DICOM Printer Quality Control <i>(if applicable)</i>	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 (Tomosynthesis Option) <i>(DBT)</i> 	Semi-annually	PASS
12. Diagnostic Review Workstation QC <i>(NA if only hardcopy read)</i>	See Hologic QC Manual	PASS
13. Mobile Unit Quality Control <i>(if applicable)</i>	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.)

John Patrick University of Health and Applied Sciences

Upon recommendation of the Faculty,

John Patrick University of Health and Applied Sciences
has conferred upon

SHANE MCCOTTER

the degree of

MASTER OF SCIENCE IN MEDICAL PHYSICS

Who has honorably fulfilled all the requirements prescribed
by the University for that degree

at South Bend, Indiana this twenty-first day of December in
the year of our Lord two thousand and twenty



Brenda Murphy
President

John Patrick University of Health and Applied Sciences

100 E. Wayne Street, Suite 140, South Bend, IN 46601

PH 574.232.2408 FAX 574.232.2200

SHANE McCOTTER

Date of Birth 03/16/1989

Social Security

Student ID Number 232109

Enrollment Date 05/06/2019

Program MS MEDICAL PHYSICS

Summer 2019

COURSE NO.	COURSE TITLE	GRADE	CRED	QPts
BIOL530	HUMAN ANATOMY & PHYSIOLOGY	B	4	12
MP590	MEDICAL & PROFESSIONAL ETHICS	A	1	4
MP502	RADIATION BIOLOGY	B	3	9

Term: EHRS	8	QPts	25	GPA	3.13
Cumulative: EHRS	8	QPts	25	GPA	3.13
Cumulative Program: EHRS	8	QPts	25	GPA	3.13
					3

Fall 2019

COURSE NO.	COURSE TITLE	GRADE	CRED	QPts
MP503	DIAGNOSTIC RADIOLOGY	A	3	12
MP505	RADIATION ONCOLOGY I	B	3	9
MP599 S9	SEMINARS SESSION 9	A	1	4

Term: EHRS	7	QPts	25	GPA	3.57
Cumulative: EHRS	15	QPts	50	GPA	3.33
Cumulative Program: EHRS	15	QPts	50	GPA	3.33

Spring 2020

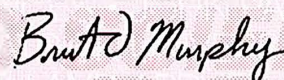
COURSE NO.	COURSE TITLE	GRADE	CRED	QPts
MP603	ADVANCED DIAGNOSTIC RADIOLOGY	A	2	8
MP520	COMPUTER SYSTEMS IN MEDICINE	A	2	8
MP506	RADIATION ONCOLOGY II	A	3	12

Term: EHRS	7	QPts	28	GPA	4.00
Cumulative: EHRS	22	QPts	78	GPA	3.55
Cumulative Program: EHRS	22	QPts	78	GPA	3.55

***** CONTINUED ON NEXT PAGE *****



Elizabeth M Datema
Office of the Registrar



Brent D. Murphy, MS, DABR
President

John Patrick University of Health and Applied Sciences

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PH 574.232.2408 FAX 574.232.2200

SHANE McCOTTER

Date of Birth 03/16/1989

Social Security [REDACTED]

Student ID Number 232109

Enrollment Date 05/06/2019

Program MS MEDICAL PHYSICS

Summer 2020

COURSE NO.	COURSE TITLE	GRADE	CRED	QPts
MHP510	HEALTH PHYSICS/RADIATION SAFETY NUCLEAR MEDICINE	A	3	12
MP504	STATISTICAL METHODS	A	3	12
STAT501		A	3	12

Term: EHRS	9	QPts	36	GPA	4.00
Cumulative: EHRS	31	QPts	114	GPA	3.68
Cumulative Program: EHRS	31	QPts	114	GPA	3.68

Fall 2020

COURSE NO.	COURSE TITLE	GRADE	CRED	QPts
MP699	CLINICAL INTERNSHIP	P	4	16
MP613	NUCLEAR ONCOLOGY	A	3	12
MP501	RADIATION DOSIMETRY	A	4	16
MP508	RADIOLOGICAL INSTRUMENTATION	A	2	8
MHP601	SHIELDING DESIGN	A	2	8

Term: EHRS	15	QPts	60	GPA	4.00
Cumulative: EHRS	46	QPts	174	GPA	3.78
Cumulative Program: EHRS	46	QPts	174	GPA	3.78

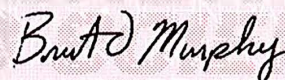
***** END OF RECORD *****

DEGREE AWARDED

12/21/2020 Master of Science in Medical Physics



Elizabeth M Datema
Office of the Registrar



Brent D. Murphy, MS, DABR
President

