March 6, 2024

Shane McCotter
[redacted]
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, 2025.

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

Patty Riesberg, Bureau Chief
Bureau of Radiological Health
Office Phone: 515-281-3478
Fax: <FaxNumber>
Email: Patricia.Riesberg@idph.iowa.gov

Radiation Physics
CONSULTANTS

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,

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/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**
TOMO	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** *(> 230 mR/sec)* mR/sec 620	**Pass**
10.	**Phantom Image Quality Evaluation**	
	Phantom image quality scores (Conventional) Fibers 5.5 Specks 4.0 Masses 4.0	**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)* 53.3	**Pass**
	CNR *(value)* 10.4 *(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	**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	5621/SecureView	☐ On-site ☒ Off-site	MAN-01476 Rev. 001 June 2009
Laser Film Printer*	NA	NA	☐ On-site ☒ 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

		PASS/FAIL
1.	**Mammographic Unit Assembly Evaluation**	
	Performs according to 1999 ACR Mammography Quality Control Manual	**Pass**
	Autodecompression can be overridden to maintain compression (& status displayed)	**Pass**
	Manual emergency compression release can be activated in the event of power failure	**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**
		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) — 124 mrad	**Pass**
	Coefficient of variation for either R or mAs ≤ 0.05 (NA for systems without AEC)	**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*	**Pass**
	(*4.5 fibers, 4.0 speck groups and 3.5 masses may be acceptable under certain circumstances)	
	Phantom image quality scores: Fibers 6.0 Specks 4.0 Masses 4.0	
	Hard copy background density must be ≥ 1.20 (with operating level ≥ 1.40)	**NA**
	Hard copy density difference (DD) over acrylic disk must be within acceptable limits	**NA**
	Optical densities: Background **NA** Disk **NA** DD **NA**	
11.	**Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR) Measurement** *(values required for all tests)*	
	SNR is ≥ 40 — SNR **61.3**	**Pass**
	CNR should not vary by more than ±15% *(NA for Equipment Evaluation)* — CNR **12.85**	**Pass**
12.	**Viewbox Luminance and Room Illuminance**	
	Mammographic viewbox is capable of a luminance of at least 3000 cd/sq m (nit)	**Pass**
	Room illuminance (viewbox surface as seen by observer) is ≤ 50 lux	**Pass**
	Room illuminance (monitor surface) is ≤ 20 lux for softcopy reading	**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

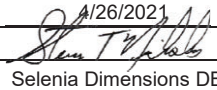
Note: Site does not print hard copy. The RWS is off-site at the Breast Center in Duluth, MN.

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)**	*(use any version applicable to model; contact mfr if questions)*	

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** *(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)*	106	mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	133	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)*	50.8		**Pass**
CNR *(value)*	10.71	*(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)***	**Pass**
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 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.)

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

Site Name	Lake View Clinic	**Report Date**	6/17/2021
Address	1010 4th Street, Two Harbors, MN 55616	**Survey Date**	6/17/2021
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	2/22/2018	**Room ID**	Mammo Room
		SN	SDM131900219

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 ☐ 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)*	112	mrad	Pass
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	142	mrad	Pass
9.	**Radiation Output Rate**			Pass

10. **Phantom Image Quality Evaluation**	Fibers	Specks	Masses	PASS/FAIL
Phantom image scores *(conventional)*	5.5	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)*	55.6		Pass
CNR *(value)*	11.05	*(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)***			Pass
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 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 (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 a Medical Physicist's annual survey.

Medical Physicist's QC Tests

No Discrepancies.

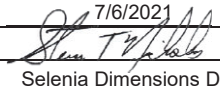
Evaluation of Site's Technologist QC Program

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 performes 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)**	*(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- **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)*	116	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**	**Fibers**	**Specks**	**Masses**	
Phantom image scores *(conventional)*	6.0	4.0	4.5	**Pass**
Phantom image scores ***(DBT)***	4.5	4.0	4.0	**Pass**

11. **Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements** *(values required for all tests)*			
SNR *(value)*	56.9		**Pass**
CNR *(value)*	11.43	*(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)***			**Pass**
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 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)**	*(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- **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)*	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**	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	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** *(values required for all tests)*			
SNR *(value)*	54.0		**Pass**
CNR *(value)*	10.60	*(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)***			**Pass**
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 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 *(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 – 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	☑ On-site ☐ 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 ☐ 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 5.5 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 57.3 CNR 2.28	**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**	**Pass**
	2D Average glandular dose for average breast is ≤3 mGy (300 mrad) 63 mrad	
	3D Average glandular dose for average breast is ≤3 mGy (300 mrad) 130 mrad	
	2D+3D Average glandular dose for average breast is ≤3 mGy (300 mrad) **TOTAL** **193** mrad	
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 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 ******

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 the 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)	*(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. 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/Polic_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** *(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)*	123	mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	150	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)*	56.6		**Pass**
CNR *(value)*	11.04	*(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)***			**Pass**
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 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 (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 Equipment Evaluation.

Medical Physicist's QC Tests

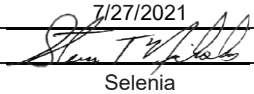
No Discrepancies.

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	☐ On-site ☑ Off-site	Man-01476 Rev001
Film Printer*	NA	NA	☐ On-site ☐ 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 ☐ Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist) ☑ Annual Survey

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 mrad	
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 ±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 <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 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 Evaluation on a mammo unit.

Medical Physicist's QC Tests

No Discrepancies

This site does not print hard copy films.

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	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)**	*(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- **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** *(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)*	121	mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	150	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)*	56.1		**Pass**
CNR *(value)*	10.79	*(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	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 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	☑ 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 ☑ 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	Pass
TOMO	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	149	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
TOMO 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)* 54.7		Pass
	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 Tomosynthsis** ***(DBT MEE only)*** TOMO		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
Full-Field Digital – Lorad/Hologic

Site Name	St. Francis Regional Medical Center	**Report Date**	10/19/2021
Address	Shakopee, MN	**Survey Date**	10/13/2021
Medical Physicist's Name	Steven T. Nicholas & Shane McCotter (Training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions
Date of Installation	10/9/2015	**Room ID**	1118 Mammo
		SN	81409155456
QC Manual Version #	**MAN-03706, Rev. 004 (April 2015)**	*(use any version applicable to model; contact mfr if questions)*	

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Hologic	SecureView	**On-Site**	MAN-03706, Rev. 004 (April 2015)
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**			**NA**
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)*	120	mrad	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	147	mrad	**Pass**
9.	**Radiation Output Rate**			**Pass**

10. **Phantom Image Quality Evaluation**	Fibers	Specks	Masses	
Phantom image scores *(conventional)*	5.5	4.0	4.5	**Pass**
Phantom image scores ***(DBT)***	5.0	4.0	4.5	**Pass**

11.	**Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements** *(values required for all tests)*		
	SNR *(value)* 54.3		**Pass**
	CNR *(value)* 11.09 *(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)***		**Pass**
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	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

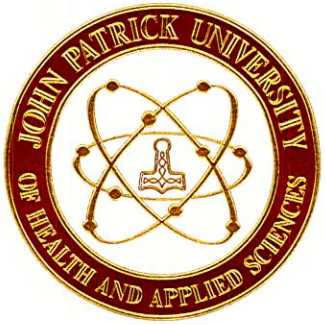
SHANE MCCOTTER

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



Brad 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 [redacted]

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

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

PH 574.232.2408 FAX 574.232.2200

SHANE McCOTTER		Student ID Number	232109
Date of Birth	03/16/1989	Enrollment Date	05/06/2019
Social Security	[redacted]	Program	MS MEDICAL PHYSICS

Summer 2020

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

John Patrick University of Health and Applied Sciences
100 E. Wayne Street, Ste. 140, South Bend, IN 46601
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KEY TO TRANSCRIPT OF ACADEMIC RECORDS

www.jpu.edu info@jpu.edu

Note: The following explanation reflects information found on the John Patrick University of Health and Applied Sciences (JPU) **Official Transcript** produced from the Student Information System implemented June 2011. Prior to August 5, 2019, JPU was doing business as Radiological Technologies University VT.

The information contained within this official transcript is protected by the Family Educational Rights and Privacy Act of 1974 and explained in the JPU Academic Catalog.

I. *Grade and Credit Point System*

The following grades are considered in computing semester or cumulative grade averages. Course hours with a grade of "F" are counted when computing grade point averages but do not count toward the earned hours required for degrees.

Graduate Courses

A (4.0 Pts) Excellent	F (0.0 Pts) Failing	
B (3.0 Pts) Good	P (4.0 Pts) Passed (Pass/Fail Option)	B (3.0 Pts)
C (0.0 Pts) Unsatisfactory	WF (0.0 Pts) Withdrawn – Failing	
D (0.0 Pts) Unsatisfactory		

Undergraduate Courses

A (4.0 Pts) Excellent		F (0.0 Pts)	Failing
Good	P (4.0 Pts)	Passed (Pass/Fail Option)	
C (2.0 Pts) Satisfactory		WF (0.0 Pts)	Withdrawn - Failing
D (0 Pts) Unsatisfactory			

Repeated Courses

Repeated courses are counted in the John Patrick University grade point average and may also be counted in the student's primary program GPA (Student Program GPA), depending on the policies of the student's program. The first attempt to complete a course is listed as attempted credits not earned.

The following grades are not considered in computing semester or cumulative grade point averages:

AU	Audit - No Credit
I	Incomplete/Pending
T	Denotes credits transferred from another Institution
W	Withdrawn
R	Repeated Course

Abbreviations and Symbols

EHRS	Credit hours earned
QPts	Quality Points Earned
GPA	Grade point average (computed by dividing QPts by EHRS)

Credit Types

Regular Credit – All John Patrick University credit is reported in terms of semester credit hours.

Academic Terms

John Patrick University of Health and Applied Sciences normally has the following terms each academic year:

Fall Semester	(15 weeks)	Usually begins early September
Spring Semester	(15 weeks)	Usually begins early January
Summer Semester	(15 weeks)	Usually begins early May

II. *Course Identification System*

Refer to the John Patrick University of Health and Applied Sciences Academic Catalog for full Course Numbering System Descriptions.

100-299	Associate level
300-499	Bachelor level
500-799	Graduate level

III. *Record Format*

The "Official Transcript" standard format lists course history, grade and GPA information in chronological order sorted by the student's career level. The "Official Transcript with Enrollment" provides the same information as the standard transcript but also includes all courses in which a student is currently enrolled or registered. "Official Transcript" or "Official Transcript with Enrollment" (Without career level designation) indicates that the document contains all work completed at John Patrick University.

The JPU GPA reflects the students GPA according to standard university wide rules. A Semester JPU GPA and a cumulative to date JPU GPA are calculated at the end of each semester. The overall JPU GPA summary statistics are reflected at the end of each student career level.

The Student Program GPA is calculated according to the rules determined by the student's primary academic program at the time of printing. The cumulative Student Program GPA summary statistics are reflected at the end of each student career level and are based on the student's last active primary program at that level.

IV. *Transfer, Test and Special Credit*

Courses accepted in transfer from other institutions are listed under a Transfer Credit heading. Generally, a grade of "T" (transfer grade) is assigned and course numbers, titles and credit hours assigned reflect JPU Equivalents. Transfer hours with a grade of "T" are not reflected in the cumulative grade averages; however, the hours are included in the "Hrs Earned" Field.

V. *Accreditation*

This Institution is authorized by the Indiana Commission for Higher Education/Board for Proprietary Education, 101 West Ohio Street, Suite 300 Indianapolis, Indiana 46204-4206.

This Institution is accredited by the Accrediting Commission of Career Schools and Colleges (ACCSC), 2101 Wilson Boulevard, Suite 302 Arlington, VA 22201. Phone (703) 247-4212. Website: www.accsc.org. ACCSC is recognized by the U.S. Department of Education.

This Institution is accredited by the Joint Review Committee on Education in Radiologic Technology, 20 North Wacker Drive, Suite 2850 Chicago, Illinois 60606-3182. Phone (312) 704-5300. Email: mail@jrcert.org

VI. *Validation*

A transcript issued by John Patrick University is official when it displays a signature and is printed on John Patrick University paper. The official University transcript is printed on SCRIP-SAFE Security paper and does not require a raised seal.

VII. *Registrar Contact*

Questions about the content of this record should be referred to the Office of the Registrar at 574-232-2408. The Key to Transcript the Transcript of Academic Records was last revised September 14, 2020.