November 19, 2024

Daniel Roach
7402 COUNTY ROAD E
SOUTH RANGE, WI 54874

Dear Daniel Roach,

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 MPHY10101** 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: 515-371-2255
Email: patty.riesberg@hhs.iowa.gov

Radiation Physics
CONSULTANTS

November 7, 2024

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, Daniel Roach, MS, a Radiation Physics Consultants, Inc. physicist, has met the Initial Qualifications requirements of MQSA and the FDA with 3 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 additional 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
Essentia Health Hospital (Graceville, MN)	DBT	Annual Physics Survey	3	1/19/23
Bigfork Valley Hospital (Bigfork, MN)	DBT	Annual Physics Survey	3.00	2/23/23
Essentia Health Clinic (Grand Rapids, MN)	DBT	Annual Physics Survey	3.5	3/3/23
Essentia Health Hospital (Moose Lake, MN)	DBT	Annual Physics Survey	3.00	12/20/23
CHI St. Joe's Hospital (Park Rapids, MN)	DBT	Annual Physics Survey	3.00	12/22/23
Essentia Health Clinic (Hermantown, MN)	DBT	Annual Physics Survey	3.00	1/5/24
Essentia Health Clinic (Detroit Lakes, MN)	DBT	Annual Physics Survey	3.50	1/25/24
Essentia Health (Sandstone, MN)	DBT	Annual Physics Survey	3.50	2/14/24
Essentia Health Clinic (I'Falls, MN)	DBT	Annual Physics Survey	2.50	7/25/24
CMDI (Pine City, MN)	Digital	Annual Physics Survey	3	7/29/24
		Total DBT (hrs):	28	
		Total Digital (hrs):	3	

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

Site Name	Bigfork Valley Hospital	**Report Date**	11/7/2024
Address	258 Pine Tree Drive, Bigfork, MN	**Survey Date**	2/23/2023
Medical Physicist's Name	Steve Nicholas and Danny Roach (Training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	5/16/2018	**Room ID**	Mammography
		SN	81002132146

QC Manual Version # **MAN-03706, Rev. 010 (August 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-02568, 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)*	113 mrad	Pass
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	130 mrad	Pass
9.	**Radiation Output Rate**		Pass

10. Phantom Image Quality Evaluation

	Fibers	Specks	Masses	PASS/FAIL
Phantom image scores *(conventional)*	6.0	4.0	4.5	Pass
Phantom image scores ***(DBT)***	5.5	4.0	4.0	Pass

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

SNR *(value)*	51.9		Pass
CNR *(value)*	10.76	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			Pass

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

****** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON 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)*** TOMO	Semi-annually	Pass
12.	Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	Pass
13.	Mobile Unit Quality Control *(if applicable)*	After every move	NA

Medical Physicist's Recommendations for Quality Improvement

This is a Medical Physicist's annual survey. There was also a software upgrade performed on 2/11/2022. It did not require an MEE but let this report serve as oversight and verification.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

There are no discrepancies.

Site does not print.

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

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

Site Name	Essentia Health - St. Mary's Clinic	**Report Date**	2/20/2024
Address	1027 Washington Ave., Detroit Lakes, MN 56501	**Survey Date**	1/25/2024
Medical Physicist's Name	Shane McCotter & Danny Roach (training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions
Date of Installation	3/27/2015	**Room ID**	Mammagraphy Room 1005
		SN	81002154467

QC Manual Version # **MAN-03706 Rev. 011 (Nov. 2021)** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMC-12133	On-site	MAN-03706 Rev. 011 (Nov. 2021)
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 & 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
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	153 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	4.0	Pass

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

SNR *(value)*	56.6		Pass
CNR *(value)*	11.52	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			Pass
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*			Pass
13. **DICOM Printer QC** *(if applicable, MEE only)*			NA
14. **Detector Flat Field Calibration** *(MEE only)*			NA
15. **Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***			NA
16. **Compression Thickness Indicator** *(MEE only)*			NA
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,*** TOMO	Semi-annually	**Fail**
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

We observed the Geometry Calibration QC was not run within 6 months in 2023. Was completed on 11/1/2022 then again on 7/5/2023. Did not perform again in 2023.

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 Sandstone Hospital	**Report Date**	3/14/2024
Address	705 Lundorff Drive, Sandstone, MN 55072	**Survey Date**	2/14/2024
Medical Physicist's Name	Steven Nicholas & Danny Roach (Training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia 3Dimensions DBT
Date of Installation	1/6/2022	**Room ID**	Mammography
		SN	3DM160101808

QC Manual Version # **MAN-03706, Rev. 011 (Nov 2021)** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	MDNG-13221	Offsite	MAN-03706, Rev. 011 (Nov 2021)
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 & 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)*	126 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)***	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)*	55.3		Pass
CNR *(value)*	10.78	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			Pass
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*			Pass
13. **DICOM Printer QC** *(if applicable, MEE only)*			NA
14. **Detector Flat Field Calibration** *(MEE only)*			NA
15. **Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***			NA
16. **Compression Thickness Indicator** *(MEE only)*			NA
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	Pass
2. Viewboxes and Viewing Conditions	Weekly	Pass
3. Artifact Evaluation	Weekly	Pass
4. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
5. Phantom Image Quality Evaluation	Weekly	Pass
6. Detector Flat-Field Calibration	Weekly	Pass
7. Compression Thickness Indicator	Bi-weekly	Pass
8. Visual Checklist	Monthly	Pass
9. Repeat/Reject Analysis	Quarterly	Pass
10. Compression	Semi-annually	Pass
11. Geometry Calibration (Tomosynthsis Option) ***(DBT,***	Semi-annually	Pass
12. Diagnostic Review Workstation QC *(NA if only hardcopy read)*	See Hologic QC Manual	Pass
13. Mobile Unit Quality Control *(if applicable)*	After every move	Pass

Medical Physicist's Recommendations for Quality Improvement

This is 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	Essentia Health- Grand Rapids Clinic	**Report Date**	4/2/2023
Address	1542 Golf Course Rd, Grand Rapids, MN 55744	**Survey Date**	3/3/2023
Medical Physicist's Name	Steven T. Nicholas and Danny Roach (trainee)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions DBT
Date of Installation	3/2/2018	**Room ID**	Mammo Room (Suite 204)
		SN	SDM131500483

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*	Hologic	SecurView	☐ On-site ☑ Off-site	MAN-03706, Rev. 009 (Sept 2019)
Film Printer*	NA	NA	NA	NA

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

Survey Type ☐ Mammo Eqpt Evaluation (MEE) following major upgrade. ☑ 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)*	122 mrad	**Pass**
TOMO	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	154 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**
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)*	57.6		**Pass**
CNR *(value)*	11.18	*(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)*** TOMO	**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 annual testing.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

No discrepancies.

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	Essentia Health - Holy Trinity Hospital	**Report Date**	2/15/2023
Address	115 West 2nd St, Graceville, MN 56240	**Survey Date**	1/19/2023
Medical Physicist's Name	Shane McCotter & Danny Roach (Training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions
Date of Installation	9/12/2018	**Room ID**	Mammography Room #1913
		SN	SDM131900425

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	SecureView	Off-site	MAN-03706 Rev. 007 (March 2018)
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 & 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)*	131	mrad	Pass
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	161	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)*	57.0		Pass
CNR *(value)*	11.06	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			Pass
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*			Pass
13. **DICOM Printer QC** *(if applicable, MEE only)*			NA
14. **Detector Flat Field Calibration** *(MEE only)*			NA
15. **Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***			NA
16. **Compression Thickness Indicator** *(MEE only)*			Pass
17. **Compression** *(MEE only)*			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

(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. Images are read at Essentia Health - Fargo Hospital. RWS testing performed annually.

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 - Hermantown Clinic	**Report Date**	1/30/2024
Address	4855W. Arrowhead Rd, Hermantown, MN 55811	**Survey Date**	1/5/2024
Medical Physicist's Name	Shane McCotter & Danny Roach (training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	3Dimensions
Date of Installation	12/2/2021	**Room ID**	Mammo Room
		SN	3DM160101598

QC Manual Version # **MAN-03706 Rev. 011 (Nov. 2021)** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	MDMC-12133	Off-site	MAN-03706 Rev. 010 (Qug 2020)
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 & 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**
TOMO	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	152	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**
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)*	55.2		**Pass**
CNR *(value)*	10.98	*(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)*** TOMO		**NA**
16.	**Compression Thickness Indicator** *(MEE only)*		**NA**
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	NA
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.

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 International Falls Clinic	**Report Date**	8/8/2024
Address	2501 Keenan Dr, International Falls, MN 56649	**Survey Date**	7/25/2024
Medical Physicist's Name	Shane McCotter & Danny Roach (training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia
Date of Installation	1/16/2015	**Room ID**	Mammo Room
		SN	2841214W8278W

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*	Off-Site	Hologic	SecurView	MAN-01476 Rev. 001
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

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 & Detector Uniformity**			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)*	128	mrad	Pass
	Average glandular dose for average breast is ≤3 mGy (300 mrad) ***(DBT)***	NA	mrad	NA
9.	**Radiation Output Rate**			Pass

10. **Phantom Image Quality Evaluation**

	Fibers	Specks	Masses	PASS/FAIL
Phantom image scores *(conventional)*	5.0	4.0	4.5	Pass
Phantom image scores ***(DBT)***	NA	NA	NA	NA

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

SNR *(value)*	56.6		Pass
CNR *(value)*	11.36	*(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 Tomosynthesis** ***(DBT MEE only)***	NA
16.	**Compression Thickness Indicator** *(MEE only)*	NA
17.	**Compression** *(MEE only)*	NA
18.	**Detector Ghosting** *(troubleshooting only)*	NA
19.	**Upright Biopsy Phantom Image Quality Evaluation**	NA
20.	**Upright Biopsy QAS Evaluation**	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 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	Essentia Health Moose Lake Hospital	**Report Date**	1/2/2024
Address	4572 Co. Rd. 61, Moose Lake, MN 55767	**Survey Date**	12/20/2023
Medical Physicist's Name	Shane McCotter & Danny Roach (training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimenions DBT
Date of Installation	1/20/2017	**Room ID**	Mammo Room
		SN	81012167628

QC Manual Version # **MAN-03706 Rev. 011 (Nov. 2021)** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco	MDMC-12133	Off-site	MAN-04426 Rev. 001
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 & 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)*	122	mrad	Pass
	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	4.5	Pass
Phantom image scores ***(DBT)***	5.5	4.0	4.0	Pass

11. **Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements** *(values required for all tests)*			
SNR *(value)*	57.2		Pass
CNR *(value)*	12.89	*(required for new unit MEE and Annual Survey)*	
CNR should not vary by more than ±15% *(NA for MEE)*			Pass
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*			Pass
13. **DICOM Printer QC** *(if applicable, MEE only)*			NA
14. **Detector Flat Field Calibration** *(MEE only)*			NA
15. **Geometry Calibration For Tomosynthsis** ***(DBT MEE only)***			NA
16. **Compression Thickness Indicator** *(MEE only)*			NA
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

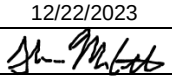
No Discrepancies.

Evaluation of Site's Technologist QC Program

No Discrepancies.

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	CHI - St. Joseph's Health Hospital	**Report Date**	1/2/2024
Address	600 Pleasant Ave., Park Rapids, MN 56470	**Survey Date**	12/22/2023
Medical Physicist's Name	Shane McCotter and Danny Roach	**Signature**	
X-Ray Unit Manufacturer	Siemens	**Model**	Mammomat Revelation
Date of Installation	11/1/2018	**Room ID**	DBT Mammo
		Serial Number	1219

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/McKesson	5421 HD	On-Site	MAN-01476 Rev. 001 (June 2009)
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 & 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**	**Pass**
	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 5.0 Specks 4.0 Masses 4.0	
2.	**Artifact Detection**	**Pass**
3.	**SNR and CNR Measurements**	**Pass**
4.	**Repeat/Reject Analysis**	**Pass**
5.	**Compression Force**	**Pass**
6.	**Printer Check** *(if applicable)*	**NA**
7.	**SNR, CNR and AEC Repeatability**	**Pass**
	Measured values: SNR 59.85 CNR 2.75	
	CV for mAs and entrance air kerma ≤5%	**Pass**
	Max deviation of mean pixel values and SNR within ±15% of mean for measurements	**Pass**
8.	**Radiation Dose**	**Pass**
	Average glandular dose for average breast is ≤3 mGy (300 mrad) 0.750 mGy	
9.	**Spatial Resolution**	**Pass**
10.	**AEC Test**	**Pass**
11.	**Detector Uniformity**	**Pass**
12.	**Mechanical Tests**	**Pass**
13.	**Acquisition Workstation Monitor Check**	**Pass**
14.	**Site Audit/Evaluation of Technologist QC Program**	**Pass**
15.	**Collimation, Dead Space & Compression Paddle Position**	**Fail**
16.	**HVL and Radiation Output**	**Pass**
17.	**Tube Voltage Measurement & Repeatability**	**Pass**
18.	**Average Glandular Dose** ***(DBT)***	**Pass**
19.	**Geometric Accuracy in X and Y Direction and Z-Resolution** ***(DBT)*** *(Optional Revelation)*	**Pass**
20.	**Radiation Field** ***(DBT)***	**Fail**
21.	**System Imaging Quality** ***(DBT)***	**Pass**
	≥ 4 fibers, ≥ 3 speck groups and ≥ 3 masses must be visible	
	Phantom image scores: Fibers 5.0 Specks 4.0 Masses 4.0	
22.	**Artifact Detection** ***(DBT)***	**Pass**
23.	**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; Fusion-Quarterly	**Pass**
5.	Repeat/Reject Analysis	Quarterly	**Pass**
6.	Compression Force	Semi-annually	**Pass**
7.	System Imaging Quality ***(DBT)***	Weekly	**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 and Inspiration, indicate NA-calibration required before QC but does not need to be documented*

Medical Physicist's Recommendations for Quality Improvement

This is a Medical Physicist's annual survey.

Medical Physicist's QC Tests

Item 15: The X-Ray Field to Light Field accuracy failed to be within the required 2% of the SID (must not exceed 13 mm combined). We measured the Left/Right combined deviation to be 14mm mainly from the right side where the light field measured 10 mm greater than the x-ray field. Please have a Service Engineer review the results on Page 12 and make the necessary corrections within 30 days of the testing.

Item 15: The chest Wall Missing Tissue measured 5.1mm which is greater than the 5mm allowed limit set by Siemens. Please have a Service Engineer review and make the necessary adjustments, possibly tightening the cover to decrease the missing tissue.

Item 20: We could easily see the edge of the tomo paddle in the first projection image. Per the Siemens manual, the edge of the collimator should not be seen in any projection image. Please have a Service Engineer make the necessary adjustments.

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	CMDI at Welia Health Clinic	**Report Date**	8/15/2024
Address	1425 N Main St, Pine City, MN 55063	**Survey Date**	7/29/2024
Medical Physicist's Name	Shane McCotter & Danny Roach (training)	**Signature**	
X-Ray Unit Manufacturer	Lorad/Hologic	**Model**	Selenia Dimensions
Date of Installation	7/10/2019	**Room ID**	Mammo
		SN	SDM131900771

QC Manual Version # **MAN-03706, Rev. 011 (Nov. 2021)** *(use any version applicable to model; contact mfr if questions)*

Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*	Barco/Hologic	MDMC-12133	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 & 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 & Detector Uniformity**		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)***	146 mrad	Pass
9.	**Radiation Output Rate**		Pass

10. **Phantom Image Quality Evaluation**

	Fibers	Specks	Masses	PASS/FAIL
Phantom image scores *(conventional)*	5.0	4.0	4.0	Pass
Phantom image scores ***(DBT)***	5.0	4.0	4.0	Pass

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

SNR *(value)*	56.8		Pass
CNR *(value)*	11.38	*(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 Tomosynthesis** ***(DBT MEE only)***	NA
16.	**Compression Thickness Indicator** *(MEE only)*	NA
17.	**Compression** *(MEE only)*	NA
18.	**Detector Ghosting** *(troubleshooting only)*	NA
19.	**Upright Biopsy Phantom Image Quality Evaluation**	NA
20.	**Upright Biopsy QAS Evaluation**	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 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.)

John Patrick University
of
Health and Applied Sciences

Upon recommendation of the Faculty,

John Patrick University of Health and Applied Sciences
has conferred upon

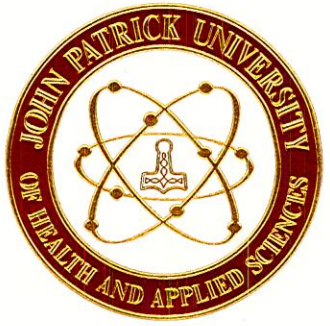
DANIEL ROACH

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 August in
the year of our Lord two thousand and twenty-three



Brad Murphy
President

John Patrick University of Health and Applied Sciences

Official Transcript

100 E. Wayne Street, Suite 140, South Bend, IN 46601
Phone: (574)232-2408, Fax: (574)232-2200

RECIPIENT:
Daniel Roach
1101 N 57th Ave. W
Duluth, MN 55907

STUDENT:
Roach, Daniel
Student ID: 2022000214
Birthdate: May 22, 1998
Enrollment Date: Sep 6, 2021

Degrees/Certificates

Master of Science in Medical Physics
Granted 8/21/2023

Transcript

2021-2022: Fall 2021 - 09/06/2021 - 12/21/2021

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
BIOL530	Human Anatomy & Physiology	4.00	4.00	A	16.00
MP502	Physics of Radiation Biology	3.00	3.00	B	9.00
MP590	Medical and Professional Ethics	1.00	1.00	A	4.00
Totals		**8.00**	**8.00**	**Term GPA: 3.63**	**Cum. GPA: 3.63**

2021-2022: Spring 2022 - 01/10/2022 - 04/25/2022

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
MP503	Physics of Diagnostic Radiology	3.00	--	W	--
MP505	Physics of Radiation Oncology I	3.00	3.00	B	9.00
MP599 S1	Seminars Session 1	1.00	1.00	A	4.00
Totals		**7.00**	**4.00**	**Term GPA: 3.25**	**Cum. GPA: 3.50**

2021-2022: Summer 2022 - 05/09/2022 - 08/22/2022

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
MHP601	Shielding Design	2.00	2.00	A	8.00
MP503	Physics of Diagnostic Radiology	3.00	3.00	A	12.00
Totals		**5.00**	**5.00**	**Term GPA: 4.00**	**Cum. GPA: 3.65**

2022-2023: Fall 2022 - 09/05/2022 - 12/19/2022

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
MHP510	Health Physics and Radiation Safety	3.00	3.00	A	12.00
MP506	Physics of Radiation Oncology II	3.00	3.00	A	12.00
MP613	Physics of Nuclear Oncology	3.00	3.00	A	12.00
Totals		**9.00**	**9.00**	**Term GPA: 4.00**	**Cum. GPA: 3.77**

2022-2023: Spring 2023 - 01/09/2023 - 04/24/2023

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
MP504	Physics of Nuclear Medicine	3.00	3.00	A	12.00
MP508	Radiological Instrumentation	2.00	2.00	A	8.00
MP599 S10	Seminars Session 10	1.00	1.00	A	4.00
MP603	Advanced Diagnostic Radiology	2.00	2.00	B	6.00
Totals		**8.00**	**8.00**	**Term GPA: 3.75**	**Cum. GPA: 3.76**

Elizabeth M Datema
Office of the Registrar

Brent D. Murphy, MS, DABR
President

2022-2023: Summer 2023 - 05/08/2023 - 08/21/2023

Course #	Name	Attempted Cr.	Earned Cr.	Grade	Points
MP501	Physics of Radiation Dosimetry	4.00	4.00	A	16.00
MP699	Clinical Internship	4.00	4.00	P	16.00
STAT501	Statistical Methods	3.00	3.00	A	12.00
Totals		**11.00**	**11.00**	**Term GPA: 4.00**	**Cum. GPA: 3.82**

Cumulative

	Attempted Credits	Earned Credits	Points	GPA
Resident	48.00	45.00	172.00	3.82
Transfer	0.00	0.00	0.00	0.00
Overall	48.00	45.00	172.00	3.82

Elizabeth M Datema
Office of the Registrar

Brent D. Murphy, MS, DABR
President

KEY TO TRANSCRIPT OF ACADEMIC RECORDS

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.

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)
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
B	(3.0 Pts)	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 of Health and Applied Sciences 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 of Health and Applied Sciences credit is reported in terms of semester hours.

II. 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 of Health and Applied Sciences.

The JPU GPA reflects the student's 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.

III. 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.

IV. Accreditation

This Institution is authorized by: the Indiana Board for Proprietary Education, 101 West Ohio Street, Suite 300 Indianapolis, Indiana 46204-4206. Phone (317) 464-4400 Ext. 138.

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 United States Department of Education.

This Institution holds programmatic accreditation by the Joint Review Committee on Education in Radiologic Technology (JRCERT), 20 North Wacker Drive, Suite 2850 Chicago, Illinois 60606-3182. Phone (312) 704-5300. Email: mail@jrcert.org. Programs Accredited: Bachelor of Science in Medical Dosimetry and Master of Science in Medical Dosimetry.

V. Validation

A transcript issued by John Patrick University of Health and Applied Sciences is official when it displays signatures. Printed official transcripts display signatures and are printed on SCRIP-SAFE Security paper. A raised seal is not required.

VI. Registrar Contact

Questions about the content of this record should be referred to the Office of the Registrar where it was printed.