

Kim Reynolds, Governor

March 11, 2025

Shane McCotter

SUPERIOR, WI 54880

Dear Shane McCotter,

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

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

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

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

Sincerely,

Patty Riesberg

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



## December 9, 2021 ATTESTATION REGARDING INITIAL REQUIREMENTS OF THE MAMMOGRAPHY QUALITY STANDARDS ACT AND/OR ACR REQUIREMENTS FOR DIGITAL AND DBT BREAST IMAGING

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

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

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

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

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

Please see the addition details on the following pages.

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

Sincerely,

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 (l'Falls, MN)	DBT	Annual Physics Survey	3.50	7/27/2021
Essentia Health Clinic (l'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



Site	Name		St Luke's - Chequa	St Luke's - Chequamegon Clinic		Report Date	3/25/20	021	
Add	ress	2201	Lakeshore Drive E	, Ashland, WI 5	4806	Survey Date	/3/25/20	$21 \Lambda \Lambda$	
Med	ical Physici	st's Name	Steven T. Nicho	las and Shane I	McCotter (training)	Signature	Hen Th	to los	
X-Ra	ıy Unit Man	ufacturer		Hologic		Model	Selenia Dimer	sions DBT	
Date	of Installat	ion		3/14/2018		Room ID	Mammography/DE	XA Room #129	
						SN	SDM1319	00240	
QCI	Manual Vers	sion #	MAN-0370	6, Rev. 007 (	March 2018)	(use any version applic	able to model; contact m	fr if questions )	
Acce	essory Equi	pment	Manufac	turer	Model	Location	QC Manual	/ersion #	
		• w Workstation*	on* Barco/Hologic MDMG-5221 Off-Site MAN-04959, F						
Film Printer* NA NA NA NA									
*FDA	recommends	that only monito	ors and printers spe	cifically cleared	for FFDM use by	FDA's Office of Device	Evaluation (ODE) be	used. See	
FDA's	Policy Guidar	nce Help Syster	n www.fda.gov/CD	RH/MAMMOGF	RAPHY/robohelp/S	TART.HTM.			
Surv	еу Туре		Annual Survey of	2D and Tomo					
			Μοσ	tical Ph	/sicist's Q	C Tosts			
("P	ass" means al	l components o					for both on and off-sit	e equinment )	
( '			<i>ine toot pubbob, i</i>					PASS/FAIL	
1.	Mammogra	phic Unit As	sembly Evalua	tion				Pass	
	-	Assessmen	-						
	Dev	iation betwee	en X-ray field an	d light field ≤	2% of SID			Pass	
	X-ra	y field does r	not extend beyo	nd any side c	of the IR by >2%	of SID		Pass	
	X-ra	y field covers	all of the IR on	the chest wa	all side			Pass	
	Pad	dle chest wal	I edge does not	extend beyo	nd IR by >1% o	f SID or appear on	mammogram	Pass	
3.	Artifact Eva	luation (no s	ignificant artifacts v	/isible)				Pass	
<b>4</b> .	-	cy and Repr	•						
		-	ge kVp within ±5		ed kVp			Pass	
			f variation $\leq 0.02$					Pass	
		•	ent - HVL Meas esolution (syste					Pass Pass	
		-				systems without AEC)		Pass	
1. 1		-	(2-8 cm; all ope					Pass	
		-	nsation steps p	-				Pass	
8.			ure, AEC Repro					1 400	
		-	ar dose for aver	-	-			Pass	
		0 0	ar to a 4.2 cm bi	•	•	, mrad 109	Conventional		
	Ave					mrad 138	Tomosynthesis O	ption	
				R or mAs $\leq 0$	0.05 (NA for sys	tems without AEC)		Pass	
		•	′ > 230 mR/sec)			mR/sec 620		Pass	
10.		nage Quality							
	Pha	ntom image o	quality scores (0	Conventional)					
	<u>////</u>			-	Fibers 5.5	Specks 4.0	Masses 4.0	Pass	
1	Pha	ntom image (	quality scores (1	omosyntnes	· _/		Maaaaa	Basa	
11	Signal-To-N	loise Ratio a	and Contrast-T	-Noise Rati	Fibers 6.0	Specks 4.0	Masses 4.5	Pass	
••••	-	(value)	53.3		o measuremen			Pass	
		R (value)		(Required for bo	oth new unit Mamn	nography Equipment F	valuations and Annual		
			vary by more that					Pass	
12.						offsite; NA if only har	dcopy read)	Pass	
13.	DICOM Prin	ter QC (Mam	mography Equipme	ent Evaluations	only)			NA	
			oration (Mammog					NA	
	-		s Indicator (Mar		uipment Evaluation	s only)		Pass	
			phy Equipment Ev	aluations only)				NA	
17.	Geometry C	alibration						Pass	

(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
. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	PASS
<ol> <li>Compression Thickness Indicator</li> </ol>	Bi-weekly	PASS
. Review Workstation QC-Overall	See FDA guidance	PASS
. Viewboxes and Viewing Conditions	Weekly	PASS
0. Visual Checklist	Monthly	PASS
1. 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

		Full-Field	d Digital	– Lorad			
Site Name	Esse	entia Health - Ashland Clini	с	Report Date	4/22/202	2/2021	
Address	1625 M	aple Lane, Ashland, WI 54	806	Survey Date	A/25/202	$21$ $\Lambda$ $\Lambda$	
Medical Phy	/sicist's Name	Steven T. Nicholas (Shane Mo	cCotter, trainee)	Signature	T. Th	1.00	
X-Ray Unit I	Manufacturer	Lorad		Model	Seleri	a	
Date of Insta	allation	11/18/2010, moved 4	/28/2016	Room ID	Mamm	0	
QC Manual	Version: (check on	e; must use version applicable	to unit tested; co	ntact mfr if questions)			
n MA	N-00093, Rev. 008	OTHER (write in):	MAN	-01476 Rev. 001 June	2009		
Accessory E	Equipment:	Manufacturer	Model	Location	QC Manual \	/ersion	
	Review Workstation*	Barco/Hologic	5621/SecureView	🗆 On-site 🛛 Off-site	MAN-01476 Rev. 0	01 June 2009	
	Laser Film Printer*	NA	NA	□ On-site	NA		
		ors and printers specifically clea 's Policy Guidance Help System			Evaluation (ODE) be u	sed, but the	
Survey Type	•	Mammo Eqpt Evaluation of nev		u • ,	checklist) 🛛	Annual Survey	
						annual carroj	
		Medical Physic	cist's QC	Tests		PASS/FAIL	
1. Mammo	ographic Unit Ass	sembly Evaluation					
	Performs accordin	ng to 1999 ACR Mammogra	aphy Quality C	ontrol Manual		Pass	
	Autodecompressi	on can be overridden to ma	aintain compre	ssion (& status displaye	ed)	Pass	
	Manual emergend	y compression release car	n be activated	in the event of power fa	ilure	Pass	
2. Collima	tion Assessment	t					
		n X-ray field and light field				Pass	
		ot extend beyond any side		2% of SID		Pass	
	•	all of the IR on the chest w				Pass	
		edge does not extend bey	ond IR by >1%	o of SID or appear on m	ammogram	Pass	
		gnificant artifacts visible)				Pass	
-	curacy and Repro						
	-	e kVp within ±5% of indicat	ted kVp			Pass	
	kVp coefficient of					Pass	
5. Beam Q	anty Assessine	ent - HVL Measurement				Pass Pass	
7. Automa	tic Exposure Co	ntrol (AEC) Function Perf	formance (NA)	for systems without AEC)		Fass	
	-	2-8 cm; all operating mode				Pass	
	-	sation steps performance				Pass	
		re, AEC Reproducibility a	-			1 400	
	-	r dose for average breast is	-		124 mrad	Pass	
		ation for either R or mAs ≤			II	Pass	
		>7.0 mGy air kerma/sec (800 mF	•	•		Pass	
10. Phantor	m Image Quality	Evaluation				·	
	5 largest fibers, 4	largest speck groups and	4 largest mass	es are visible*		Pass	
	(*4.5 fibers, 4.0 s	beck groups and 3.5 masse	es may be acc	eptable under certain ci	rcumstanc <u>es)</u>	_	
	Phantom image q	uality scores: Fi	ibers 6.0	Specks 4.0	Masses 4.0		
	Hard copy backgr	ound density must be ≥ 1.2	20 (with operat	ing level ≥ 1.40)		NA	
	Hard copy density	v difference (DD) over acry	lic disk must b	e within acceptable limit		NA	
		tical densities: Backgro		Disk <b>NA</b>	DD NA		
-	•	SNR) and Contrast-To-No	ise Ratio (CNI	· · · ·			
	SNR is $\geq 40$	any by more than +15% (M	A for Fauinmont F	SNR		Pass	
		ary by more than ±15% <i>(N/</i> <b>I Room Illuminance</b>	uor ⊑quipment E	Evaluation) CNR	12.85	Pass	
		ewbox is capable of a lumi	nance of at lea	ast 3000 cd/sa m (nit)		Pass	
		(viewbox surface as seen				Pass	
		(monitor surface) is $\leq 20$ l				Pass	
	•	/S) Tests* (for all RWS, e		,			
	Overall Results ("	Pass" means all tests pass; indic	cate "Fail" if any to	est 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.)

(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.)

		FA35/FAIL
	Frequency	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.)

Site Name	Essentia Health Moose Lake	Report Date	e 4/30/2021				
	2 Co. Rd. 61, Moose Lake, MN 55767			Survey Date			
Medical Physicist's Name			(trainee))	Signature		1.11	
X-Ray Unit Manufacturer	Steven T. Nicholas (w/ Shane McCotter (trainee)) Lorad/Hologic			Model		enia Dimens	None DRT
Date of Installation	1/20/201	0		Room ID			
Date of instanation	1/20/20	17		SN	-	Mammo F 81012167	
QC Manual Version #	MAN 02706 Boy 0	06 ( Juno 2	017)	1			
QC Manual Version # MAN-03706, Rev. 006 (June 2017) (use any version applicable to model; contact mfr if questions )							
Accessory Equipment	Manufacturer	Мо	del	Location	Q	C Manual V	ersion #
Review Workstation*	Barco	Secur	eView	Off-Site	MAN-03	706, Rev. 0	09 (June 2019)
Film Printer*	NA	N	A	NA		NA	
*FDA recommends that only monit FDA's Policy Guidance Help Syste	m (www.accessdata.fda.gov/c						used. See
Survey Type- Features-	Annual survey2DandDigit	tal Breast T	omosynthe	esis (DBT)			
	Medical P	hysici	st's Q	C Tests			
("Pass" means all components o					for both or	n and off-site	e equipment.)
							PASS/FAIL
1. Mammographic Unit As							Pass
2. Collimation Assessme	nt						Pass
3. Artifact Evaluation							Pass
4. kVp Accuracy and Rep	•						Pass
-	ent - HVL Measurement						Pass
6. Evaluation of System R							Pass
-	ontrol (AEC) Function P				)		Pass
	ure, AEC Reproducibilit	-	-		r	-	r
	e for average breast is ≤3	• •			106	mrad	Pass
	e for average breast is ≤3	mGy (300	mrad) <i>(D</i>	BT)	133	mrad	Pass
9. Radiation Output Rate							Pass
10. Phantom Image Quality		Fibers	Specks	Masses			
-	cores (conventional)	6.0	4.0	4.5			Pass
Phantom image s		6.0	4.0	4.5			Pass
11. Signal-To-Noise Ratio			surement	(values required to	or all tests)		Deee
SNR (value) CNR (value)	50.8						Pass
	10.71 <i>(required for</i> ary by more than ±15% <i>(</i>			ual Survey)			Pass
12. Diagnostic Review Wo				officito: NA if only have	doony road	1	
		<i>III AVIS, EVE</i>	n n localeu	Unsite, NA II Uniy nai	ucopy reau	)	Pass NA
13. DICOM Printer QC (if applicable, MEE only) 14. Detector Flat Field Calibration (MEE only)						NA	
15. Geometry Calibration For Tomosynthsis ( <i>DBT MEE only</i> )					Pass		
16. Compression Thickness Indicator (MEE only)						Pass	
17. Compression (MEE only)							NA
18. Detector Ghosting (trout							NA
							INA

(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.

Site Name	Lake View Clinic			Repo	rt Date	Date 6/17/2021			
Address 101	0 4th Street, Two Harbors, MN	55616		Surve	ey Date	1	6/17/2021 1 A		
Medical Physicist's Name	Steven T. Nicholas and Shar	ne McCotter	(training)	Sig	nature	Ĵ	Th	1.0.12	
X-Ray Unit Manufacturer	Lorad/Hologic				Model	Sel	Selenia Dimensions DBT		
Date of Installation	2/22/201	•		R	oom ID		Mammo F	Room	
				1	SN		SDM13190		
QC Manual Version #	MAN-03706, Rev. 00	MAN-03706, Rev. 006 (June 2017) (use any version applicable to me							
Accessory Equipment	Manufacturer	Мо	del	Locati	ion	C	C Manual V	/ersion #	
Review Workstation*	Barco/Hologic	MDMG	G-5221	☑ On-site □	Off-site	М	AN-04959,	Rev. 002	
Film Printer*	NA	N	A	NA			NA		
*FDA recommends that only monitor Policy Guidance Help System (www Survey Type Features	w.accessdata.fda.gov/cdrh_doc Mammo Eqpt Evaluation (MEE	s/presentatio	ons/pghs/Po it (include N	olic_Guidanc IQSA Rqmts	e_Help_S	System.htn	n).		
<ol> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> </ol>	nt roducibility ent - HVL Measurement	n <b>Gy</b> (300 n	r <b>age Glan</b> mrad) <i>(col</i>	idular Dos nventional)		<u>112</u> 142	mrad mrad	PASS/FAIL Pass Pass Pass Pass Pass Pass Pass Pas	
9. Radiation Output Rate					-		_	Pass	
10. Phantom Image Quality	<sup>v</sup> Evaluation	Fibers	Specks	Masses				,	
Phantom image s	cores (conventional)	5.5	4.0	4.5				Pass	
Phantom image s		6.0	4.0	4.5				Pass	
11. Signal-To-Noise Ratio a	and Contrast-To-Noise Ra	atio Meas	urements	(values req	uired for a	all tests)			
SNR (value)	55.6							Pass	
CNR (value)	11.05 (required for		E and Annu	ual Survey)					
	vary by more than ±15% <i>(N</i>	-						Pass	
12. Diagnostic Review Wor		RWS, even	if located o	offsite; NA if c	only hardc	opy read)		Pass	
13. DICOM Printer QC (if app								NA	
14. Detector Flat Field Calibration (MEE only)						NA			
15. Geometry Calibration For Tomosynthsis (DBT MEE only)							Pass		
16. Compression Thicknes	s Indicator (MEE only)							Pass	
17. Compression (MEE only)								NA	
18. Detector Ghosting (trouk	pleshooting only)							NA	

(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.

Olta Nama				Demant	Data 🗌		8/5/202	
	CMDI at FirstLight Health System			Report				
	5 N Main Street, Pine City, MN 55063			Survey		6	7/6/202	21 1 1
Medical Physicist's Name	Steven T. Nicholas and Shane McCotter (training)			Signa		81	en 17/2	taby
X-Ray Unit Manufacturer	Lorad/Holo	-			odel	Sele	enia Dimen	sions DBT
Date of Installation	7/10/201	7/10/2019			m ID		Mamm	
				1	SN		SDM13190	
QC Manual Version #	MAN-03706, Rev. 0	08 (Dec 2	2018)	(use any version	applicable	to mode	l; contact mfi	r if questions )
Accessory Equipment Manufacturer Model Location					Q	C Manual V	/ersion #	
Review Workstation*	Barco/Hologic	MDM	G-5221	On-site Off-	site	MA	AN-04959, I	Rev. 002
Film Printer*	NA	Ν	A	NA			NA	
*FDA recommends that only monit FDA's Policy Guidance Help Syste Survey Type- Features-	em (www.accessdata.fda.gov/co Annual Survey	drh_docs/pr		/pghs/Polic_Gu				used. See
("Pass" means all components c					e done for	both on	and off-sit	e equipment.) PASS/FAIL
1. Mammographic Unit A	ssembly Evaluation							Pass
2. Collimation Assessme	nt							Pass
3. Artifact Evaluation								Pass
4. kVp Accuracy and Rep	-							Pass
2	ent - HVL Measurement							Pass
6. Evaluation of System F								Pass
	ontrol (AEC) Function Po							Pass
-	sure, AEC Reproducibilit	-	-		·		т.	
	e for average breast is ≤3	• •				116	mrad	Pass
	e for average breast is ≤3	mGy (300	) mrad) (D	вт)		143	mrad	Pass
<ol> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> </ol>	, Evaluation	Fibers	Snaaka	Masses				Pass
	SCORES (conventional)	6.0	Specks	4.5				Pass
Phantom image s		4.5	4.0 4.0	4.0				Pass
11. Signal-To-Noise Ratio			-		ired for al	ll tests)		F 835
SNR (value)	56.9	tutio mou	ouronnonn	e (values regul		1 (0010)		Pass
CNR (value)	11.43 (required for	new unit M	FF and Δnn	ual Survey)				1 433
	vary by more than ±15% ( <i>i</i>			uul Gulvey)				PASS
12. Diagnostic Review Wo				offsite: NA if on	lv hardco	oov read	)	Pass
13. DICOM Printer QC (if ap						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	·	NA
14. Detector Flat Field Cali								NA
15. Geometry Calibration For Tomosynthsis (DBT MEE only)					Pass			
16. Compression Thicknes	-							Pass
17. Compression (MEE only)								NA
18. Detector Ghosting (trou								NA

(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.

Site Name North Shore Health					Repo	ort Date		7/26/20	21
Address	ddress 515 5th Ave West, Grand Marais, MN 55604			Surv	ey Date	(	7/13/20	2111	
Medical Physic	ist's Name	st's Name Steven T. Nicholas and Shane McCotter (training)				gnature	A	TYL	lab
X-Ray Unit Mar	nufacturer	Lorad/Hold	ogic			Model	Sele	enia Dimen	sions DBT
Date of Installa	tion	6/21/201	9		R	oom ID		Mamm	10
	L				1	SN		SDM13190	00754
QC Manual Ver	sion #	MAN-03706, Rev. 0	08 (Dec 2	018)	(use any ver	sion applica	ble to mode	l; contact mf	r if questions )
. –			 		· ·				
Accessory Equ	-	Manufacturer	Мо	del	Loca			C Manual V	
Revie	w Workstation*	Barco/Hologic	MDMG	6-5221	🗆 On-site 🛛		MA	AN-04959,	Rev. 002
	Film Printer*	NA	N	A	N/	4		NA	
		ors and printers specifically cle m (www.accessdata.fda.gov/co							used. See
		11 (www.accessuala.lua.gov/co	um_uocs/pre	esentations	/pgris/Polic_	_Guidance	_neip_sys	item.mm).	
		Annual Survey							
Feat	tures-	2D and Digit	al Breast To	omosynthe	esis (DBT)				
		Madiaal D	hyoioid	ot'o O	C Toot	•			
<i>"</i>		Medical P							
("Pass" means al	i components of	the test passes; indicate "Fail	" if any com	ponent tails	s. Tests mus	st be done	tor both on	and off-sit	
1. Mammogra	nhic Unit Ac	sembly Evaluation							PASS/FAIL Pass
-	n Assessmen	-							Pass
Z. Commation	ASSESSINE	1.							
3 Artifact Ev	aluation								
3. Artifact Eva		oducibility							Pass
4. kVp Accura	acy and Repr	•							Pass Pass
<ol> <li>4. kVp Accura</li> <li>5. Beam Qual</li> </ol>	acy and Repr lity Assessm	ent - HVL Measurement							Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> </ol>	acy and Repr lity Assessm of System R	ent - HVL Measurement esolution		e (NA for	systems wit	hout AFC)			Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> </ol>	acy and Repr lity Assessm of System R Exposure Co	ent - HVL Measurement esolution ontrol (AEC) Function Pe	erformand						Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entre</li> </ol>	acy and Repr lity Assessm of System R Exposure Co rance Expos	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit	erformanc y and Ave	erage Gla	ndular Do	ose		Imrad	Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra Average g</li> </ol>	acy and Repr lity Assessm of System R Exposure Co rance Expose landular dose	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit of average breast is ≤3	erformand y and Ave mGy (300	mrad) (co	ndular De	ose	119	mrad	Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Enternal</li> <li>Average g</li> <li>Average g</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit	erformand y and Ave mGy (300	mrad) (co	ndular De	ose		]mrad ]mrad	Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation (</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3	erformand y and Ave mGy (300	mrad) (co	ndular De	ose	119	-	Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra Average g Average g</li> <li>Radiation 0</li> <li>Phantom In</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate nage Quality	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 Evaluation	erformanc y and Ave mGy (300 mGy (300 Fibers	erage Gla mrad) (co mrad) (D	ndular De onventional, BT)	ose	119	-	Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom In</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate nage Quality	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional)	erformand y and Ave mGy (300 mGy (300	erage Gla mrad) (ca mrad) (D Specks	ndular De onventional, BT) Masses	ose	119	-	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom In</li> <li>Phantom Phantom</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate mage Quality ntom image s ntom image s	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional)	erformance y and Ave mGy (300 mGy (300 Fibers 5.5 5.0	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0	ndular De onventional, BT) Masses 5.0 4.5	ose	119 143	-	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation (10)</li> <li>Phantom Ir</li> <li>Phantom Ir</li> <li>Phantom Ir</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate mage Quality ntom image s ntom image s	ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional) cores (DBT)	erformance y and Ave mGy (300 mGy (300 Fibers 5.5 5.0	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0	ndular De onventional, BT) Masses 5.0 4.5	ose	119 143	-	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation (10)</li> <li>Phantom Ir</li> <li>Phantom Ir</li> <li>Phantom Ir</li> <li>Phantom Ir</li> <li>Phantom Ir</li> <li>SNF</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate mage Quality ntom image s Noise Ratio a	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional) cores (DBT) and Contrast-To-Noise F	erformand y and Ave mGy (300 mGy (300 <u>Fibers</u> 5.5 5.0 2.0 Catio Meas	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement	ndular De onventional, BT) Masses 5.0 4.5 ts (values r	ose	119 143	-	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation (10)</li> <li>Phantom Ir</li> <li>Phan</li> <li>Phan</li> <li>Phan</li> <li>SNF</li> <li>CNF</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Exposure landular dose landular dose Dutput Rate mage Quality ntom image s ntom image s Noise Ratio a R (value) R (value)	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise R 54.0	erformand y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Catio Meas new unit ME	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement	ndular De onventional, BT) Masses 5.0 4.5 ts (values r	ose	119 143	-	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra Average g</li> <li>Radiation 0</li> <li>Phantom Ir Phan</li> <li>11. Signal-To-I SNR CNR</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose Dutput Rate mage Quality ntom image s ntom image s Noise Ratio a (value) (value) (should not v	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 for average breast is ≤3 Fevaluation cores (conventional) cores (DBT) and Contrast-To-Noise R 54.0 10.60 (required for	erformand y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Meas new unit ME NA for MEE)	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra Average g</li> <li>Radiation 0</li> <li>Phantom Ir Phan</li> <li>11. Signal-To-I SNR CNR</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular dose landular dose landular dose dandular dose landular	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional) cores (DBT) and Contrast-To-Noise R 54.0 10.60 (required for ary by more than ±15% (r kstation (RWS) QC (for a	erformand y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Meas new unit ME NA for MEE)	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom Ir</li> <li>Phantom Ir</li></ol>	acy and Repr lity Assessme of System R Exposure Co rance Exposure landular dose landular dose landul	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 for average breast is ≤3 for average breast is ≤3 Evaluation cores (conventional) cores (DBT) and Contrast-To-Noise R 54.0 10.60 (required for ary by more than ±15% (r kstation (RWS) QC (for a	erformand y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Meas new unit ME NA for MEE)	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom Ir</li> <li>Phan</li> <li>Phan</li> <li>The Signal-To-I</li> <li>SNF</li> <li>CNF</li> <li>Diagnostic</li> <li>DICOM Print</li> <li>Detector File</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibility a for average breast is ≤3 for average breast is ≤3 for average breast is ≤3 <b>Evaluation</b> cores ( <i>conventional</i> ) cores ( <i>DBT</i> ) <b>and Contrast-To-Noise R</b> 54.0 10.60 ( <i>required for</i> ary by more than ±15% ( <i>I</i> <b>kstation (RWS) QC</b> ( <i>for a</i> <i>blicable, MEE only</i> )	erformance y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Mease new unit ME VA for MEE) II RWS, evel	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom Ir</li> <li>Phan</li> <li>11. Signal-To-I</li> <li>SNF</li> <li>CNF</li> <li>12. Diagnostic</li> <li>13. DICOM Print</li> <li>14. Detector FI</li> <li>15. Geometry 0</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibility e for average breast is ≤3 for average breast is ≤3 for average breast is ≤3 <b>Evaluation</b> cores ( <i>conventional</i> ) cores ( <i>DBT</i> ) and Contrast-To-Noise R 54.0 10.60 ( <i>required for</i> ary by more than ±15% ( <i>l</i> kstation (RWS) QC ( <i>for a</i> <i>blicable, MEE only</i> ) oration ( <i>MEE only</i> )	erformance y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Mease new unit ME VA for MEE) II RWS, evel	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>kVp Accura</li> <li>Beam Qual</li> <li>Evaluation</li> <li>Automatic</li> <li>Breast Entra</li> <li>Average g</li> <li>Average g</li> <li>Radiation 0</li> <li>Phantom Ir</li> <li>Phan</li> <li>11. Signal-To-I</li> <li>SNF</li> <li>CNF</li> <li>12. Diagnostic</li> <li>13. DICOM Print</li> <li>14. Detector FI</li> <li>15. Geometry 0</li> </ol>	acy and Repr lity Assessme of System R Exposure Co rance Expose landular dose landular	ent - HVL Measurement esolution ontrol (AEC) Function Pe- ure, AEC Reproducibility e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 Fevaluation cores ( <i>conventional</i> ) cores ( <i>DBT</i> ) and Contrast-To-Noise R 54.0 ( <i>required for</i> ary by more than ±15% ( <i>l</i> kstation (RWS) QC ( <i>for a</i> <i>bicable, MEE only</i> ) or Tomosynthsis ( <i>DBT M</i>	erformance y and Ave mGy (300 mGy (300 Fibers 5.5 5.0 Ratio Mease new unit ME VA for MEE) II RWS, evel	erage Gla mrad) (ca mrad) (D Specks 4.0 4.0 surement EE and Ann	ndular De onventional, BT) Masses 5.0 4.5 ts (values r ual Survey)	equired for	119 143 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass Pass

(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) ( <b>דھ</b> ر)	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.

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

<b>.</b>	N				( <b>n</b> ( [			
		Memorial Medical Ce			port Date		/2021	
		Maple Ln, Ashland, '	NI 54806	1	rvey Date		/2021 11	
	dical Physicist's Name	Steven T. Nicholas	and Shane McCotter	5	Signature	Stem 77	faile in	
	ay Unit Manufacturer	Sie	mens		Model	Mammomat Revela	ation Tomosynthesis	
Date	e of Installation	6/14	/2018		Room ID	DBT N	lammo	
<b>QC Manual Version #</b> Tomo QC 56.01.24, 2D QC 51.01.24 (use version applicable to unit tested; contact mfr if questions							:)	
Acc	essory Equipment	Manufacturer	Model	Location		QC Manual Vers	sion #	
	Review Workstation	* Barco	MDMG-5121	☑ On-site  □ Off-site		Hologic Man-01	478	
	Film Printer		NA	NA		NA	-	
*ED/	A recommends that only mo				Office of Dev		) he 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							
/							<b>.</b>	
("ł	Pass" means all component	ts of the test passes	indicate "Fail" if any	component fails. Test	s must be do	ne for both on and o		
4	Imaga Quality						PASS/FAIL Pass	
1.	Image Quality	s 4 speck around	and 4 masses vi	sihle*			F d 5 5	
	Ũ			e if spatial resolution a	nd CNR nas	5)		
	Phantom imag		Fibers 5.5	Specks 4.0	Masses	4.5		
2.	Artifact Detection	0 300103.	110013 0.0		Masses	4.5	Pass	
	Printer Check (if applic	able)					NA	
	SNR, CNR and AEC I						Pass	
ч.	Measured valu		57.3 CNR	2.28			1 455	
		d entrance air ke		2.20			Pass	
				nin ±15% of mean f	or measure	ements	Pass	
5.	Radiation Dose				or modeur	omonio	Pass	
•	2D Average gland	ular dose for ave	rage breast is <3 ı	mGy (300 mrad)	Г	63 mrad		
	3D Average gland			• • • •		130 mrad		
	2D+3D Average gland	ular dose for ave	rage breast is <u>&lt;</u> 3 ı	mGy (300 mrad)	TOTAL	193 mrad		
6.	Spatial Resolution			,	L		Pass	
7.	AEC Test						Pass	
8.	Detector Uniformity						Pass	
9.	Mechanical Tests						Pass	
10.	Acquisition Workstat	ion Monitor Che	eck				Pass	
11.	Site Audit/Evaluation	of Technologis	t QC Program				Pass	
	Collimation, Dead Sp	•	sion Paddle Posi	tion			Pass	
	HVL and Radiation O	-					Pass	
	Tube Voltage Measu	•	tability				Pass	
	Average Glandular D						Pass	
	Geometric Accuracy	in X and Y Direc	tion and Z-Reso	lution (DBT)			Pass	
	Radiation Field (DBT)						Pass	
18.	System Imaging Qua			6 h			Pass	
			l ≥ 3 masses must					
40	Phantom imag		Fibers 6.0	Specks 4.0	Masses	4.0		
	Artifact Detection (DE					0	Pass	
20.	<b>Review Workstation</b>	(KVVS) Lests (for	all RWS, even if loca	ted offsite; NA if only l	nardcopy rea	a)	Pass	

(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
Phantom Image Quality	Novation & Fusion-Daily; Inspiration-Weekly	Pass
Artifact Detection	Weekly	Pass
SNR and CNR Measurements	Weekly	Pass
Detector Calibration*	Novation-Weekly; Inspiration & Fusion-Quarterly	NA
Repeat/Reject Analysis	Quarterly	Pass
Compression Force	Semi-annually	Pass
System Imaging Quality (DBT)	Daily when DBT performed	Pass
Printer Check (if applicable)	Daily, when images printed	NA
Review Workstation QC-Overall (NA if only h	nardcopy read) See FDA guidance	Pass
Mobile Unit Quality Control (if applicable)	After every move	NA
	Artifact Detection SNR and CNR Measurements Detector Calibration* Repeat/Reject Analysis Compression Force System Imaging Quality <i>(DBT)</i> Printer Check <i>(if applicable)</i> Review Workstation QC-Overall <i>(NA if only f</i>	Phantom Image QualityNovation & Fusion-Daily; Inspiration-WeeklyArtifact DetectionWeeklySNR and CNR MeasurementsWeeklyDetector Calibration*Novation-Weekly; Inspiration & Fusion-QuarterlyRepeat/Reject AnalysisQuarterlyCompression ForceSemi-annuallySystem Imaging Quality (DBT)Daily when DBT performedPrinter Check ( <i>if applicable</i> )Daily, when images printedReview Workstation QC-Overall (NA if only hardcopy read)See FDA guidance

\* 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

		•		Ŭ			
Site Name	Rainy Lake Medical Center		Repo	ort Date		8/4/202	21
Address 1400	Highway 71, International Falls, I	ighway 71, International Falls, MN 56649			(	7/27/20	21//
Medical Physicist's Name	Steven T. Nicholas and Shar	Steven T. Nicholas and Shane McCotter (training)			X	en Th	lab
X-Ray Unit Manufacturer	Lorad/Hold	ogic		Model	Sele	enia Dimen	sions DBT
Date of Installation	10/15/20	20	R	oom ID		Mamm	10
				SN		SDM1319	01306
QC Manual Version #	MAN-03706, Rev. 07	10 (Aug 2020)	(use any vers	sion applicab	le to mode	l; contact mf	r if questions )
Accessory Equipment	Manufacturer	Model	Locat	ion	Q	C Manual V	/ersion #
Review Workstatio	n* Barco/Hologic	MDMG-5221	☑ On-site □	Off-site		AN-04959.	
Film Printe		NA	NA			NA	107.000
	nitors and printers specifically cle	4			Evaluatio		used See
FDA's Policy Guidance Help Sys							
Survey Type-	Annual Mammography Equi	pment Survey					
Features-		tal Breast Tomos	nthesis (DBT)				
	3-						
	Medical P	hvsicist's	QC Test	S			
("Pass" means all components	of the test passes; indicate "Fail				or both or	n and off-sit	e equipment.)
· · ·							PASS/FAIL
1. Mammographic Unit	Assembly Evaluation						Pass
2. Collimation Assessm	ent						Pass
3. Artifact Evaluation							Pass
4. kVp Accuracy and Re	producibility						Pass
	ment - HVL Measurement						Pass
6. Evaluation of System	Resolution						Pass
	Control (AEC) Function Po						Pass
-	osure, AEC Reproducibilit			se _		-	
	se for average breast is ≤3	•	,		123	mrad	Pass
Average glandular do	se for average breast is ≤3	mGy (300 mrae	l) <i>(DBT</i> )		150	mrad	Pass
9. Radiation Output Rat		· · · · ·					Pass
10. Phantom Image Qual	-	Fibers Spe					<b></b>
0	SCORES (conventional)	6.0 4.					Pass
Phantom image		6.0 4.					Pass
11. Signal-To-Noise Ratio	and Contrast-To-Noise F	Ratio Measurer	nents (values re	equired for a	all tests)		
SNR (value)	56.6						Pass
CNR (value)		new unit MEE and	Annual Survey)				<b></b>
	t vary by more than ±15% (/						Pass
12. Diagnostic Review W	orkstation (RWS) QC (for a	ll RWS, even if loo	ated offsite; NA i	f only hardo	copy read	)	Pass
13. DICOM Printer QC (if a							NA
14. Detector Flat Field Ca	libration (MEE only)						NA
<ol> <li>14. Detector Flat Field Ca</li> <li>15. Geometry Calibration</li> </ol>	llibration (MEE only) For Tomosynthsis (DBT M	IEE only)					NA Pass
<ol> <li>14. Detector Flat Field Ca</li> <li>15. Geometry Calibration</li> <li>16. Compression Thickness</li> </ol>	libration (MEE only) For Tomosynthsis (DBT M ess Indicator (MEE only)	IEE only)					NA Pass Pass
14. Detector Flat Field Ca 15. Geometry Calibration	Ilibration (MEE only) For Tomosynthsis (DBT M ess Indicator (MEE only) y)	IEE only)					NA Pass

(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 Evaluati	on 🖉	Weekly	PASS
4. Signal-To-Noise	and Contrast-To-Noise Measurements	Weekly	PASS
5. Phantom Image	Quality Evaluation	Weekly	PASS
6. Detector Flat-Fi	eld Calibration	Weekly	PASS
7. Compression T	nickness Indicator	Bi-weekly	PASS
8. Visual Checklis		Monthly	PASS
9. Repeat/Reject /	Analysis	Quarterly	PASS
10. Compression		Semi-annually	PASS
11. Geometry Calib	ration (Tomosynthsis Option) ( <b>דמס</b> )	Semi-annually	PASS
12. Diagnostic Revi	ew Workstation QC (NA if only hardcopy read)	See Hologic QC Manual	PASS
13. Mobile Unit Qua	lity 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.

Site Name	Esse	Essentia Health International Falls Report Dat			8/24/2021
Address	2501 Ke	enan Dr, International Falls, M	N 56649	Survey Date	7/27/2021
Medical Physicist's Name Steven Nicholas and Shane McCotter(training)			Signature	Hern TV hilds	
X-Ray Unit	ay Unit Manufacturer Lorad/Hologic			Model	Selenia
Date of Inst	Date of Installation 1/16/15			Room ID	Mammo
QC Manual	Version #	MAN-01476 Rev. 00	2 Sept 2014	(use any version applica	ble 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
Mammographic Unit Assembly Evaluation	Pass
Collimation Assessment	Pass
Artifact Evaluation	Pass
kVp Accuracy and Reproducibility	Pass
Beam Quality Assessment - HVL Measurement	Pass
Evaluation of System Resolution	Pass
Automatic Exposure Control (AEC) Function Performance (NA for systems without AEC)	Pass
Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose	Pass
Average glandular dose for average breast is ≤3 mGy (300 mrad) 120 mrad	
Radiation Output Rate	Pass
Phantom Image Quality Evaluation	Pass
Phantom image scores: Fibers 5.0 Specks 4.0 Masses 4.5	
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
Diagnostic Review Workstation (RWS) QC (for all RWS, even if located offsite; NA if only hardcopy read)	Pass
DICOM Printer QC (Mammography Equipment Evaluations only)	NA
Detector Flat Field Calibration (Mammography Equipment Evaluations only)	NA
Compression Thickness Indicator (Mammography Equipment Evaluations only)	Pass
Compression (Mammography Equipment Evaluations only)	Pass
	Collimation Assessment         Artifact Evaluation         kVp Accuracy and Reproducibility         Beam Quality Assessment - HVL Measurement         Evaluation of System Resolution         Automatic Exposure Control (AEC) Function Performance (NA for systems without AEC)         Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose         Average glandular dose for average breast is ≤3 mGy (300 mrad)       120 mrad         Radiation Output Rate         Phantom Image Quality Evaluation       120 mrad         Phantom Image Scores:       Fibers 5.0       Specks 4.0       Masses 4.5         Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements (values required for all tests)       SNR (value)       54.4         CNR (value)       11.07       (Required for both new unit Mammography Equipment Evaluations and Annual - CNR should not vary by more than ±15% (NA for Equipment Evaluation)       Diagnostic Review Workstation (RWS) QC (for all RWS, even if located offsite; NA if only hardcopy read)         DICOM Printer QC (Mammography Equipment Evaluations only)       Detector Flat Field Calibration (Mammography Equipment Evaluations only)         Detector Flat Field Calibration (Mammography Equipment Evaluations only)       Compression Thickness Indicator (Mammography Equipment Evaluations only)

(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 ( <i>if applicable</i> )	Daily	NA
2. Processor Quality Control ( <i>if applicable</i> )	Daily	NA
3. Laser Printer Quality Control	Weekly*	NA
4. Viewboxes and Viewing Conditions	Weekly	Pass
5. Artifact Evaluation	Weekly	Pass
5. Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Pass
. Phantom Image	Weekly	Pass
<ol> <li>Detector Flat-Field Calibration</li> </ol>	Weekly	Pass
<ol> <li>Compression Thickness Indicator</li> </ol>	Bi-weekly	Pass
0. Visual Checklist	Monthly	Pass
1. Analysis of Fixer Retention in Film (if applicable)	Quarterly	NA
2. Repeat Analysis	Quarterly	Pass
3. Darkroom Fog (if applicable)	Semi-annually	NA
4. Compression	Semi-annually	Pass
5. 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.

Site Name	e	Marine	er Medical Clinic			Repo	ort Date		9/20/20	21
Address	10	9 North 28th St, Superior, WI 54880		Surv	ey Date			2,1 / /		
Medical P	hysicist's Name	Steven T	. Nicholas and Shar	ne McCotter	(training)	Si	gnature	Å	I. TWING	
	it Manufacturer		Lorad/Holo	ogic			Model	Sele	enia Dimens	sions DBT
Date of In			9/11/202	÷		R	loom ID		Mamm	10
				-			SN		SDM13190	
QC Manua	al Version #	MAN	l-03706, Rev. 00	9 (Sept. 2	2019)	(use any ver	sion applica	ble to mode	l; contact mfi	r if questions )
Accessor	y Equipment	Ma	anufacturer	Мо	del	Loca	tion	Q	C Manual V	ersion #
	Review Workstation?	Bar	co/Hologic	MDMG	G-5221	🗆 On-site 🛛	Off-site	MA	N-04959, I	Rev. 002
	Film Printer	r	NA	N	IA	N	Α		NA	
	mends that only moni Guidance Help Syste Survey Type- Features-	em (www.aco	cessdata.fda.gov/cc	drh_docs/pre	esentations ollowing tu	/pghs/Polic_ Ibe replace	_Guidance	_Help_Sys	tem.htm).	
	eans all components c							for both on	and off-site	e equipment.) PASS/FAIL
1. Mamr	nographic Unit A	ssembly E	Evaluation							Pass
	nation Assessme	nt								Pass
	ct Evaluation									Pass
-	Accuracy and Rep		-							Pass
	Quality Assessn									Pass
	ation of System I									Pass
	natic Exposure C	•	,			-				Pass
	st Entrance Expos			-	-		-		т.	r
	rage glandular dos	e for avera	age breast is ≤3	mGy (300	mrad) (co	nventional)				
	and a second				, .			121	mrad	Pass
	rage glandular dos	e for avera	age breast is ≤3	mGy (300	, .			121 150	mrad	Pass
9. Radia	tion Output Rate		•		mrad) (D	BT)			4	
9. Radia	tion Output Rate	y Evaluati	on	Fibers	mrad) (D Specks	BT) Masses			4	Pass Pass
9. Radia	tion Output Rate tom Image Qualit Phantom image	<b>y Evaluati</b> scores <i>(cor</i>	<b>on</b> nventional)	Fibers 6.0	mrad) (D Specks 4.0	BT) Masses 4.5	ļ		4	Pass Pass Pass
9. Radia 10. Phant	tion Output Rate tom Image Qualit Phantom image Phantom image	<b>y Evaluati</b> scores <i>(cor</i> scores <b>(DB</b>	on nventional) 87)	Fibers           6.0           6.0	mrad) (D Specks 4.0 4.0	<b>BT</b> ) Masses 4.5 4.5	]	150	4	Pass Pass
9. Radia 10. Phant	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio	y Evaluati scores <i>(cor</i> scores <i>(DB</i> and Contr	on nventional) 87)	Fibers           6.0           6.0	mrad) (D Specks 4.0 4.0	<b>BT</b> ) Masses 4.5 4.5	]	150	4	Pass Pass Pass Pass
9. Radia 10. Phant	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value)	y Evaluati scores (cor scores (DB and Conti 56.1	on nventional) 87) rast-To-Noise R	Fibers 6.0 6.0 Ratio Meas	Specks 4.0 4.0 surement	Masses 4.5 4.5 S (values r	equired for	150	4	Pass Pass Pass
9. Radia 10. Phant	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value)	y Evaluati scores (cor scores (DE and Contr 56.1 10.79	on nventional) BT) rast-To-Noise R	Fibers 6.0 6.0 Catio Meas	Specks 4.0 4.0 surement	Masses 4.5 4.5 S (values r	equired for	150	4	Pass Pass Pass Pass Pass
9. Radia 10. Phan 11. Signa	tion Output Rate tom Image Qualit Phantom image Phantom image I-To-Noise Ratio SNR (value) CNR (value) CNR should not	y Evaluati scores (cor scores (DB and Contr 56.1 10.79 vary by mo	on nventional) BT) rast-To-Noise R (required for pore than ±15% (N	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE)	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass
<ol> <li>Radia</li> <li>Phani</li> <li>Signa</li> <li>Diagr</li> </ol>	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value) CNR should not tostic Review Wo	y Evaluati scores (cor scores (DB and Contri 56.1 10.79 vary by mo rkstation	on nventional) 8T) rast-To-Noise R (required for in pore than ±15% (N (RWS) QC (for al	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE)	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass Pass Pass
<ol> <li>9. Radia</li> <li>10. Phan</li> <li>11. Signa</li> <li>12. Diagr</li> <li>13. DICO</li> </ol>	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value) CNR should not nostic Review Wo M Printer QC (if ap	y Evaluati scores (cor scores (DB and Contri 56.1 10.79 vary by mo rkstation pplicable, ME	on nventional) BT) rast-To-Noise R (required for l pore than ±15% (N (RWS) QC (for all EE only)	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE)	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass Pass NA
<ol> <li>9. Radia</li> <li>10. Phant</li> <li>11. Signa</li> <li>12. Diagn</li> <li>13. DICO</li> <li>14. Detect</li> </ol>	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value) CNR should not nostic Review Wo M Printer QC (if ap ctor Flat Field Cal	y Evaluati scores (cor scores (DB and Contr 56.1 10.79 vary by mo rkstation pplicable, ME ibration (A	on nventional) BT) rast-To-Noise R (required for l pre than ±15% (N (RWS) QC (for all E only) MEE only)	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE) II RWS, even	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass Pass NA Pass
<ol> <li>9. Radia</li> <li>10. Phant</li> <li>11. Signa</li> <li>12. Diagn</li> <li>13. DICO</li> <li>14. Detect</li> <li>15. Geom</li> </ol>	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value) CNR should not nostic Review Wo M Printer QC (if ap tor Flat Field Cal netry Calibration I	y Evaluati scores (cor scores (DB and Contri 56.1 10.79 vary by mo rkstation rkstation pplicable, ME ibration (A For Tomos	on nventional) ar rast-To-Noise R (required for i pre than ±15% (N (RWS) QC (for al EE only) MEE only) synthsis (DBT Mil	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE) II RWS, even	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass Pass NA Pass Pass Pass
<ol> <li>Radia</li> <li>Phant</li> <li>Phant</li> <li>Signa</li> <li>Signa</li> <li>Diagr</li> <li>Diagr</li> <li>Diagr</li> <li>Diagr</li> <li>Diagr</li> <li>Diagr</li> <li>Diagr</li> <li>Geom</li> <li>Comp</li> </ol>	tion Output Rate tom Image Qualit Phantom image Phantom image II-To-Noise Ratio SNR (value) CNR (value) CNR should not nostic Review Wo M Printer QC (if ap ctor Flat Field Cal	y Evaluati scores (cor scores (DE and Contr 56.1 10.79 vary by mo rkstation phicable, ME ibration (A For Tomos ss Indicate	on nventional) ar rast-To-Noise R (required for i pre than ±15% (N (RWS) QC (for al EE only) MEE only) synthsis (DBT Mil	Fibers 6.0 6.0 Ratio Meas new unit ME NA for MEE) II RWS, even	Specks 4.0 4.0 surement	BT) Masses 4.5 4.5 S (values round ual Survey)	equired for	150 r all tests)	mrad	Pass Pass Pass Pass Pass Pass NA Pass

(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 Q	uality Control (if applicable)	Weekly	NA
2. Viewboxes and V	iewing Conditions	Weekly	Pass
3. Artifact Evaluatio	n 🦓	Weekly	Pass
4. Signal-To-Noise	and Contrast-To-Noise Measurements	Weekly	Pass
5. Phantom Image	Quality Evaluation	Weekly	Pass
6. Detector Flat-Fie	ld Calibration	Weekly	Pass
7. Compression Thi	ckness Indicator	Bi-weekly	Pass
8. Visual Checklist		Monthly	Pass
9. Repeat/Reject A	nalysis	Quarterly	Pass
10. Compression		Semi-annually	Pass
11. Geometry Calibra	ation (Tomosynthsis Option) ( <b>דמס</b> )	Semi-annually	Pass
12. Diagnostic Revie	w Workstation QC (NA if only hardcopy read)	See Hologic QC Manual	Pass
13. Mobile Unit Qual	ty 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.

Site Name		Riverwood Health Care Center			<b>Report Date</b> 10/15/2021				)21
Address	200	) Bunker Hill Drive, Aitkin, MN 5	6431		Surv	vey Date	(	$21_{A}AA$	
<b>Medical Physicist's</b>	Name	Steven T. Nicholas & Shane	McCotter (	Training)	Si	ignature	A	en TW	- lala
X-Ray Unit Manufac	turer	Lorad/Holo	gic			Model	Sele	sions DBT	
Date of Installation	3/14/2018			F	Room ID	Mamm Rm #230		#230	
						SN		SDM13150	0537
QC Manual Version	#	MAN-03706 Rev. 007	(March 2	2018)	(use any ve	rsion applic	able to mode	el; contact mf	fr if questions )
Accessory Equipme	nt	Manufacturer	Ма	del	Loca	ation	Q	C Manual V	ersion #
Review Wo	rkstation*	Barco/Hologic	MDMC	G-5221	🗸 On-site	Off-site		MAN-04959, R	ev. 002
Filr	n Printer*	NA	N	IA	N	A		NA	
		ors and printers specifically clea w.accessdata.fda.gov/cdrh_doc						• •	sed. See FDA's
Survey Type Features	✓ ✓	Mammo Eqpt Evaluation (MEE 2D 🛛 Digita		it (include M mosynthesis		s for Mamr	no Eqpt che	ecklist)	Annual Survey
<ol> <li>Mammographic</li> <li>Collimation Ass</li> <li>Artifact Evaluati</li> <li>kVp Accuracy a</li> <li>Beam Quality A</li> <li>Evaluation of Sy</li> <li>Automatic Exponent</li> </ol>	Unit As essmer on nd Rep ssessm ystem R sure Co e Expos	roducibility ent - HVL Measurement desolution ontrol (AEC) Function Pe ure, AEC Reproducibility	rformanc and Ave	ponent fails e (NA for s rage Glar	. Tests mus ystems with ndular Do	st be done		7	PASS/FAIL Pass Pass Pass Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu	ılar dose u <b>t Rate</b>	e for average breast is ≤3 r	nGy (300	mrad) (DE	BT)		125 149	mrad mrad	Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image	ilar dose u <b>t Rate</b> Quality	e for average breast is ≤3 r • Evaluation	nGy (300 Fibers	mrad) (DE Specks	BT) Masses			-	Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image	ilar dose <b>it Rate Quality</b> image s	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional)	nGy (300 Fibers 6.0	mrad) (DE Specks 4.0	Masses 5.0			-	Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom	ilar dose ut Rate Quality image s image s	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT)	nGy (300 Fibers 6.0 6.0	mrad) <i>(DE</i> <u>Specks</u> <u>4.0</u> <u>4.0</u>	Masses 5.0 4.5	equired for	149	-	Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise	Ilar dose ut Rate Quality image s image s Ratio a	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra	nGy (300 Fibers 6.0 6.0	mrad) <i>(DE</i> <u>Specks</u> <u>4.0</u> <u>4.0</u>	Masses 5.0 4.5	equired for	149	-	Pass Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (value	Ilar dose ut Rate Quality image s image s Ratio a e)	e for average breast is ≤3 r <b>v Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7	Fibers 6.0 6.0 atio Meas	mrad) (DE Specks 4.0 4.0 surements	Masses 5.0 4.5 S (values re	equired for	149	-	Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu	Ilar dose ut Rate Quality image s image s Ratio a e) e)	e for average breast is ≤3 r <b>v Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7 10.80 (required for r	nGy (300 Fibers 6.0 6.0 atio Meas	mrad) (DE Specks 4.0 4.0 surements	Masses 5.0 4.5 S (values re	equired for	149	-	Pass Pass Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shot	llar dose <b>ut Rate</b> <b>Quality</b> image s image s <b>Ratio</b> a e) e) uld not v	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7 10.80 (required for r vary by more than ±15% (No	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE)	mrad) (DE Specks 4.0 4.0 surements	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shoi 12. Diagnostic Revi	ular dose ut Rate Quality image s image s e Ratio a e) e) uld not v ew Wor	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7 10.80 (required for r rary by more than ±15% (N. ckstation (RWS) QC (for all	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE)	mrad) (DE Specks 4.0 4.0 surements	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass Pass
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shot	ular dose ut Rate Quality image s image s e Ratio a e) e) uld not v ew Wor QC (if app	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise R 54.7 10.80 (required for r vary by more than ±15% (N. rkstation (RWS) QC (for all blicable, MEE only)	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE)	mrad) (DE Specks 4.0 4.0 surements E and Annu n if located o	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass NA
Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shoi 12. Diagnostic Revi 13. DICOM Printer O 14. Detector Flat Fie	ular dose ut Rate Quality image s image s e Ratio a e) uld not v ew Wor QC (if app eld Cali	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7 10.80 (required for r vary by more than ±15% (N. restation (RWS) QC (for all blicable, MEE only) bration (MEE only)	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE) RWS, ever	mrad) (DE Specks 4.0 4.0 surements E and Annu n if located o	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass Pass
Average glandu Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shot 13. DICOM Printer O 14. Detector Flat Fie 15. Geometry Calib	Ilar dose <b>ut Rate</b> <b>Quality</b> image s image s <b>Ratio</b> a e) e) uld not v <b>ew Wor</b> <b>QC</b> ( <i>if app</i> <b>eld Cali</b> <b>ration F</b>	e for average breast is ≤3 r <b>Evaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise R 54.7 10.80 (required for r vary by more than ±15% (N. rkstation (RWS) QC (for all blicable, MEE only)	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE) RWS, ever	mrad) (DE Specks 4.0 4.0 surements	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass NA Pass
Average glandu Average glandu Average glandu 9. Radiation Outpu 10. Phantom Image Phantom Phantom 11. Signal-To-Noise SNR (valu CNR (valu CNR shot 13. DICOM Printer O 14. Detector Flat Fie 15. Geometry Calib	Ilar dose <b>Jt Rate</b> <b>Quality</b> image s image s <b>Ratio</b> a e) e) uld not v <b>ew Wor</b> <b>QC</b> ( <i>if app</i> <b>eld Cali</b> <b>ration F</b> <b>hicknes</b>	e for average breast is ≤3 r <b>Exaluation</b> cores (conventional) cores (DBT) and Contrast-To-Noise Ra 54.7 10.80 (required for r vary by more than ±15% (N. rkstation (RWS) QC (for all blicable, MEE only) bration (MEE only) for Tomosynthsis (DBT ML	nGy (300 Fibers 6.0 6.0 atio Meas new unit ME A for MEE) RWS, ever	mrad) (DE Specks 4.0 4.0 surements E and Annu n if located o	Masses 5.0 4.5 S (values re val Survey)		149 all tests)	-	Pass Pass Pass Pass Pass Pass NA Pass Pass Pass

(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.

Site Name	St	. Francis Regional Medical Cer	nter		Rep	ort Date		10/19/2	021
Address		Shakopee, MN			Surv	vey Date	/	021/1	
Medical Phy	sicist's Name	Steven T. Nicholas & Shane	McCotter (	Training)	Si	gnature	E.	in	
X-Ray Unit M	<b>Nanufacturer</b>	Lorad/Holo		Model	20,5	ensions			
Date of Insta	allation	10/9/2015			F	Room ID		1118 Ma	mmo
	-					SN		8140915	5456
QC Manual	Version #	MAN-03706, Rev. 00	94 (April 2	015)	(use any vei	sion applica	ble to model	l; contact mfr	if questions )
Accessory E	Equipment	Manufacturer	Mo	del	Loca	tion	Q	C Manual \	/ersion #
R	eview Workstation*	Hologic	Secure	eView	On-	Site	MAN-03	706, Rev. 0	04 (April 2015)
	Film Printer*	NA	N	A	N	Α		NA	
Policy Guidance	e Help System (www	rs and printers specifically clea accessdata.fda.gov/cdrh_doc.							ised. See FDA's
	5 51	Annual Survey 2D and Digit:	al Breast To	omosynthe	sis (DBT)				
					• <b>-</b>				
		Medical P							
("Pass" mea	ns all components o	f the test passes; indicate "Fail	" if any com	ponent fails	. Tests mus	st be done i	for both on	and off-site	
4									PASS/FAIL
	graphic Unit Ass	sembly Evaluation							Pass
		L							NA
3. Artifact	Evaluation	-							Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> </ol>	Evaluation curacy and Repr	oducibility							Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> </ol>	Evaluation curacy and Repro-	oducibility ent - HVL Measurement							Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> </ol>	Evaluation curacy and Repro- uality Assessme ion of System Re	oducibility ent - HVL Measurement esolution	rformance	p (NA for s	vstems with	out AEC)			Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> </ol>	Evaluation curacy and Repr uality Assessme on of System Re tic Exposure Co	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per							Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E</li> </ol>	Evaluation curacy and Repre- cuality Assessme fon of System Re tic Exposure Co Entrance Exposu	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Pe ure, AEC Reproducibility	and Aver	age Glan	ndular Do		120	Imrad	Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E Average</li> </ol>	Evaluation curacy and Repre- uality Assessme ion of System Re- tic Exposure Co Entrance Exposu- le glandular dose	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per irre, AEC Reproducibility for average breast is ≤3 r	n <b>Gy</b> (300 n	<b>rage Glan</b> mrad) <i>(col</i>	ndular Do nventional)		<u>120</u> 147	mrad	Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E Average Average</li> </ol>	Evaluation curacy and Repre- uality Assessme ion of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Pe ure, AEC Reproducibility	n <b>Gy</b> (300 n	<b>rage Glan</b> mrad) <i>(col</i>	ndular Do nventional)		120 147	mrad mrad	Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag Averag</li> <li>Radiation</li> </ol>	Evaluation curacy and Repre- cuality Assessme ton of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose on Output Rate	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Pe ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r	n <b>Gy</b> (300 n	<b>rage Glan</b> mrad) <i>(col</i>	ndular Do nventional)				Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag Averag</li> <li>Radiation</li> <li>Phantom</li> </ol>	Evaluation curacy and Repre- cuality Assessme ton of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose on Output Rate n Image Quality	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r	m <b>Gy (300</b> mGy (300 mGy (300 m	<b>rage Glan</b> mrad) <i>(col</i> mrad) <b>(DE</b>	ndular Do nventional) 37)				Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast B Average Average</li> <li>Radiation</li> <li>Phantom</li> </ol>	Evaluation curacy and Repre- cuality Assessme ton of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose on Output Rate n Image Quality	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional)	mGy (300 mGy	rage Glan mrad) (co mrad) (DE Specks	ndular Do nventional) 37) Masses				Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E Average</li> <li>Radiation</li> <li>Phantom</li> </ol>	Evaluation curacy and Repre- cuality Assessme ion of System Re- tic Exposure Co Entrance Exposu- ge glandular dose on Output Rate on Output Rate on Image Quality Phantom image se Phantom image se	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional)	and Aver mGy (300 m mGy (300 m 5.5 5.0	rage Glan mrad) (col mrad) (DE Specks 4.0 4.0	Masses 4.5 4.5	se	147		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E Average Average</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> </ol>	Evaluation curacy and Repre- cuality Assessme ion of System Re- tic Exposure Co Entrance Exposu- ge glandular dose on Output Rate on Output Rate on Image Quality Phantom image se Phantom image se	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT)	and Aver mGy (300 m mGy (300 m 5.5 5.0	rage Glan mrad) (col mrad) (DE Specks 4.0 4.0	Masses 4.5 4.5	se	147		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E</li> <li>Averag</li> <li>Averag</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> </ol>	Evaluation curacy and Repre- cuality Assessme fon of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose on Output Rate on Output Rate on Image Quality Phantom image se Fo-Noise Ratio a	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra	and Aver nGy (300 m nGy (300 m <u>Fibers</u> 5.5 5.0 atio Meas	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements	Masses 4.5 4.5 5 (values re	se	147		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E</li> <li>Averag</li> <li>Averag</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>Signal-T</li> </ol>	Evaluation curacy and Repre- cuality Assessme fon of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose on Output Rate n Image Quality Phantom image se Co-Noise Ratio a ENR (value) CNR (value)	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra	and Aver nGy (300 m nGy (300 m Fibers 5.5 5.0 atio Measure new unit ME	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements	Masses 4.5 4.5 5 (values re	se	147		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag</li> <li>Averag</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>O</li> </ol>	Evaluation curacy and Repre- cuality Assessme ton of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose ge glandular dose on Output Rate n Image Quality Phantom image se Phantom image se Co-Noise Ratio a SNR (value) CNR (value)	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r	and Aver           nGy (300 n           nGy (300 n           Fibers           5.5           5.0           atio Mease           new unit ME           A for MEE)	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag</li> <li>Averag</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>C</li> <li>Diagnos</li> </ol>	Evaluation curacy and Repre- cuality Assessme ton of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose ge glandular dose on Output Rate n Image Quality Phantom image se Phantom image se Co-Noise Ratio a SNR (value) CNR (value)	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Pea ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r ary by more than ±15% (N. station (RWS) QC (for all	and Aver           nGy (300 n           nGy (300 n           Fibers           5.5           5.0           atio Mease           new unit ME           A for MEE)	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag</li> <li>Radiation</li> <li>Phantom</li> <li>P</li> <li>Signal-T</li> <li>Signal-T</li> <li>C</li> <li>Diagnos</li> <li>DICOM I</li> </ol>	Evaluation curacy and Repre- cuality Assessme to of System Re- tic Exposure Co Entrance Exposu- ge glandular dose on Output Rate n Image Quality Phantom image se Phantom image se Co-Noise Ratio a ENR (value) CNR (value) CNR should not va stic Review Worl	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ire, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r ary by more than ±15% (N. estation (RWS) QC (for all licable, MEE only)	and Aver           nGy (300 n           nGy (300 n           Fibers           5.5           5.0           atio Mease           new unit ME           A for MEE)	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements E and Annu- if located c	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automa</li> <li>Breast E Averag</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>Signal-T</li> <li>Diagnoss</li> <li>DICOM I</li> <li>Detector</li> </ol>	Evaluation curacy and Repre- quality Assessme fon of System Re- tic Exposure Co Entrance Exposure ge glandular dose ge glandular dose on Output Rate in Image Quality Phantom image se Phantom image se Co-Noise Ratio a SNR (value) CNR (value) CNR (value) CNR should not va stic Review Worl Printer QC (if appart r Flat Field Calib	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ire, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r ary by more than ±15% (N. estation (RWS) QC (for all licable, MEE only)	and Aver mGy (300 m mGy (300 m 5.5 5.0 atio Meas hew unit ME A for MEE) RWS, even	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements E and Annu- if located c	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E</li> <li>Average</li> <li>Average</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>Signal-T</li> <li>Diagnost</li> <li>DICOM I</li> <li>Detector</li> <li>Geomet</li> <li>Compre</li> </ol>	Evaluation curacy and Repre- cuality Assessme fon of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose ge glandular dose ge glandular dose on Output Rate n Image Quality Phantom image se con Output Rate n	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r ary by more than ±15% (N. estation (RWS) QC (for all licable, MEE only) pration (MEE only)	and Aver mGy (300 m mGy (300 m 5.5 5.0 atio Meas hew unit ME A for MEE) RWS, even	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Artifact</li> <li>kVp Acc</li> <li>Beam Q</li> <li>Evaluati</li> <li>Automation</li> <li>Breast E</li> <li>Average</li> <li>Average</li> <li>Radiation</li> <li>Phantom</li> <li>F</li> <li>Signal-T</li> <li>Signal-T</li> <li>Diagnost</li> <li>DICOM I</li> <li>Detector</li> <li>Geomet</li> <li>Compre</li> </ol>	Evaluation curacy and Repre- cuality Assessme fon of System Re- tic Exposure Co Entrance Exposu- ge glandular dose ge glandular dose ge glandular dose on Output Rate n Image Quality Phantom image se Co-Noise Ratio a SNR (value) CNR (value) CNR should not va stic Review Worl Printer QC (if app) r Flat Field Calib ry Calibration Fo	oducibility ent - HVL Measurement esolution ntrol (AEC) Function Per ure, AEC Reproducibility for average breast is ≤3 r for average breast is ≤3 r Evaluation cores (conventional) cores (DBT) nd Contrast-To-Noise Ra 54.3 11.09 (required for r ary by more than ±15% (N. (station (RWS) QC (for all licable, MEE only) pration (MEE only) or Tomosynthsis (DBT ME	and Aver mGy (300 m mGy (300 m 5.5 5.0 atio Meas hew unit ME A for MEE) RWS, even	rage Glan mrad) (con mrad) (DE <u>Specks</u> 4.0 4.0 urements E and Annu- if located c	Masses 4.5 4.5 5 (values re ual Survey)	se	147 all tests)		Pass Pass Pass Pass Pass Pass Pass Pass

(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

Madical Physicist's OC Tasts		
Medical Physicist's QC Tests		
No Discrepancies.		
Evaluation of Site's Technologist QC Program		
No Discrepancies.		
Site does not print.		
•		

# John Patrick Aniversity Bealth and Applied Sciences

Apon recommendation of the Faculty,

John Patrick University of Health and Applied Sciences has conferred upon

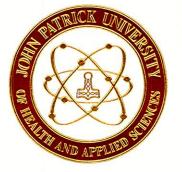
# SHANE MCCOTTER

the dearee 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



# 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 Social Security	03/16/1989	Student ID Number Enrollment Date Program		232109 05/06/2019 MS MEDICAL PHYSICS		
Summer 2019						
COURSE NO.	COURSE TITLE			GRADE	CRED	QPts
BIOL530	HUMAN ANATOMY & PHYSIOLOGY			В	4	12
MP590	MEDICAL & PROFESSIONAL ETHICS			A	1	4
MP502	RADIATION BIOLOGY			В	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
	Cumulative Program. Links	•	Qi ta	23	ULA.	3
Fall 2019						
COURSE NO.	COURSE TITLE			GRADE	CRED	QPts
MP503	DIAGNOSTIC RADIOLOGY			Α	3	12
MP505	RADIATION ONCOLOGY I			В	3	9
MP599 \$9	SEMINARS SESSION 9			Α	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				CRADE	COLD	0.00
COURSE NO.				GRADE	CRED	QPts
MP603	ADVANCED DIAGNOSTIC RADIOLOGY			A	2 2	8 8
MP520	COMPUTER SYSTEMS IN MEDICINE			A	17.000	100
MP506	RADIATION ONCOLOGY II			A	3	12
	Term: EHRS	7	QPts	28	GPA	4.00
No. of all and a	Cumulative: EHRS	22	QPts	78	GPA	3.55
	Cumulative Program: EHRS	22	QPts	78	GPA	3.55

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Elizabeth M Datema Office of the Registrar

Brut Murphy

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 Date of Birth Social Security	03/16/1989		Student ID Number Enrollment Date Program		232109 05/06/2019 MS MEDICAL PHYSICS			
Summer 2020	COURSE TITLE							
COURSE NO.	HEALTH PHYSICS/RADIATION			GRADE	CRED	QPts		
MHP510	SAFETY NUCLEAR MEDICINE			Α	3	12		
MP504	STATISTICAL METHODS			A	3	12		
STAT501	interest of the second second second			Α	3	12		
$(\mathbf{Q}_{i}, \mathbf{Q}_{i})$	Term: EHRS Cumulative: EHRS	9 31	QPts QPts	36 114	GPA GPA	4.00 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			А	2	8		
	Term: EHRS	15	QPts	60	GPA	4.00		
and the second second	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

Efterth Dolern

Elizabeth M Datema Office of the Registrar

Brut Murphy

Brent D. Murphy, MS, DABR President

## John Patrick University of Health and Applied Sciences 100 E. Wayne Street, Ste. 140, South Bend, IN 46601 PH 574.232.2408 FAX 574.232.2200

### 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.

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 Cours

Grade and Credit Point System

Graduate Courses			Undergraduate Courses							
A (4.0 Pts) Excellent	F (0.0 Pts) Failing		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)	Good		Ρ	(4.0 Pts)	Passed (Pass/	Fail Option)		
C (0.0 Pts) Unsatisfactory	WF (0.0 Pts) Withdrawn - Failing		C (2.0 Pts)	Satisfactory			WF (0.0 Pts)	Withdrawn - Failing		
D (0.0 Pts) Unsatisfactory			D (OPts)	Unsatisfactory	Y					

#### 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.

**TO TEST FOR AUTHENTICITY**: Translucent globe icons MUST be visible from both sides when held toward a light source. The face of this transcript is printed on red SCRIP-SAFE<sup>\*</sup> paper with the name of the institution appearing in white type over the face of the entire document.

JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES\*JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH AND APPLIED SCIENCES • JOHN PATRICK UNIVERSITY OF HEALTH

ADDITIONAL TESTS: The institutional name and the word COPY appear on alternate rows as a latent image. When this paper is touched by fresh liquid bleach, an authentic document will stain brown. A black and white or color copy of this document is not an original and should not be accepted as an official institutional document. This document cannot be released to a third party without the written consent of the student. This is in accordance with the Family Educational Rights and Privacy Act of 1974. If you have any questions about this document, please contact our office. ALTERATION OF THIS DOCUMENT MAY BE A CRIMINAL OFFENSE!