

#### July 18, 2023 MQSA PHYSICIST CONTINUING EXPERIENCE

This document expires on May 8, 2025.

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

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

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

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

Sincerely,

Hen This

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



Site Nam	e	North Shore Health			Report Date	7/6/202	23
Address	515 5th	h Ave West, Grand Marais, MN 55604			Survey Date		
Medical I	Physicist's Name	Steven T. N			Signature	Hen The los	
X-Ray Ur	nit Manufacturer	Lorad/Hologic			Model	Selenia Dimen	2 · · · ·
•	nstallation	6/21/20	•		Room ID	Mamn	10
					SN	SDM1319	
QC Manu	al Version #	MAN-03706, Rev.	010 (Aug 2	2020)	(use any version applicabl	le to model; contact mfi	if questions)
Accesso	ry Equipment	Manufacturer	M	odel	Location	QC Manual \	/ersion #
	Review Workstation*	Barco/Hologic	MDM	G-5221	🛛 On-site 🗳 Off-site	MAN-04959,	Rev. 002
	Film Printer*	NA	1	٨٨	NA	NA	
Policy Guid	Survey Type- N	accessdata.fda.gov/cdrh_dd IEE following AEC recalib D and Dig Medical I	pration and A gital Breast T	Innual Surv	vey esis (DBT)	vstem.ntm).	
ו "Pass" ו	means all components of a	the test passes; indicate "Fa	•			or both on and off-site	•••
							PASS/FAIL
	mographic Unit Ass	embly Evaluation					Pass
	mation Assessment						Pass
	act Evaluation						Pass
-	Accuracy and Repro	•					Pass
	-	nt - HVL Measurement	t				Pass
	uation of System Res		)orformond	• (NIA fam.)			Pass
	-	trol (AEC) Function P re, AEC Reproducibility		-	-		Pass
	•	•	•	-			
	aye yianuulai uuse i	or average breast is < -					Bass
AVE	erade diandular dose f	or average breast is ≤3 or average breast is ≤3				118 mrad	Pass
	0 0	for average breast is ≤3 for average breast is ≤3				118 mrad 148 mrad	Pass
9. Radia	ation Output Rate	or average breast is ≤3	3 mGy (300	mrad) <i>(D</i>	вт)		
9. Radia	ation Output Rate tom Image Quality E	or average breast is ≤3 Evaluation	3 mGy (300 Fibers	mrad) <i>(Dl</i> Specks	BT) Masses		Pass Pass
9. Radia	ation Output Rate Itom Image Quality E Phantom image sco	for average breast is ≤3 Evaluation Dres <i>(conventional)</i>	3 mGy (300 Fibers 6.0	mrad) <i>(DI</i> Specks 4.0	BT) Masses 4.5		Pass Pass Pass
9. Radia 10. Phan	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco	for average breast is ≤3 Evaluation Dres <i>(conventional)</i> Dres <i>(DBT)</i>	3 mGy (300 Fibers 6.0 6.0	mrad) <i>(D</i> <b>Specks</b> 4.0 4.0	BT) Masses 4.5 4.5	148 mrad	Pass Pass
9. Radia 10. Phan	ation Output Rate ntom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an	for average breast is ≤3 Evaluation Dres <i>(conventional)</i> Dres <i>(DBT)</i> d Contrast-To-Noise I	3 mGy (300 Fibers 6.0 6.0	mrad) <i>(D</i> <b>Specks</b> 4.0 4.0	BT) Masses 4.5 4.5	148 mrad	Pass Pass Pass Pass
9. Radia 10. Phan	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value)	for average breast is ≤3 Evaluation ores <i>(conventional)</i> ores <i>(DBT)</i> d Contrast-To-Noise I	3 mGy (300 Fibers 6.0 6.0 Ratio Meas	mrad) <i>(D</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al	148 mrad	Pass Pass Pass
9. Radia 10. Phan	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value)	For average breast is ≤3 Evaluation Dres <i>(conventional)</i> Dres <i>(DBT)</i> d Contrast-To-Noise I 56.7 11.16 <i>(required fo</i>	B mGy (300 Fibers 6.0 6.0 Ratio Meas	mrad) <i>(DI</i> Specks 4.0 4.0 surements EE and Ann	BT) Masses 4.5 4.5 S (values required for al	148 mrad	Pass Pass Pass Pass Pass
9. Radia 10. Phan 11. Signa	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val	For average breast is ≤3 Evaluation pres (conventional) pres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15%	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE)	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass
9. Radia 10. Phan 11. Signa 12. Diage	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val	For average breast is ≤3 Evaluation Dres (conventional) Dres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15% of station (RWS) QC (for a	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE)	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass Pass
9. Radia 10. Phan 11. Signa 12. Diaga 13. DICC	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val nostic Review Works	Tor average breast is ≤3 Evaluation Dres (conventional) Dres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15% ( station (RWS) QC (for a cable, MEE only)	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE)	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass Pass Pass Pass
<ol> <li>9. Radia</li> <li>10. Phan</li> <li>11. Signa</li> <li>12. Diaga</li> <li>13. DICC</li> <li>14. Detee</li> </ol>	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val nostic Review Works OM Printer QC (if applic ctor Flat Field Calibr	Tor average breast is ≤3 Evaluation Dres (conventional) Dres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15% ( station (RWS) QC (for a cable, MEE only)	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE) all RWS, even	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass Pass Pass NA
<ol> <li>9. Radia</li> <li>10. Phan</li> <li>11. Signa</li> <li>12. Diaga</li> <li>13. DICO</li> <li>14. Detea</li> <li>15. Geor</li> </ol>	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val nostic Review Works OM Printer QC (if applic ctor Flat Field Calibr	Tor average breast is ≤3 Evaluation Dres (conventional) Dres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15% ( station (RWS) QC (for a cable, MEE only) ration (MEE only) ration (MEE only) r Tomosynthsis (DBT I	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE) all RWS, even	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass Pass Pass NA Pass
<ol> <li>Radia</li> <li>Phan</li> <li>Phan</li> <li>Signa</li> <li>Signa</li> <li>Diaga</li> <li>Di</li></ol>	ation Output Rate tom Image Quality E Phantom image sco Phantom image sco al-To-Noise Ratio an SNR (value) CNR (value) CNR should not val nostic Review Works OM Printer QC (if applic ctor Flat Field Calibr metry Calibration For	Tor average breast is ≤3 Evaluation Dres (conventional) Dres (DBT) d Contrast-To-Noise I 56.7 11.16 (required for ry by more than ±15% ( station (RWS) QC (for a cable, MEE only) ration (MEE only) ration (MEE only) r Tomosynthsis (DBT I	B mGy (300 Fibers 6.0 6.0 Ratio Meas or new unit Mi (NA for MEE) all RWS, even	mrad) <i>(DI</i> Specks 4.0 4.0 surements	BT) Masses 4.5 4.5 S (values required for al oual Survey)	148 mrad	Pass Pass Pass Pass Pass Pass NA 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**

is an annual Medical Physicist's survey on a DBT unit.
ical Physicist's QC Tests
Discrepancies.
uation of Site's Technologist QC Program
e are no discrepancies.
does not print.

Site Name	÷	Mariner Medical Clinic				Report Dat	<b>e</b> 7/18/20	)23
Address	1(	09 North 28th St, Superior, WI 54880		54880		Survey Dat	e	)2,3 <sub>1</sub>
Medical P	hysicist's Name	Steven T. Nic		cholas		Signatur	e Tw	Job
X-Ray Uni	Ray Unit Manufacturer Lorad/Holo		ogic		Mode	Selenia Dimer	sions DBT	
Date of In	stallation		9/11/202	20		Room II	D Mamr	no
						SI	N SDM1319	01270
QC Manua	al Version #		MAN-03706, Rev. 0	09 (Sept. 2	2019)	(use any version appli	cable to model; contact mf	r if questions )
Accessor	y Equipment		Manufacturer	M	odel	Location	QC Manual	/ersion #
	Review Workstation	*	Barco/Hologic	MDM	G-5221	□ On-site	MAN-04959,	Rev. 002
	Film Printer	ł	NA	1	NA	NA	NA	
rolicy Guida	Survey Type- Features-		ssdata.fda.gov/cdrh_doo for new detector and Digi Medical P	tal Breast T	omosynthe	esis (DBT)	_System.num).	
("Pass" n	eans all components	of the te	est passes; indicate "Fai				e for both on and off-site	e equipment.)
(	<i>p</i>			,,,				PASS/FAIL
I. Mamn	nographic Unit As	ssemb	bly Evaluation					Pass
2. Collin	nation Assessme	nt	-					Pass
B. Artifa	ct Evaluation							Pass
l. kVpA	ccuracy and Rep	roduc	ibility					Pass
5. Beam	Quality Assessm	ent -	HVL Measurement					Pass
	ation of System F			_				Pass
	-		(AEC) Function Pe				)	Pass
	-		EC Reproducibility	•	-			
			verage breast is ≤3 verage breast is ≤3		, .	,	133 mrad	Pass
	tion Output Rate		verage breast is =5	11Gy (300	illiau) (Di	51)	156 mrad	Pass Pass
	com Image Quality	, Eval	uation	Fibers	Specks	Masses		F 855
	om mage gaung			T IDCI 3	орсска	11113355		
		scores	(conventional)	6.0	4 0	50		Pass
	Phantom image		,	6.0 6.0	4.0	5.0		Pass Pass
0. Phant	Phantom image s	scores	(DBT)	6.0	4.0	4.0	or all tests)	Pass Pass
10. Phant	Phantom image s	scores and C	,	6.0	4.0	4.0	r all tests)	
0. Phant	Phantom image s Phantom image s I-To-Noise Ratio	scores and C	ontrast-To-Noise R	6.0 atio Meas	4.0 surements	4.0 <b>s</b> (values required fo	er all tests)	Pass
0. Phant	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value)	and C	ontrast-To-Noise R	6.0 atio Meas	4.0 surements	4.0 <b>s</b> (values required fo	or all tests)	Pass
I0. Phant	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not y	and Contract of Co	<b>(DBT)</b> ontrast-To-Noise R 57.8 11.35 (required for	6.0 atio Meas new unit Mi NA for MEE)	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass
I0. Phant I1. Signa I2. Diagn I3. DICOI	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not s ostic Review Wo M Printer QC (if ap	and Contract of the secores and Contract of the second sec	<b>(DBT)</b> ontrast-To-Noise R 57.8 11.35 (required for y more than ±15% ( <i>I</i> ion (RWS) QC (for all b, MEE only)	6.0 atio Meas new unit Mi NA for MEE)	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass Pass
10. Phant 11. Signa 12. Diagn 13. DICOI 14. Detec	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not s ostic Review Wor M Printer QC (if ap tor Flat Field Cali	and C and C vary by rkstati plicable bratio	<b>(DBT)</b> <b>ontrast-To-Noise R</b> 57.8 11.35 (required for y more than ±15% ( <i>I</i> <b>ion (RWS) QC</b> (for all b, MEE only) <b>in</b> (MEE only)	6.0 atio Meas new unit Mi NA for MEE) II RWS, even	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass Pass Pass NA Pass
<ol> <li>Phant</li> <li>Signa</li> <li>Diagn</li> <li>DICOI</li> <li>DECOI</li> <li>Geom</li> </ol>	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not s ostic Review Wo M Printer QC (if ap tor Flat Field Cali	and Contract of the second sec	(DBT) ontrast-To-Noise R 57.8 (required for y more than ±15% (I ion (RWS) QC (for al e, MEE only) on (MEE only) mosynthsis (DBT M	6.0 atio Meas new unit Mi NA for MEE) II RWS, even	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass Pass Pass NA Pass Pass
10. Phant 11. Signa 12. Diagn 13. DICOI 14. Detec 15. Geom 16. Comp	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not s ostic Review Wor M Printer QC (if ap tor Flat Field Cali etry Calibration F pression Thicknes	vary by rkstati bratio	(DBT) ontrast-To-Noise R 57.8 (required for y more than ±15% (I ion (RWS) QC (for al e, MEE only) on (MEE only) mosynthsis (DBT M	6.0 atio Meas new unit Mi NA for MEE) II RWS, even	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass Pass Pass NA Pass Pass Pass
10. Phant 11. Signa 11. Diagn 13. DICOI 14. Detec 15. Geom 16. Comp 17. Comp	Phantom image s Phantom image s I-To-Noise Ratio s SNR (value) CNR (value) CNR should not s ostic Review Wo M Printer QC (if ap tor Flat Field Cali	vary by rkstatio bratio	ontrast-To-Noise R 57.8 (required for y more than ±15% ( <i>I</i> ion (RWS) QC (for al e, MEE only) on (MEE only) mosynthsis (DBT M icator (MEE only)	6.0 atio Meas new unit Mi NA for MEE) II RWS, even	4.0 surements	4.0 <b>s</b> (values required fo ual Survey)		Pass Pass Pass Pass NA Pass 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	NA
3.	Artifact Evaluation	Weekly	NA
4.	Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	NA
5.	Phantom Image Quality Evaluation	Weekly	NA
6.	Detector Flat-Field Calibration	Weekly	NA
7.	Compression Thickness Indicator	Bi-weekly	NA
8.	Visual Checklist	Monthly	NA
9.	Repeat/Reject Analysis	Quarterly	NA
10	Compression	Semi-annually	NA
11	Geometry Calibration (Tomosynthsis Option) (DBT)	Semi-annually	NA
12	Diagnostic Review Workstation QC (NA if only hardcopy read)	See Hologic QC Manual	NA
13	Mobile Unit Quality Control (if applicable)	After every move	NA

### **Medical Physicist's Recommendations for Quality Improvement**

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

#### Medical Physicist's QC Tests

No Discrepancies.

**Evaluation of Site's Technologist QC Program** Not performed. Keep your current baselines.

Site Name	Osceola Medical Center		Report Date	<b>e</b> 6/14/2	023	
Address	2600 65th Ave, Osceola, WI 54020			Survey Date	e6/13/2	023, 1 1
Medical Physicist's Name	Steven T. Nicholas			Signature	e Hem Th	files
X-Ray Unit Manufacturer	Lorad/Hologic			Mode	Selenia Dime	nsions DBT
Date of Installation	9/20/2018			Room IE	Mammo	Rm 1
				SN	SDM131	500755
QC Manual Version #	MAN-03706, Rev. 0	09 (Sept 2	2019)	(use any version applic	cable to model; contact m	fr if questions)
Accessory Equipment	Manufacturer	M	odel	Location	QC Manual	Version #
Review Workstation*	Barco	MDM	G-5221	On-Site	MAN-03706, Rev.	009 (Sept 2019)
Film Printer*	NA	1	NA	NA	NA	١
*FDA recommends that only monite Policy Guidance Help System (www Survey Type-			•		. ,	used. See FDA's
Features-	2D and Dig	ital Breast 1	Fomosynthe	esis (DBT)		
						PASS/FAIL
<ol> <li>Mammographic Unit As</li> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> </ol>	nt					Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> </ol>	nt roducibility					Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> </ol>	nt roducibility ent - HVL Measurement					Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> </ol>	nt roducibility ent - HVL Measurement		<b>:e</b> (NA for s	ystems without AEC)		Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> </ol>	nt roducibility ent - HVL Measurement resolution	erformanc				Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe	erformand y and Ave	erage Glar	ndular Dose	124 mrad	Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <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 esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit	erformand y and Ave mGy (300	erage Glar ) mrad) <i>(</i> co	ndular Dose		Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> </ol>	nt roducibility 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	erage Glar ) mrad) <i>(</i> co	ndular Dose	124 mrad	Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> </ol>	nt roducibility 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	erage Glar ) mrad) <i>(</i> co	ndular Dose	124 mrad	Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos Average glandular dose Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality Phantom image s</li> </ol>	nt roducibility ent - HVL Measurement desolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 r Evaluation scores (conventional)	erformance y and Ave mGy (300 mGy (300 Fibers 6.0	erage Glar ) mrad) <i>(co</i> ) mrad) <i>(D</i>	ndular Dose nventional) 3T)	124 mrad	Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom image s</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 v Evaluation scores (conventional) scores (DBT)	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0	erage Glar (co mrad) (co mrad) (D Specks 4.0 4.0	ndular Dose nventional) BT) Masses 4.5 4.5	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> <li>Phantom image s</li> <li>Phantom image s</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 <b>r Evaluation</b> scores ( <i>conventional</i> ) scores ( <i>DBT</i> ) and Contrast-To-Noise F	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0	erage Glar (co mrad) (co mrad) (D Specks 4.0 4.0	ndular Dose nventional) BT) Masses 4.5 4.5	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SNR (value)</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 v Evaluation scores (conventional) scores (DBT) and Contrast-To-Noise R 56.9	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Ratio Meas	erage Glar (co mrad) (co mrad) (Dr Specks 4.0 4.0 surements	ndular Dose nventional) 37) Masses 4.5 4.5 5 (values required for	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SIR (value)</li> <li>CNR (value)</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 v Evaluation scores (conventional) scores (DBT) and Contrast-To-Noise F 56.9 10.73 (required for	erformance y and Ave mGy (300 mGy (300 <u>Fibers</u> 6.0 6.0 8 atio Meas	erage Glar mrad) (co mrad) (D Specks 4.0 4.0 surements EE and Ann	ndular Dose nventional) 37) Masses 4.5 4.5 5 (values required for	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SIGNAI-To-Noise Ratio a</li> <li>SNR (value)</li> <li>CNR (value)</li> <li>CNR should not v</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 e for average breast is ≤3 v Evaluation scores (conventional) scores (DBT) and Contrast-To-Noise R 56.9 10.73 (required for vary by more than ±15% (required for	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Ratio Meas r new unit M. NA for MEE)	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SIR (value) CNR (value)</li> <li>CNR should not w</li> <li>Diagnostic Review Wor</li> </ol>	nt roducibility ent - HVL Measurement esolution ontrol (AEC) Function Pe ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 for average breast	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Ratio Meas r new unit M. NA for MEE)	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> <li>Phantom image s</li> <li>Signal-To-Noise Ratio a</li> <li>SNR (value)</li> <li>CNR (value)</li> <li>CNR should not w</li> <li>Diagnostic Review Wor</li> <li>DICOM Printer QC (if app</li> </ol>	nt roducibility ent - HVL Measurement desolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is $\leq 3$ e for average breast is $\leq$	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Ratio Meas r new unit M. NA for MEE)	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SIR (value)</li> <li>CNR (value)</li> <li>CNR should not v</li> <li>Diagnostic Review Wor</li> <li>DICOM Printer QC (if app</li> <li>Detector Flat Field Calil</li> </ol>	nt roducibility ent - HVL Measurement desolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 e for average breast is ≤3 for average breast is ≤3 <b>v Evaluation</b> scores (conventional) scores (DBT) and Contrast-To-Noise R <u>56.9</u> 10.73 (required for vary by more than ±15% (restation (RWS) QC (for a plicable, MEE only) bration (MEE only)	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Catio Meas r new unit Ma NA for MEE II RWS, even	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> <li>Phantom image s</li> <li>Phantom image s</li> <li>SIR (value)</li> <li>CNR (value)</li> <li>CNR should not v</li> <li>Diagnostic Review Wor</li> <li>DICOM Printer QC (if app</li> <li>Geometry Calibration F</li> </ol>	nt roducibility ent - HVL Measurement desolution Dutrol (AEC) Function Per ure, AEC Reproducibility e for average breast is ≤3 e for average breast is ≤3 e for average breast is ≤3 <b>r Evaluation</b> Scores (conventional) Scores (DBT) and Contrast-To-Noise R 56.9 10.73 (required for vary by more than ±15% (restand for vary by more than ±15% (restand for vary by more than ±15% (restand for bration (MEE only) for Tomosynthsis (DBT M	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Catio Meas r new unit Ma NA for MEE II RWS, even	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
<ol> <li>Collimation Assessmer</li> <li>Artifact Evaluation</li> <li>kVp Accuracy and Repr</li> <li>Beam Quality Assessm</li> <li>Evaluation of System R</li> <li>Automatic Exposure Co</li> <li>Breast Entrance Expos</li> <li>Average glandular dose</li> <li>Average glandular dose</li> <li>Radiation Output Rate</li> <li>Phantom Image Quality</li> <li>Phantom image s</li> <li>SNR (value)</li> <li>CNR (value)</li> </ol>	nt roducibility ent - HVL Measurement desolution ontrol (AEC) Function Pe- ure, AEC Reproducibilit e for average breast is ≤3 e for average breast is ≤3 e for average breast is ≤3 v Evaluation scores (conventional) scores (DBT) and Contrast-To-Noise R 56.9 10.73 (required for vary by more than ±15% (restation (RWS) QC (for a colicable, MEE only) bration (MEE only) for Tomosynthsis (DBT M as Indicator (MEE only)	erformance y and Ave mGy (300 mGy (300 Fibers 6.0 6.0 Catio Meas r new unit Ma NA for MEE II RWS, even	erage Glar (co mrad) (co mrad) (De Specks 4.0 4.0 surements	nventional) BT) Masses 4.5 4.5 5 (values required for ual Survey)	124 mrad 144 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) (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**

his is an annual Medical Physicist's survey.
Iedical Physicist's QC Tests
lo Discrepancies.
valuation of Site's Technologist QC Program
lo discrepancies.
ite does not print.

Site Name		DM	S Health Technologies			Rep	ort Date	6/7/20	023
Address	728 Bento	on Drive, Suite 101, West Fargo, ND 58		, ND 58078	3		vey Date	<u> </u>	023 11
Medical Ph	ysicist's Name		Steven T. Nic	holas			ignature	The Th	
X-Ray Unit	-Ray Unit Manufacturer Lorad/Hole		ogic			Model	Selenia Dime	nsions DBT	
Date of Inst			5/24/202	-			Room ID	MM2	28
						1	SN	SDM1319	
QC Manual	Version #		MAN-03706, F	Rev. 011		(use any ve	rsion applicat	ole to model; contact m	fr if questions)
Accessory	Equipment		Manufacturer	Mo	odel	Loca	ation	QC Manual	Version #
1	Review Workstation*		Hologic	Secu	urView	Off-	Site	MAN-03706	, Rev. 011
	Film Printer*		NA	١	١A	N	Α	NA	١
Policy Guidan	ce Help System (www Survey Type-	w.acces	printers specifically clea ssdata.fda.gov/cdrh_doc ollowing an upgrade a	s/presentat nd AEC rec	ions/pghs/P calibration.	olic_Guidai A full annu	nce_Help_S	ystem.htm).	used. See FDA's
	Features-	2D	and Digit	al Breast T	omosynthe	sis (DBT)			
<ol> <li>Collima</li> <li>Artifact</li> <li>kVp Ac</li> <li>Beam C</li> <li>Evaluat</li> <li>Evaluat</li> <li>Automa</li> <li>Breast</li> <li>Avera</li> </ol>	tion of System R atic Exposure Co Entrance Expose ge glandular dose	nt oduci ent - H esolu ontrol ure, A e for av	ibility IVL Measurement	n <b>Gy</b> (300	rage Glar mrad) <i>(co</i>	ndular Do	se	31 mrad 52 mrad	Pass Pass Pass Pass Pass Pass Pass Pass
9. Radiati	on Output Rate								Pass
	om Image Quality	Evalu	uation	Fibers	Specks	Masses			
	Phantom image s	cores	(conventional)	5.5	5.0	4.5			Pass
					010				газэ
	Phantom image s	cores	(DBT)	5.5	4.0	4.5			Pass
11. Signal-	<b>To-Noise Ratio a</b> SNR (value) CNR (value)	nd Co	Ontrast-To-Noise Ra       59.2       0.70   (required for lateral sector)	atio Meas	4.0 surements	4.5 6 (values re	-	III tests)	
11. Signal-	<b>To-Noise Ratio a</b> SNR ( <i>value</i> ) CNR ( <i>value</i> ) CNR should not v	nd Co 1 ary by	0.70 (required for 1 more than ±15% (N	atio Meas new unit MI IA for MEE)	4.0 surements	4.5 6 (values re ual Survey)			Pass
11. Signal- 12. Diagno	<b>To-Noise Ratio a</b> SNR (value) CNR (value) CNR should not v <b>estic Review Wor</b>	nd Co 1 ary by kstati	ontrast-To-Noise Ra 59.2 0.70 (required for a more than ±15% (N on (RWS) QC (for all	atio Meas new unit MI IA for MEE)	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass
<ol> <li>Signal-</li> <li>Diagno</li> <li>DICOM</li> </ol>	To-Noise Ratio a SNR (value) CNR (value) CNR should not v stic Review Wor Printer QC (if app	and Co 1 ary by kstati	ontrast-To-Noise Ra 59.2 0.70 (required for 1 more than ±15% (N on (RWS) QC (for all MEE only)	atio Meas new unit MI IA for MEE)	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass Pass Pass NA
<ol> <li>Signal-</li> <li>Diagno</li> <li>DICOM</li> <li>Detector</li> </ol>	To-Noise Ratio a SNR (value) CNR (value) CNR should not v ostic Review Wor Printer QC (if app or Flat Field Calib	and Co 1 ary by kstati blicable, pratio	ontrast-To-Noise Ra 59.2 0.70 (required for a more than ±15% (N on (RWS) QC (for all MEE only) n (MEE only)	new unit Ml IA for MEE) RWS, evel	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass Pass Pass NA NA
<ol> <li>Signal-</li> <li>Diagno</li> <li>DICOM</li> <li>Detecto</li> <li>Geome</li> </ol>	To-Noise Ratio a SNR (value) CNR (value) CNR should not v stic Review Wor Printer QC (if app or Flat Field Calib etry Calibration F	nd Co 1 ary by kstati blicable, pratio	ontrast-To-Noise Ra 59.2 0.70 (required for 1 r more than ±15% (N on (RWS) QC (for all , MEE only) n (MEE only) mosynthsis (DBT ME	new unit Ml IA for MEE) RWS, evel	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass Pass Pass NA NA NA
<ol> <li>Signal-</li> <li>Diagno</li> <li>DICOM</li> <li>Detecto</li> <li>Geome</li> <li>Compression</li> </ol>	To-Noise Ratio a SNR (value) CNR (value) CNR should not v ostic Review Wor Printer QC (if app or Flat Field Calib etry Calibration For ession Thicknes	nd Co 1 ary by kstati blicable, pratio	ontrast-To-Noise Ra 59.2 0.70 (required for 1 r more than ±15% (N on (RWS) QC (for all , MEE only) n (MEE only) mosynthsis (DBT ME	new unit Ml IA for MEE) RWS, evel	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass Pass Pass NA NA NA Pass
<ol> <li>Signal-</li> <li>Diagno</li> <li>DICOM</li> <li>DICOM</li> <li>Detecto</li> <li>Geome</li> <li>Compression</li> <li>Compression</li> </ol>	To-Noise Ratio a SNR (value) CNR (value) CNR should not v stic Review Wor Printer QC (if app or Flat Field Calib etry Calibration F	nd Co 1 ary by kstati blicable, pratio or Toi s Indi	ontrast-To-Noise Ra 59.2 0.70 (required for 1 more than ±15% (N on (RWS) QC (for all MEE only) n (MEE only) n (MEE only) mosynthsis (DBT ME cator (MEE only)	new unit Ml IA for MEE) RWS, evel	4.0 surements	4.5 6 (values re ual Survey)			Pass Pass Pass Pass NA NA NA

(Lorad, continued)

### **Evaluation of Site's Technologist QC Program**

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

#### **Medical Physicist's Recommendations for Quality Improvement**

This is an Annual survey of a mobile DBT unit.

Medical Physicist's QC Tests

No Discrepancies.

Evaluation of Site's Technologist QC Program

No discrepancies.

Cito Nome	Г				- 11 - 12 - 2	20
Site Name		St. Luke's Hospital		Report Date	7/18/2023	
Address		915 E 1st St, Duluth, MN 55805		Survey Date	<u> 5/8/2023</u>	
	ysicist's Name	Steven T. Nicholas		Signature	- Alem / 1/	toby
•	Manufacturer	Hologic		Model	Selenia Dimens	
Date of Ins	tallation	3/10/2017			Mammo Ro	
QC Manual	Version #	MAN 02706 Boy 006	( Jupa 2017)	SN (use any version applicable	81002177	
		MAN-03706, Rev. 006	, , , , , , , , , , , , , , , , , , ,			. ,
Accessory	Equipment	Manufacturer	Model	Location	QC Manual V	
	Review Workstation*	Barco/Hologic	MDMG-5221	On-site	MAN-04959, F	Rev. 002
	Film Printer*	NA	NA	NA	NA	
	-	s and printers specifically cleared da.gov/CDRH/MAMMOGRAPHY/	•		luation (ODE) be use	ed. See FDA's
Survey Typ		Annual Survey of 2D and Tomo				
	eans all components o ographic Unit Ass	<b>Medical Phy</b> f the test passes; indicate "Fail" if a sembly Evaluation			both on and off-site	equipment.) PASS/FAIL Pass
	ation Assessment	-				1 435
	Deviation betweer	n X-ray field and light field $\leq 2$	2% of SID			Pass
	X-ray field does n	ot extend beyond any side of	f the IR by >2% o	of SID		Pass
	X-ray field covers	all of the IR on the chest wa	ll side			Pass
	Paddle chest wall	edge does not extend beyor	nd IR by >1% of	SID or appear on ma	mmogram	Pass
3. Artifac	t Evaluation (no sig	gnificant artifacts visible)				Pass
4. kVp Ac	curacy and Repro	oducibility				
	Measured averag	e kVp within ±5% of indicate	d kVp			Pass
	kVp coefficient of	variation ≤ 0.02				Pass
	•	nt - HVL Measurement				Pass
	•	solution (system limiting spatia	-			Pass
7. Autom	atic Exposure Co	ntrol (AEC) Function Perfor	mance (NA for sy	vstems without AEC)		
	•	2-8 cm; all operating modes)				Pass
		sation steps performance w	•			Pass
8. Breast	•	re, AEC Reproducibility an	-			
	00	r dose for average breast is :		<i>′</i>		Pass
	Average glandula	r to a 4.2 cm breast on your	unitis		onventional	4i.o.o
TOMO	Coofficient of veri	ation for aither $\mathbf{P}$ or $\mathbf{mAa} < 0$	OF (NIA for evet		omosynthesis Op	
9. Radiat	ion Output Rate (	ation for either R or mAs $\leq 0$ .	.05 (INA IOI SYSTE	· · · · · · · · · · · · · · · · · · ·		Pass Pass
	om Image Quality	,		mR/sec 700		F 035
	• •	uality scores (Conventional)				
	r nantom image q	adity soures (Conventional)	Fibers 6.0	Specks 4.0	Masses 4.5	Pass
	Phantom image g	uality scores (Tomosynthesis				
TOMO			Fibers 6.0	Specks 4.0	Masses 4.5	Pass
11. Signal-	-To-Noise Ratio ar	nd Contrast-To-Noise Ratio				
	SNR (value)	52.0				Pass
	CNR (value)	10.5 (Required for bo	oth new unit Mamme	ography Equipment Evalu	ations and Annual S	urveys)
		ary by more than ±15% (NA f		,		Pass
		station (RWS) QC (for all RW		offsite; NA if only hardcop	y read)	Pass
	•	nography Equipment Evaluations o	• ·			NA
		ration (Mammography Equipmen				NA
•		Indicator (Mammography Equi	ipment Evaluations	only)		Pass
16. Compr	ession (Mammograp	hy Equipment Evaluations only)				NA

NA

17. Geometry Calibration

(Lorad, continued)

#### **Evaluation of Site's Technologist QC Program**

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

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

### **Medical Physicist's Recommendations for Quality Improvement**

This is an annual survey.

Medical Physicist's QC Tests

No Discrepancies.

#### Evaluation of Site's Technologist QC Program

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

#### This facility does not print hard copy.

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

Site Name		keWood Health Ce	ptor		Poport	Dato		E/21	/2022
Address					Report Date		5/31/2023		
		Ave S., Baudette,			Survey Date Signature		5/24/2023		12023, A
	ysicist's Name		. Nicholas		•	-		en /	for the top
•	Manufacturer		mens			lodel	Mammon		ation Tomosynthesis
Date of Ins	tallation	6/10	/2021		ROO	m ID		DBIN	Mammo
QC Manual	Version #	Tomo QC VC2	20, 2D QC VC20	(use version a	oplicable to unit	tested;	contact mfr	if questions	5)
Accessory	Equipment	Manufacturer	Model	Locatio	on		QC Ma	anual Vers	sion #
Re	eview Workstation*	Double Black	Wide 5MP	□ On-site    Of	f-site		X-Cal S	Software 5	5.2.0.5
	Film Printer*	NA	NA	NA				NA	
	ends that only moni ce Help System (wv	• •	•	•				• • •	) be used. See FDA's
Survey Typ		qpt Evaluation (ME	, , , , , , , , , , , , , , , , , , , ,	•	nts for Mammo	o Eqpt o	checklist)		Annual Survey
Features	⊠ 2D	Digital Brea	ast Tomosynthes	sis (DBT)					
		Ме	dical Phy	/sicist's C	QC Test	S			
("Pass" me	ans all components						ne for both	n on and o	ff-site equipment.)
									PASS/FAIL
1. Image	•								Pass
	•	, 4 speck groups							
		speck groups and	3 masses accep			· · ·	s)	-	
	Phantom image	scores:	Fibers 6.0	Specks	4.0 Ma	asses	4.5		
	Detection								Pass
	Check (if applical								NA
4. SNR, C	NR and AEC Re	• • •							Pass
	Measured value	L. L.		NR 2.65					
	CV for mAs and						1 -		Pass
E Dedicti		f mean pixel val	ues and SNR	within ±15% of	mean for m	easure	ements		Pass
5. Radiati	on Dose	lar daga far ava	rada bradat ia	(200 m)	arad)	] مە			Pass
	Average glandu		age pleast is	<u>&lt;</u> 3 mGy (300 m	liau)	2D	0.80	mGy	
					סנ	3D + 3D	1.70	mGy	
6. Spatial	Resolution				20	+ 30	2.50	mGy	Pass
7. AEC Te									Pass
	or Uniformity								Pass
	nical Tests								Pass
	ition Workstatio	on Monitor Che	ck						Pass
-	dit/Evaluation of								Pass
	ation, Dead Spa	-	-						Pass
	d Radiation Ou	-		osition					Pass
	oltage Measure	•	ability						Pass
	e Glandular Do	•				3D	1.70	mGy	Pass
-	tric Accuracy in	•	tion and Z-Re	solution (DBT)		L		,	Pass
	on Field (DBT)			. ,					Pass
18. System	Imaging Qualit	ty <i>(DBT)</i>							Pass
-	$\geq$ 4 fibers, $\geq$ 3 sp	beck groups and	l ≥ 3 masses n	nust be visible					
	Phantom image	scores:	Fibers 6.0	) Specks	4.0 Ma	asses	4.0	7	
19. Artifact	Detection (DBT	)				L		_	Pass

20. Review Workstation (RWS) Tests (for all RWS, even if located offsite; NA if only hardcopy read)

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

### **Medical Physicist's Recommendations for Quality Improvement**

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

#### Important:

1. The facility's "quality assurance program shall be **substantially the same** as the quality assurance program recommended by the **image receptor [digital detector] manufacturer**." This is required by the FDA.

2. Use the QC manual version provided by the manufacturer for the digital system surveyed.

3. If the RWS or printer is FDA-cleared for FFDM, their **QC manual** is considered to be **"substantially the same"** and may be followed. (Check with the RWS or printer manufacturers for their clearance status and QC manual.)

4. If the RWS or printer is not cleared by the FDA for FFDM, *follow the QC manual provided by the image receptor manufacturer*. (Check with the image receptor manufacturer for their required tests.)

5. All tests must be evaluated for the facility's **on and off-site** equipment. If the evaluation was done on a different day than the survey date, note the date above.

6. See the FDA-approved alternative standard for Siemens FFDM regarding corrective action periods when components fail QC. However, if these tests are performed as part of a Mammography Equipment Evaluation (e.g., for a new system), corrective action must be taken before mammographic images are acquired.