

US Internal
c/o Fluke Biomedical
6045 Cochran Rd

Order Number: 756214
Print date: 2/13/2019

44139 SOLON, OH
United States

Service Activity:

Description

Serial#

SERVICE PROGRAM - ANNUAL CALIBRATION	141430
Unfors Xi Base Unit w/ mAs Platinum	141430
RaySafe Xi R/F & MAM detector	129160
RaySafe Xi CT detector	141619
RaySafe Xi Light detector	141544
RaySafe Xi Transparent detector	176628
----- service and new parts -----	
Internal Service Program Xi	
RaySafe Xi mammo M-Pro 2.0 Plus calibration	

Certificate of Calibration

US Internal
c/o Fluke Biomedical
6045 Cochran Rd
44139 SOLON, OH
United States

Product:	RaySafe Xi
Model:	mAs
Serial Number:	141430
Arrival Check	Date: 02/12/19
Calibration Certificate	Date: 02/12/19
Calibration Equipment List	

Your instrument has passed several strict tests and has been approved for delivery.
Enclosed you will find detailed documents for your instrument.



This laboratory is accredited by the American Association for Laboratory Accreditation (A2LA) and the results shown in this certificate have been determined within the scope of accreditation unless stated otherwise in this certificate.

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Certificate of Calibration

Date of Calibration:	02/12/19	Product:	RaySafe Xi
Serial Number:	141430	Model:	mAs

Current, As Found			
Nominal Settings	Measured Data		
Current (mA)	Reference Current (mA)	Xi Current (mA)	Current Deviation
1	0.99992	0.992	-0.80%
10	10.0001	9.964	-0.36%
100	99.996	99.78	-0.21%

Charge, As Found			
Nominal Settings	Measured Data		
Charge (mAs)	Reference Charge (mAs)	Xi Charge (mAs)	Charge Deviation
100	99.995	99.63	-0.36%
1000	1000.02	997.8	-0.22%

Current, As Left			
Nominal Settings	Measured Data		
Current (mA)	Reference Current (mA)	Xi Current (mA)	Current Deviation
1	0.99992	0.991	-0.94%
10	10.0001	9.961	-0.40%
100	99.996	99.74	-0.26%

Charge, As Left			
Nominal Settings	Measured Data		
Charge (mAs)	Reference Charge (mAs)	Xi Charge (mAs)	Charge Deviation
100	99.995	99.60	-0.39%
1000	1000.02	997.4	-0.26%

mA/mAs Specification:
 mA: $\pm 1\%$ or 0,02 mA
 mAs: $\pm 1\%$ or 0,02 mAs

For further specification details, please refer to your RaySafe Xi Manual.

CALIBRATION CERTIFICATE issued by an Accredited Calibration Laboratory

US Internal
 c/o Fluke Biomedical
 6045 Cochran Rd
 44139 SOLON, OH
 United States

Product:	Xi
Model:	R/F & Mammo
Serial Number:	129160

R/F Arrival Check: Date: 02/11/19
Mammo Arrival Check: Date: 02/07/19
R/F Calibration Certificate: Date: 02/12/19
Mammo Calibration Certificate: Date: 02/12/19
Calibration Equipment List

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Arrival Check

XI R/F

Date of Arrival Check:	02/11/19	Product:	XI
Serial Number:	129160	Model:	R/F & Mammo

Measurement details, as found:

kVp Total Filtration = 2.5 mm Al

R/F Low				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	XI kV	Tolerance *) 3,1%
50	32	50.60	50.45	-0.3%
70	16	70.67	71.10	0.6%
100	8	100.8	100.4	-0.4%
150	5	150.8	148.5	-1.5%

kVp Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	XI kVp	Tolerance *) 3,1%
50	51	50.60	50.70	0.2%
70	26	70.67	71.40	1.0%
100	10	100.8	102.2	1.4%
150	5	150.8	152.4	1.0%

Dose Total Filtration = 2.5 mm Al

R/F Low				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μGy	XI dose μGy	Tolerance *) 6,5%
50	32	370.7	368.7	-0.6%
70	16	238.5	240.4	0.8%
100	8	226.0	227.8	0.8%
150	5	278.7	277.7	-0.4%

Dose Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μGy	XI dose μGy	Tolerance *) 6,5%
50	51	5901	5790	-1.9%
70	26	2995	2972	-0.8%
100	10	2197	2204	0.3%
150	5	3422	3401	-0.6%

Time (Non-Accredited) Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set ms	Ref. Time ms	XI Time ms	Tolerance *) 0,5%
70	320	319.9	320.2	0.1%

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Arrival Check

Xi Mammography

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	129160	Model:	R/F & Mammo

Measurement details, as found:

kVp

Mo / 30µm Mo

Mo/Mo No Paddle				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Tolerance *) 03% or 01 kV
23	50	22.88	22.99	0.5%
25	50	24.89	24.93	0.2%
28	50	27.86	27.79	-0.2%
32	50	31.89	31.93	0.1%
35	50	34.88	34.92	0.1%

Mo / 30µm Mo + 0,1mm Al

Mo/Mo Paddle				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Tolerance *) 03% or 01 kV
23	50	22.88	22.93	0.3%
25	50	24.89	24.85	-0.1%
28	50	27.86	27.79	-0.2%
32	50	31.89	31.91	0.1%
35	50	34.88	34.79	-0.3%

Dose

Mo / 30µm Mo

0mm Al Added Filtration				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi dose µGy	Tolerance *) 07%
23	50	2956	2956	0.0%
25	50	3995	3983	-0.3%
28	50	5798	5779	-0.3%
32	50	8685	8713	0.3%
35	50	11024	11084	0.5%

Mo / 30µm Mo + 0,1mm Al

0,1mm Al Added Filtration				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi dose µGy	Tolerance *) 07%
23	50	2173	2180	0.3%
25	50	3019	3039	0.7%
28	50	4494	4532	0.9%
32	50	6878	6952	1.1%
35	50	8857	8977	1.4%

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Certificate of Calibration

XI R/F

Date of Calibration:	02/12/19	Product:	Xi
Serial Number:	129160	Model:	R/F & Mammo

Measurement details, as left:

kVp Total Filtration = 2.5 mm Al

R/F Low				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation
50	32	50.60	50.61	0.0%
70	16	70.67	70.66	0.0%
100	8	100.8	101.3	0.5%
150	5	150.8	150.0	-0.5%
Active Compensation		Total Filtration = 2.5 + 10 mm Al		
100	16	100.8	101.5	0.7%

kVp Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Deviation
50	51	50.60	50.76	0.3%
70	26	70.67	71.00	0.5%
100	10	100.8	101.5	0.7%
150	5	150.8	150.0	-0.6%
Active Compensation		Total Filtration = 2.5 + 10 mm Al		
100	16	100.8	101.5	0.7%

Dose Total Filtration = 2.5 mm Al

R/F Low				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μ Gy	Xi dose μ Gy	Deviation
50	32	370.8	370.0	-0.2%
70	16	239.3	241.3	0.8%
100	8	226.8	230.1	1.5%
150	5	279.5	280.2	0.3%
Active Compensation		Total Filtration = 2.5 mm Al + 26 mm Al		
80	64	140.2	141.4	0.9%

Dose Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μ Gy	Xi dose μ Gy	Deviation
50	51	5920	5905	-0.3%
70	26	3005	3028	0.8%
100	10	2199	2233	1.6%
150	5	3443	3455	0.4%
Active Compensation		Total Filtration = 2.5 + 26 mm Al		
80	102	971.4	978.3	0.7%

HVL (Non-Accredited) Total Filtration = 2.5 mm Al

R/F Low				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
70	16	2.60	2.57	-1.3%

HVL (Non-Accredited) Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
70	26	2.60	2.58	-0.9%

Time (Non-Accredited) Total Filtration = 2.5 mm Al

R/F High				
Generator settings		Measurements		
Set kVp	Set ms	Ref. Time ms	Xi Time ms	Deviation
70	320	319.9	320.6	0.2%

RF Low Specification:
 kV/kVp for <0.5mm Cu \pm 2%, for >0.5mm Cu \pm 3%, Dose \pm 5%,
 HVL \pm 10% or \pm 0.2 mm Al, Time \pm 0.5% or \pm 0.2 ms,
 Total Filtration \pm 10% or 0.2mm Al

RF High Specification:
 kV/kVp for <0.5mm Cu \pm 2%, for >0.5mm Cu \pm 3%, Dose \pm 5%,
 HVL \pm 10% or \pm 0.2 mm Al, Time \pm 0.5% or \pm 0.2 ms,
 Total Filtration \pm 10% or 0.2mm Al

For further specification details, please refer to your Xi Manual.

Certificate of Calibration

Xi Mammography

Date of Calibration:	02/12/19	Product:	Xi
Serial Number:	129160	Model:	R/F & Mammo

Measurement details, as left:

kVp Mo / 30 μ m Mo

Mo/Mo No Paddle				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation
20	50	19.57	19.51	-0.3%
23	50	22.88	22.94	0.3%
25	50	24.89	24.85	-0.1%
28	50	27.86	27.74	-0.4%
32	50	31.89	31.87	-0.1%
35	50	34.88	34.84	-0.1%
39	50	38.67	38.48	-0.5%

Mo / 30 μ m Mo + 0,1mm Al

Mo/Mo Paddle				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Deviation
20	50	19.57	19.53	-0.2%
23	50	22.88	22.91	0.1%
25	50	24.89	24.83	-0.2%
28	50	27.86	27.77	-0.3%
32	50	31.89	31.94	0.2%
35	50	34.88	34.76	-0.3%
39	50	38.67	38.63	-0.1%

Dose Mo / 30 μ m Mo

0mm Al Added Filtration				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μ Gy	Xi dose μ Gy	Deviation
23	50	2928	2922	-0.2%
25	50	3939	3933	-0.1%
28	50	5723	5693	-0.5%
32	50	8586	8587	0.0%
35	50	10930	10933	0.0%

Mo / 30 μ m Mo + 0,1mm Al

0,1mm Al Added Filtration				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μ Gy	Xi dose μ Gy	Deviation
23	50	2156	2180	1.1%
25	50	2990	3017	0.9%
28	50	4444	4481	0.8%
32	50	6805	6874	1.0%
35	50	8796	8887	1.0%

Mo / 30 μ m Mo + 2mm Al

2mm Al Added Filtration				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. Dose μ Gy	Xi dose μ Gy	Deviation
23	100	168.0	168.6	0.4%
25	50	141.8	140.1	-1.2%
28	50	256.4	253.1	-1.3%
32	50	471.6	471.6	0.0%
35	50	672.1	676.1	0.6%

HVL (Non-Accredited) Mo / 30 μ m Mo

Mo/Mo No Paddle				
Generator settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
28	50	0.330	0.336	1.9%

 Mo/Mo No Paddle Specification:
 kV \pm 2% or \pm 0.5 kV, Dose \pm 5% and \pm HVL 5%

 Mo/Mo Paddle Specification:
 kV \pm 2% or \pm 0.7 kV, Dose \pm 5% and \pm HVL 5%

For further specification details, please refer to your Xi Manual.

Calibration Equipment

Date of Calibration(s):	02/12/19	Product:	Xi
Serial Number:	129160	Model:	R/F & Mammo

The listed equipment below were used as main references for the calibration

	R/F Arrival Check	R/F Calibration	Mammo Arrival Check	Mammo Calibration
GENERATOR	CPI INDICO 100	CPI INDICO 100	Siemens Mammomat 3000	Siemens Mammomat 3000
WAVEFORM TYPE	HF	HF	HF	HF
ANODE/FILTER	W / 2.5 mm Al	W / 2.5 mm Al	Mo / 30µm Mo	Mo / 30µm Mo
FIELD SIZE	10 x 10 cm	10 x 10 cm	18x23 cm	18x23 cm
FDD	R/F Low: 200/100 cm R/F High: 50 cm	R/F Low: 200/100 cm R/F High: 50 cm	63cm	63cm

	R/F Arrival Check	Calibration Date	R/F Calibration	Calibration Date	Mammo Arrival Check	Calibration Date	Mammo Calibration	Calibration Date
REFERENCE SYSTEM DOSE	RaySafe X2 S/N: 251789	04/30/18	RaySafe X2 S/N: 251789	04/30/18	Raysafe X2 S/N: 246643	11/01/18	Raysafe X2 S/N: 246643	11/01/18
REFERENCE SYSTEM kV	CPI Indico 100 S/N: AM8497E07 Varian A-196 S/N: 19995-N8	04/25/18	CPI Indico 100 S/N: AM8497E07 Varian A-196 S/N: 19995-N8	04/25/18	Siemens Mammomat 3000 S/N: 5853 Siemens P40 Mo W S/N: 533211	11/01/18	Siemens Mammomat 3000 S/N: 5853 Siemens P40 Mo W S/N: 533211	11/01/18
REFERENCE SYSTEM TIME	RaySafe X2 S/N: 251789	04/27/18	RaySafe X2 S/N: 251789	04/27/18	Raysafe X2 S/N: 246643	11/01/18	Raysafe X2 S/N: 246643	11/01/18

The expanded uncertainties for the presented deviations are:

R/F: kVp: 1,1% Dose: 1,5% (without added filtration), 1,5% (with added filtration)

Mammo: kVp: 1,5% Dose: 2,2 % (< 1 mm added Al-filtration), 2,6 % (> 1 mm added Al-filtration)

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

All reference systems are calibrated once a year. kV systems are calibrated by the Swedish National Testing and Research Institute and are traceable to PTB. All dose systems are calibrated by PTB and are traceable to NIST on available beam qualities. NIST does not currently have traceable dose standards for the W/Rh, Mo/Rh (2 mmAl), Rh/Al and Mo/Al beam qualities. Unfors RaySafe certifies the W/Rh, Mo/Rh, Rh/Al, Rh/Rh and Mo/Al (if applicable) beam quality measurements, made with this Xi, to be accurate within its published specifications.

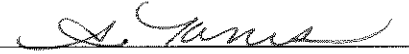
Xi is calibrated according to FDA MQSA requirements.

Calibration condition:

Ambient Temperature: 59-86°F
Relative Humidity: <60%

Unfors RaySafe calibration method: "Calibration method for kV meters ACCR-0454 ver. 3" and/or "Calibration method for Air Kerma ACCR-0453 ver. 3".

Tested by: Mike Head, Justin Johns

Approved by: 
Stacey Torres
Finalization Clerk

RaySafe Inc.

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CALIBRATION CERTIFICATE *issued by an Accredited Calibration Laboratory*

US Internal
 c/o Fluke Biomedical
 6045 Cochran Rd
 44139 SOLON, OH
 United States

Product:	Xi
Model:	Mammo Pro
Serial Number:	129160

Mo/Rh Arrival Check: *Date: 02/07/19*
W/Ag Arrival Check: *Date: 02/07/19*
W/Rh Arrival Check: *Date: 02/07/19*
Mo/Rh Calibration Certificate: *Date: 02/12/19*
W/Ag Calibration Certificate: *Date: 02/12/19*
W/Rh Calibration Certificate: *Date: 02/12/19*
Calibration Equipment List

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Arrival Check

Xi Mammography Mo/Rh

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Found:

kVp Mo / 25µm Rh + 2 mm Al

Mo/Rh 2mm Al Added Filtration					
Generator Settings		Measurements			
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation	Tolerance *)
32	50	31.89	31.99	0.3%	2,8% or 0,92 kV
35	50	34.88	34.94	0.2%	2,8% or 0,92 kV
38	50	37.67	37.82	0.4%	2,8% or 0,92 kV

Dose Mo / 25µm Rh

Mo/Rh 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *)
23	50	1950	1979	1.5%
25	50	2770	2814	1.6%
28	50	4198	4257	1.4%
32	50	6483	6582	1.5%
35	50	8361	8499	1.6%

Dose Mo / 25µm Rh + 0,1mm Al

Mo/Rh 0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *)
23	50	1510	1544	2.2%
25	50	2200	2254	2.5%
28	50	3405	3471	1.9%
32	50	5329	5440	2.1%
35	50	6921	7087	2.4%

*) The tolerance is calculated as the manufacturer specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Arrival Check

Mammography W/Ag

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Found:

Dose W / 50µm Ag

W/Ag 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *) 7,5%
23	50	865.0	854.0	-1.3%
25	50	1247	1241	-0.5%
28	50	1872	1858	-0.8%
32	50	2685	2682	-0.1%
35	50	3279	3297	0.5%

W / 50µm Ag + 0,1mm Al

W/Ag 0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *) 7,5%
23	50	714.5	710.9	-0.5%
25	50	1055	1073	1.6%
28	50	1606	1608	0.1%
32	50	2327	2348	0.9%
35	50	2872	2909	1.3%

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement In Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Arrival Check

Mammography W/Rh

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Found:
kVp

W / 50µm Rh

W/Rh No Paddle				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Tolerance *) 2,8% or 0,7 kV
23	50	22.88	22.80	-0.4%
25	50	24.90	24.92	0.1%
28	50	27.87	28.00	0.5%
32	50	31.91	31.82	-0.3%
35	50	34.90	34.94	0.1%

W / 50µm Rh + 0,1mm Al

W/Rh Paddle				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Tolerance *) 2,8% or 0,9 kV
23	50	22.88	22.80	-0.4%
25	50	24.90	25.08	0.8%
28	50	27.87	27.92	0.2%
32	50	31.91	31.74	-0.5%
35	50	34.90	35.00	0.3%

Dose

W / 50µm Rh

0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *) 7,0%
23	50	765.9	764.1	-0.2%
25	50	1092	1091	0.0%
28	50	1524	1523	-0.1%
32	50	2106	2108	0.1%
35	50	2543	2551	0.3%

W / 50µm Rh + 0,1mm Al

0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *) 7,0%
23	50	637.7	643.6	0.9%
25	50	923.0	930.9	0.9%
28	50	1299	1330	2.3%
32	50	1824	1835	0.6%
35	50	2210	2234	1.1%

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Certificate of Calibration

Xi Mammography Mo/Rh

Date of Calibration:	02/12/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Left:

kVp Mo /25µm Rh + 2 mm Al

Mo/Rh 2mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation
32	50	31.89	31.90	0.03%
35	50	34.88	34.80	-0.24%
38	50	37.67	37.64	-0.08%

Dose Mo /25µm Rh

Mo/Rh 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	50	1955	1937	-0.95%
25	50	2777	2784	0.23%
28	50	4189	4211	0.53%
32	50	6494	6525	0.48%
35	50	8379	8434	0.65%

Mo /25µm Rh + 0,1mm Al

Mo/Rh 0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	50	1508	1629	1.39%
25	50	2194	2229	1.58%
28	50	3392	3447	1.62%
32	50	5332	5409	1.44%
35	50	6932	7050	1.70%

Mo /25µm Rh + 2 mm Al

Mo/Rh 2mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	100	159.89	160.76	0.54%
25	100	296.12	290.97	-1.74%
28	100	532.53	527.63	-0.92%
32	50	470.92	469.08	-0.39%
35	50	657.40	653.90	-0.53%

HVL (Non-Accredited) Mo / 50µm Rh

Mo/Rh 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
28	50	0.399	0.400	0.33%

Mo/Rh Specification:
 kV ± 2% or ± 0.5 kV, Dose ± 5% and HVL ± 5%

For further specification details, please refer to your Xi Manual.

Certificate of Calibration

Mammography W/Ag

Date of Calibration:	02/12/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Left:

W / 50µm Ag

W/Ag 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose	Xi Dose	Deviation
23	50	865.4	865.1	0.0%
25	50	1250	1241	-0.7%
28	50	1867	1845	-1.1%
32	50	2683	2646	-1.4%
35	50	3281	3250	-0.9%

W / 50µm Ag + 0,1mm Al

W/Ag 0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose	Xi Dose	Deviation
23	50	717.7	724.2	0.9%
25	50	1060	1073	1.3%
28	50	1608	1607	-0.1%
32	50	2322	2330	0.3%
35	50	2865	2871	0.2%

W / 50µm Ag + 2mm Al

W/Ag 2mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	100	119.2	120.6	1.2%
25	50	120.0	120.3	0.3%
28	50	236.3	235.4	-0.4%
32	50	393.2	390.4	-0.7%
35	50	521.8	519.3	-0.5%

W / 50µm Ag

HVL (Non-Accredited)

W/Ag 0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
28	50	0.555	0.566	2.0%

W/Ag Specification:
Dose ± 5% and HVL ± 5%

For further specification details, please refer to your Xi Manual.

Certificate of Calibration

Mammography W/Rh

Date of Calibration:	02/12/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

Measurement Details, As Left:

kVp W / 50µm Rh

W/Rh No Paddle				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation
23	50	22.88	22.81	-0.3%
25	50	24.90	24.80	-0.4%
28	50	27.87	27.85	-0.1%
32	50	31.91	31.62	-0.9%
35	50	34.90	34.91	0.0%

W / 50µm Rh + 0,1mm Al

W/Rh Paddle				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Deviation
23	50	22.88	22.79	-0.4%
25	50	24.90	24.90	0.0%
28	50	27.87	27.95	0.3%
32	50	31.91	31.74	-0.5%
35	50	34.90	34.85	-0.1%

Dose W / 50µm Rh

0mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	50	768.3	758.9	-1.2%
25	50	1092	1082	-0.9%
28	50	1522	1510	-0.8%
32	50	2108	2088	-0.9%
35	50	2540	2523	-0.7%

W / 50µm Rh + 0,1mm Al

0,1mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	50	638.2	639.8	0.3%
25	50	925.5	921.8	-0.4%
28	50	1300	1311	0.8%
32	50	1818	1807	-0.6%
35	50	2204	2200	-0.2%

W / 50µm Rh + 2mm Al

2mm Al Added Filtration				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	100	112.9	113.3	0.4%
25	100	206.5	205.9	-0.3%
28	50	162.8	162.0	-0.5%
32	50	255.7	253.2	-1.0%
35	50	338.3	336.6	-0.5%

HVL (Non-Accredited) W / 50µm Rh

W/Rh No Paddle				
Generator Settings		Measurements		
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation
28	50	0.533	0.541	1.5%

W/Rh No Paddle Specification:
kV ± 2% or ± 0.5 kV, Dose ± 5% and HVL ± 5%

W/Rh Paddle Specification:
kV ± 2% or ± 0.7 kV, Dose ± 5% and HVL ± 5%

For further specification details, please refer to your Xi Manual.

Calibration Equipment

Date of Callbration(s):	02/12/19	Product:	Xi
Serial Number:	129160	Model:	Mammo Pro

The listed equipment below were used as main references for the calibration

	Mammo Arrival Check	Mammo Calibration
GENERATOR	Siemens Mammomat 3000	Siemens Mammomat 3000
WAVEFORM TYPE	HF	HF
ANODE/FILTER	Mo / 25 µm Rh, W / 50 µm Rh, W / 50 µm Ag	Mo / 25 µm Rh, W / 50 µm Rh, W / 50 µm Ag
FIELD SIZE	18x23 cm	18x23 cm
FDD	63cm	63cm

	Mammo Arrival Check	Calibration Date	Mammo Calibration	Calibration Date
REFERENCE SYSTEM DOSE	Raysafe X2 S/N: 246643	11/01/18	Raysafe X2 S/N: 246643	11/01/18
REFERENCE SYSTEM kV	Siemens Mammomat 3000 S/N: 5853 Siemens P40 Mo W S/N: 533211	11/01/18	Siemens Mammomat 3000 S/N: 5853 Siemens P40 Mo W S/N: 533211	11/01/18
REFERENCE SYSTEM TIME	Raysafe X2 S/N: 246643	11/01/18	Raysafe X2 S/N: 246643	11/01/18

The expanded uncertainties for the presented deviations are:

MoRh: kVp: <27kV 1%, >27 0,8% Dose: 2% (< 1 mm added Al-filtration), 2,5% (> 1 mm added Al-filtration)
 W/Rh: kVp: 0,8% Dose: 2% (< 1 mm added Al-filtration), 2,2% (> 1 mm added Al-filtration)
 W/Ag: Dose: 2,5% (< 1 mm added Al-filtration), 2,7% (> 1 mm added Al-filtration)

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

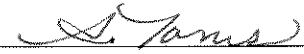
Calibration Condition:

Ambient Temperature: 59-86°F
 Relative Humidity: <80%

All reference systems are calibrated once a year. kV systems are calibrated by the Swedish National Testing. All dose systems are calibrated by PTB and are traceable to NIST on available beam qualities. NIST does not currently have traceable dose standards for the W/Rh, Mo/Rh (2 mmAl), Rh/Al and Mo/Al beam qualities. Unless RaySafe certifies the W/Rh, Mo/Rh, Rh/Al, Rh/Rh and Mo/Al (if applicable) beam quality measurements, made with this Xi, to be accurate within its published specifications. Xi is calibrated according to FDA MQSA requirements.

Unless RaySafe calibration method: "Calibration method for kV meters.ACCR-0454" and "Calibration method for Air Kerma.ACCR-0453".

Tested by: Justin Johns , Tanner Hogan

Approved by: 
 Stacey Torres
 Finalization Clerk

RaySafe Inc.
 a Fluke Biomedical Company
 6045 Cochran RD, Cleveland, OH 44139-3303
 Phone: 800.850.4608 FAX: 440.349.2307
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CALIBRATION CERTIFICATE *issued by an Accredited Calibration Laboratory*

US Internal
c/o Fluke Biomedical
6045 Cochran Rd
44139 SOLON, OH
United States

Product:	Xi
Model:	CT
Serial Number:	141619

CT Arrival Check: Date: 02/12/19

CT Calibration Certificate: Date: 02/12/19

Calibration Equipment List

*Your instrument has passed several strict test and has been approved for delivery.
Enclosed you will find detailed documents for your instrument.*



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This certificate may not be reproduced other than in full, except with the prior written approval of RaySafe.

Arrival check

XI CT

Date of Arrival Check:	02/12/19	Product:	XI
Serial Number:	141619	Model:	CT

Measurement Details, As Found:
Dose

Generator settings				Measurements			
Set kVp	Set mA	Total Filtration mm Al	Total Filtration mm Cu	Ref. Dose μGy	XI Dose μGy	Deviation	Tolerance *)
80	125	2,5	0	1521,6	1556,7	2,3%	10,7%
100	160	2,5+1,0	0,2	1116,7	1121,9	0,5%	10,7%
120	100	2,5+1,2	0,25	996,4	998,0	0,2%	8,7%
150	80	2,5+2,0	0,3	1236,9	1223,4	-1,1%	10,7%

Calibration Condition:

Ambient Temperature (°F)	22,5 to 23,4
Atmospheric Pressure (kPa):	96,2 to 98,2
Relative Humidity:	<80 %RH

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)).
For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Certificate of Calibration

Xi CT

Date of Calibration:	02/12/19	Product:	XI
Serial Number:	141619	Model:	CT

Measurement Details, As Left:
Dose

Generator Settings				Measurements		
Set kVp	Set mA	Total Filtration mm Al	Total Filtration mm Cu	Ref. Dose μGy	Xi Dose μGy	Deviation
80	125	2.5	0	1524.6	1553.4	1.9%
100	160	2,5+1,0	0.2	1116.7	1127.8	1.0%
120	100	2,5+1,2	0.25	995.4	990.6	-0.5%
150	80	2,5+2,0	0.3	1238.9	1217.9	-1.7%

Calibration Condition:

Ambient Temperature (°F)	22,56 to 23,46
Atmospheric Pressure (kPa):	96,2 to 98,2
Relative Humidity:	<80 %RH

CT Specification:

Uncertainty 5 %
 (at reference point RQT9; 120 kV, 3.7 mm Al and 0.25 mm Cu)
 Energy dependence < 5 % (at 80 kV to 150 kV, RQA, RQR and RQT qualities)
 Radial uniformity ± 2 %
 Axial uniformity ± 3 %, within rated length
 Influence of relative humidity < 0.3 % (for RH < 80 %)
 Uncertainty in temp. and pressure correction 2 %

For further specification details, please refer to your CT Manual

Calibration Equipment

Date of Calibration:	02/12/19	Product:	XI
Serial Number:	141619	Model:	CT

The listed equipment below was used as a main reference for the calibration

	Arrival Check	Calibration
GENERATOR	CPI Indico 100	CPI Indico 100
WAVEFORM TYPE	HF	HF
ANODE/FILTER	W / 2.5 mm Al	W / 2.5 mm Al
FIELD SIZE	12 x 12 cm	12 x 12 cm
FDD	85 cm	85 cm

Reference System		Calibration Date		Calibration Date
DOSE	X2 CT S/N: 248514	9/3/2018	X2 CT S/N: 248514	9/3/2018

The expanded uncertainties for the presented deviations are:

3,3 % for Dose

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

Dose systems are calibrated by PTB.

All dose reference systems are traceable to NIST and PTB.

Unfors RaySafe calibration method: "Calibration method for kV meters.ACCR-0454 ver. 3" and/or "Calibration method for Air Kerma.ACCR-0453 ver. 3".

Tested by: Adam Denney

Approved by: 

Stacey Torres
Finalization Clerk

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Certificate of Calibration

US Internal
c/o Fluke Biomedical
6045 Cochran Rd
44139 SOLON, OH
United States

Product:	XI
Model:	Light
Serial Number:	141544

Light Arrival Check: Date: 02/13/19

Light Calibration Certificate: Date: 02/13/19

Calibration Equipment List

*Your instrument has passed several strict tests and has been approved for delivery.
Enclosed you will find detailed documents for your instrument.*

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Arrival Check

Xi Light Detector

Date of Arrival Check:	02/13/19	Product:	Xi
Serial Number:	141544	Model:	Light

Measurement Details, As Found:

Luminance

Measurements		
Ref. Value (cd/m ²)	Xi Value (cd/m ²)	Tolerance *)
4.988	5.105	2.3%
997.7	1020	2.2%

Illuminance

Measurements		
Ref. Value (lux)	Xi Value (lux)	Tolerance *)
200.2	202.3	1.1%

Luminance measured with Xi setting at Luminance CRT

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution, and a one-sided tolerance interval, provides a level of confidence of approximately 95%. (ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

Certificate of Calibration

Xi Light Detector

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	141544	Model:	Light

Measurement Details, As Left:
Luminance

Measurements		
Ref. Value (cd/m ²)	Xi Value (cd/m ²)	Deviation
4.992	5.010	0.4%
998.7	999.8	0.1%
3002	3005	0.1%

Illuminance

Measurements		
Ref. Value (lux)	Xi Value (lux)	Deviation
200.1	200.2	0.0%

Luminance measured with Xi setting at Luminance CRT

*Unfors Xi Light Specification:
Luminance ± 3% and Illuminance ± 3%*

For further specification details, please refer to your Xi Light Manual.

Calibration Equipment

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	141544	Model:	Light

The listed equipment below was used as a main reference for the calibration

Reference System	Calibration Date
OL 462 Controller, S/N: 07407139 OL 462-8U Integrating Sphere Calibration Standard, S/N: 07202010 Opal Diffuser, S/N: 07202010-A	10/31/18

The expanded uncertainties for the presented deviations are:

Luminance: 1.8%
 Illuminance: 2.0%

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

The reference instruments are traceable to SP Technical Research Institute of Sweden providing traceability to international standards

Calibration condition:

Ambient Temperature: 15-30°C
 Relative Humidity: <80%

Tested by: Adam Denney

Approved by: _____

Stacey Torres
 Stacey Torres
 Finalization Clerk

RaySafe Inc.

a Fluke Biomedical Company
 6045 Cochran RD, Cleveland, OH 44139-3303
 Phone: 800.850.4608 FAX: 440.349.2307
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CALIBRATION CERTIFICATE *Issued by an Accredited Calibration Laboratory*

US Internal
c/o Fluke Biomedical
6045 Cochran Rd
44139 SOLON, OH
United States

Product:	XI
Model:	Transparent Detector
Serial Number:	178628

Arrival Check

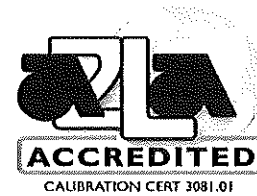
Date 02/12/19

Calibration Certificate:

Date 02/12/19

Calibration Equipment List

*Your instrument has passed several strict tests and has been approved for delivery.
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Date of Calibration:	02/12/19	Product:	Xi
Serial No:	176628	Model:	Transparent Detector

Your instrument has passed several strict tests and has been approved for delivery.

Arrival Check:

Dose, Xi Transparent Detector

Measurement Details, As Found:

Generator Settings				Measurements			Tolerance *):
kVp	mA	ms	Total Filtration	Reference μGy	Xi μGy	Deviation	
70	100	320	2,5 mm Al	855.38	857.14	0.21%	7.8%
100	80	320	2,5 mm Al	1353.63	1375.54	1.62%	7.8%
120	80	320	2,5 mm Al	1849.84	1892.44	2.30%	7.8%

Calibration

Dose, Unfors Xi Transparent Detector

Measurement Details, As Left:

Generator Settings				Measurements			Specification
kVp	mA	ms	Total Filtration	Reference μGy	Xi μGy	Deviation	
70	100	320	2,5 mm Al	837.5	832.0	-0.65%	5%
100	80	320	2,5 mm Al	1323.5	1336.7	0.54%	5%
120	80	320	2,5 mm Al	1818.8	1839.8	1.15%	5%

*) The tolerance is calculated as the manufacture specification plus the expanded uncertainty. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

Calibration Equipment

Date of Calibration:	02/12/19	Product:	Xi
Serial No:	176628	Model:	Transparent Detector

The listed equipment below was used as a main reference for the calibration

	Arrival Check	Calibration
GENERATOR	CPI Indico 100	CPI Indico 100
WAVEFORM TYPE	HF	HF
ANODE	W	W
FIELD SIZE	10 x 10 cm	10 x 10 cm
FDD	130 cm	130 cm

DOSE	Reference System	Calibration Date	Reference System	Calibration Date
	Unfors Xi S/N: 206331	09/03/18	Unfors Xi S/N: 206331	09/03/18

The expanded uncertainties for the presented deviations are:
2.8 % for Dose


The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Calibration) and ISO/IEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GUM))

All reference systems are calibrated once a year.
All dose reference systems are traceable to NIST and PTB.

Calibration Condition:
Ambient Temperature: 59-86°F
Relative Humidity: <80%

Unfors RaySafe calibration method: "Calibration method for Air Kerma ACCR-0453".

Tested by: Adam Denney

Approved by: 
Stacel Torres
Finalization Clerk