

US Internal c/o Fluke Biomedical 6045 Cochran Rd Order Number: Print date:

756200 2/13/2019

44139 SOLON, OH United States

# **Service Activity:**

Description	Serial#
SERVICE PROGRAM - ANNUAL CALIBRATION	133904
RaySafe Xi Base unit w/ mAs	133904
RaySafe Xi R/F & MAM detector	133957
RaySafe Xi CT detector	164572
RaySafe Xi Light detector	160504
RaySafe Xi Survey detector	163193
RaySafe Xi Transparent detector	191441
RaySafe DXR+	195536

----- 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			mAs	
Serial Number:	133904				
Arrival Check	Date:	02/13/19			
Celibration Certificate	Date: 02/13/19				

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

Calibration Equipment List



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:	02/13/19	Product:	RaySafe XI
Serial Number:	133904	Model:	mAs

Current, As Found				
Nominal Settings	Nominal Settings Measured Data			
Current (mA)	Reference Current (mA)	XI Current (mA)	Current Deviation	
1	0,99992	0.995	-0.48%	
10	10.0001	10.000	0.00%	
100	99,996	99.96	-0.03%	

Charge, As Found				
Nominal Settings Measured Data				
Charge (mAs)	Reference Charge (mAs)	Xi Charge (mAs)	Charge Deviation	
100	99.995	100.00	0.00%	
1000	1000.02	999.6	-0.04%	

C	Current, As Left				
Nominal Settings	Nominal Settings Measured Data				
Current (mA)	Reference Xi Current Current Current (mA) (mA) Deviation				
1	0.99992	0.994	-0.54%		
10	10.0001	9.998	-0.02%		
100	99.996	99,99	-0.01%		

Charge, As Left				
Nominal Settings		Measured Data	i	
Charge (mAs)	Reference Charge (mAs)	XI Charge (mAs)	Charge Deviation	
100	99.995	99,99	-0.01%	
1000	1000.02	999.9	-0.01%	

mA/mAs Specification: mA: ±1% or 0,02 mA mAs: ±1% or 0,02 mAs

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



# Calibration Equipment

Date of Calibration:	,	Product:	RaySafe Xi
Serial Number:	133904	Model:	mAs

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

REFERENCE SYSTEM Current / Charge	Kelihley 2601B S/N: 4008620	07/11/1B	Keithley 2601B S/N: 4008820	07/11/18
	As Found	CALIBRATION DATE	As Left	CALIBRATION DATE

The reference system is calibrated once a year by SP Technical Research Institute of Sweden.

The expanded uncertainties of measurement for the RaySafe Xi Base Unit w/ mAs are: 0,24% for Current 0,25% for Charge

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)) Unfors RaySafe calibration method: "Calibration method for Electrical CurrenLACCR-1385" and "Calibration method for Electrical Charge.ACCR-1386".

#### **Calibration Condition:**

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

Tested by: Juan Long

Approved by:

Stacel 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:	R/F & Mammo
Serial Number:	133957

 R/F Arrival Check:
 Date:
 02/07/19

 Mammo Arrival Check:
 Date:
 02/07/19

 R/F Calibration Certificate:
 Date:
 02/13/19

 Mammo 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

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	133957	Model:	R/F & Mammo

#### Measurement details, as found:

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к	ν	1	)

Total Filtration = 2.5 mm AJ

alegneses.		R/F Lov	<b>v</b> PP-MP-pymyr	Kalyagojnij pryvak
Generator	settings	Measuremer	ıts	
Set kVp	Set mAs	Ref. kVp	Xi kV	Tolerance *) 3,1%
50	32	50.60	50.64	0.1%
70	16	70.67	72.08	2.0%
100	8	100.8	102.5	1.7%
150	5	150.8	152.7	1.3%

Total	Filtration	= 2 !	5 mm	ΑI

depayment		R/F Hig	<b>h</b> aya (ayalada)	yaşındığıyışı s	
Generato	r settings	Measureme	Measurements		
Set kVp	Set mAs	Ref. kVp	XI kVp	Tolerance *) 3,1%	
50	51	50.60	50.99	0.8%	
70	26	70,67	71.99	1,9%	
100	10	100.8	102.6	1.8%	
150	5	150.8	152,4	1.1%	

Dose

Total Filtration = 2,5 mm Al

Otal   (Ittasol) - 2,5				1001 - 2.5 HBH M
	SVERIŠE ISA)	R/F Low	Lugajajajajajaja	ergerias invansiólife
Generator settings Measurements				
Set kVp	Set mAs	Ref. Dose µGy	Xi dose μGy	Tolerance *) 6,5%
50	32	371.1	368.7	-0.6%
70	16	239.7	241.2	0.6%
100	8	228.5	230,9	1.1%
150	5	281.8	282.0	0.1%

Total Filtration = 2.5 mm Al

	restrence in the state of the s				
Generato	r settings	Measureme	Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi dose μGy	Tolerance *) 6,5%	
50	51	5899	5824	-1.3%	
70	26	2990	2984	-0,2%	
100	10	2201	2209	0.3%	
150	5	3413	3393	-0.6%	

Time (Non-Accredited)

Total Filtration = 2.5 mm Al

R/F High					
Generator settings Measurements					
Set KVp	Set ma	Ref. Time	Xi Time	Tolerance *)	
70	320	319.9	320.6	0.2%	

<sup>\*)</sup> 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 Compilance with Specification".



# **Arrival Check**

#### Xi Mammography

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

#### Measurement details, as found:

kVp

Mo / 30µm Mo

0.650.000.000		Mo/Mo No Pa	addle	
Generator	sellings	Measuremen	ts	
Set kVp	Set mAs	Ref. kVp	XI kV	Tolerance *) 2,7% or 0,8 kV
23	50	23.01	23.08	0.3%
25	50	25.02	25.04	0.0%
28	50	28.02	28.03	0.0%
32	50	32.05	32,12	0.2%
35	50	35.06	35.06	0.0%

Mo / 30µm Mo + 0,1mm Al

Mo/Mo Paddle				
Generator	r settings	Measureme	nts	
Set kVp	Set mAs	Ref. kVp	XI kVp	Tolerance *) 2,7% or 1,0 kV
23	50	23.01	23.04	0.1%
25	50	25.02	24,96	-0.3%
28	50	28.02	28.02	0.0%
32	50	32.05	32.21	0.5%
35	50	35.06	34.99	-0.2%

Dose

Mo / 30µm Mo

100000000000000000000000000000000000000	Omi	n Al Added f	-iltration		
Generator	settings	Measuremen	Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi dose μGy	Tolerance *) 7,2%	
23	50	3393	3385	-0.2%	
25	50	4531	4508	-0.5%	
28	50	6475	6484	0.1%	
32	50	9549	9563	0.2%	
35	50	12147	12062	-0.7%	

Mo / 30µm Mo + 0,1mm Al

Strangers and	0,1mı	n Al Added	Filtration	
Generato	r sellings	Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi dose μGy	Tolerance *) 7,2%
23	50	2551	2560	0.4%
25	50	3480	3485	0.1%
28	50	5115	5115	0.0%
32	50	7703	7712	0.1%
35	50	9897	9912	0.1%

<sup>\*)</sup> 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

Date of Calibration:	02/13/19	Product:	Χi
Serial Number:	133957	Model:	R/F & Mammo

#### Measurement details, as left:

kVp

Total Filtration = 2.5 mm Al

R/F Low				
Generator seltings Measurements				
Set kVp	Set mAs	Ref. kVp	Xi kV	Deviation
50	32	50.33	50.47	0.3%
70	16	70.37	70.98	0.9%
100	8	100.4	100.9	0.5%
150	5	150.3	150.8	0.3%
Active Comp	pensation	Т	otal Filtration = 2	.5 + 10 mm Al
100	16	100.4	100.7	0.3%

Total Filtration = 2.5 mm At	Total	Filtration	= 2.5	mm At
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				AWII - Z.O IIIII 74
		R/F Hig	h	
Generato	Generator settings Measurements			
Set kVp	Set mAs	Ref. kVp	Xi kVp	Deviation
50	51	50.33	50.35	0.0%
70	26	70.37	70.69	0.5%
100	10	100.4	100.2	-0.3%
150	5	150.3	150.9	0.4%
Active Compensation Total Filtration = 2.5 + 10 mm A				2.5 + 10 mm Al
100	16	100.4	100.7	0.2%

Dose

Total Filtration = 2.5 mm Al

	paleVitaliye wer	R/F Low		ili i elli elli elemente elemen
Generator	ator setlings Measurements			
Set kVp	Set mAs	Ref. Dose µGy	Xi dose μGy	Deviation
50	32	412.0	414.1	0.5%
70	16	269.8	272.8	1.1%
100	8	259.1	263.0	1.5%
150	5	350.3	349.7	-0.2%
Active Compensation Total Filtration = 2.5 mm At + 26 mm			Ai + 26 mm Al	
80	64	153.8	156.3	1.6%

Total Filtration = 2.5 mm Al

R/F High					
Generator settings Measurements					
Set kVp	Set mAs	Ref. Dose XI dose Deviation μGy			
50	51	6482	6482	0.0%	
70	26	3355	3392	1.1%	
100	10	2439	2468	1.2%	
150	5	4269	4266	-0.1%	
Active Compensation Total Filtration = 2.5 + 26 mm At				2.5 + 26 mm Al	
80	102	1078	1091	1,2%	

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

	1.10	u,	10101 / 1101	, L		
R/F Low						
Generator	settings	Measurements				
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation		
70	16	2.74	2.78	1.3%		

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	2.74	2.75	0.2%	

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	320.4	320.7	0.1%	

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%, HVI.  $\pm$  10% or  $\pm$  0.2 mm AI , Time  $\pm$  0.5% or  $\pm$  0.2 ms, Total Filtration  $\pm$  10% or 0.2mm AI

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



# **Certificate of Calibration**

Xi Mammography

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	133957	Model:	R/F & Mammo

#### Measurement details, as left:

kVp

Mo / 30µm Mo

	Mo/Mo No Paddle				
Generator	settings	Measurements			
Set kVp	Set mAs	Ref. kVp	XIKV	Deviation	
20	50	19.74	19.72	-0.1%	
23	50	23.01	23.04	0.1%	
25	50	25.02	24.97	-0.2%	
28	50	28.02	27.99	-0.1%	
32	50	32.05	32.04	0.0%	
35	50	35.06	35.01	-0.2%	
39	50	39.03	39.02	0.0%	

Mo / 30µm Mo + 0,1mm Al

\$5000000000000000000000000000000000000	Mo/Mo Paddle				
Generato	r settings	Measureme	/leasurements		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Deviation	
20	50	19.74	19.75	0.1%	
23	50	23.01	23.03	0.1%	
25	50	25.02	24.94	-0.3%	
28	50	28.02	27.98	-0.2%	
32	50	32.05	32,18	0.4%	
35	50	35.06	34.96	-0.3%	
39	50	39.03	38.94	-0.2%	

Dose

Mo / 30µm Mo

0mm Al Added Filtration					
Generator	settings	Measuremen	Measurements		
Set kVρ Set mAs		Ref. Dose ุมGy			
23	50	3400	3378	-0.7%	
25	50	4518	4498	-0.4%	
28	50	6468	6484	0.2%	
32	50	9543	9629	0.9%	
35	50	12158	12145	-0.1%	

Mo / 30μm Mo + 0,1mm Al

	<b>0,1</b> mi	n Al Added	Filtration	
Generator	settings	Measurements		
Set kVp Set mAs		Ref. Dose µGy	Xì dose µGy	Deviation
23	50	2553	2571	0.7%
25	50	3484	3501	0.5%
28	50	5092	5149	1.1%
32	50	7683	7799	1.5%
35	50	9896	10007	1.1%

Mo / 30µm Mo + 2mm Al

	2mn	n Al Added I	Filtration			
Generator	settings	Measuremen	Measurements			
Set kVp Set mAs		Ref. Dose µGy	XI dose µGy	Deviation		
23	100	191.8	195.9	2.1%		
25	50	160.2	160.7	0.3%		
28	50	287.0	290.9	1.4%		
32	50	522.0	526.1	0.8%		
35	50	747.8	741.3	-0.9%		

HVL (Non-Accredited)

Mo / 30µm Mo

Mo/Mo No Paddle					
Generator settings Measurements					
Set kVp	Set mAs	Ref. HVL mm Al	XI HVL mm Al	Deviation	
28	50	0.324	0.328	1.4%	

Mo/Mo No Paddle Specification: kV  $\pm\,2\%$  or  $\pm\,0.5$  kV, Dose  $\pm\,6\%$  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 condition:

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

# Calibration Equipment

Date of Calibration(s):	02/13/19	Product:	Xi
Serial Number:	133957	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	Мо / 30µm Мо	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 XI S/N: 251807	03/18/18	RaySafe X2 S/N; 202378	04/30/18	RaySafe X2 S/N: 202378	04/30/18
REFERENCE SYSTEM <b>kV</b>	CPI Indico 100 S/N: AM8497E07 Varian A-196 S/N: 19995-N8	04/25/18	CPI Indico 100 S/N: AM14819G11 Varian A196 S/N: 98755-R1	03/24/18	Siemens Mammomat 3000 S/N: 3671 Siemens P40 Mo W S/N: 532921	05/02/18	Siemens Mammomat 3000 S/N: 3671 Siemens P40 Mo W S/N: 532921	05/02/18
REFERENCE SYSTEM TIME	RaySafe X2 S/N: 251789	04/27/18	RaySafe Xi S/N: 251807	03/24/18	RaySafe X2 S/N: 202378	05/02/18	RaySafe X2 S/N: 202378	05/02/18

The expanded uncertainties for the presented deviations are:

R/F: kVp: 1,1% Dose: 1,5% (without added filtration), 1,5% (with added filtration) Dose: 2,2 % (< 1 mm added Al-filtration), 2,6 % (> 1 mm added Al-filtration)

kVp: 1,5 % 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 ISOMEC Guide 98-3:2008, Guide to the Expression of Uncertainty in Measurement (GLIM)).

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 m/Al), Rh/Al and Mo/Al beam qualities. Unfors RaySafe certifies the W/Rh, Mo/Rh, Rh/Al, Rh/Rh end Mo/Al (if applicable) beam quality measurements, made with this XI, to be accurate within its published specification:

XI is calibrated according to FDA MQSA requirements.

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

Tested by: Robin Fisk, Adam Denney

Approved by:

Stacei Torres Finalization Clerk

RaySafe Inc.

a Fluke Biomedical Company 6045 Cochran RD, Cleveland, OH 44139-3303 Phone: 800.850.4608 FAX: 440.349.2307 customerservice.us@raysafe.com. www.RaySafe.com



## CALIBRATION CERTIFICATE issued by an Accredited Calibration Laboratory

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

Product:	Xi
Model:	Mammo Pro
Serial Number:	133957
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: 02/13/19
W/Ag Calibration Certificate:	Date: 02/13/19
W/Rh Calibration Certificate:	Date: 02/13/19
Calibration Equipment List	

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# Arrival Check

Xi Mammography Mo/Rh

Date of Arrival Check:	02/07/19	Product:	Xi	
Serial Number:	133957	Model:	Mammo Pro	

#### Measurement Details, As Found:

kVp					Mo / 25µm Rb + 2 mm A)		
1888 SAN	desire di Gregoria	Mo/Rh 2	mm Al Ad	ided Filtratio	<b>n</b> 55 (55 (55 (55 (55 (55 (55 (55 (55 (55		
Generato	r Settings	Measuren	Measurements				
Set kVp	SetmAs	Ref. kVp	XIKV	Deviation	Tolerance *}		
32	50	32.05	32.16	0.4%	2,8% or 0,92 kV		
35	50	35.06	35.09	0.1%	2,8% or 0,92 kV		
38	50	38.02	38.02	0.0%	2,8% or 0,92 kV		

Dose	Mo / 25µm Rh

	4500000000	Mo/Rh 0n	ım Al Add	ed Filtrat	ion
	Generator	r Settings	Measurements		
	Set kVp Set mAs		Ref. Dose µGy	Xí Dosa µGy	Tolerance *) 7,0%
	23	50	2267	2273	0.2%
İ	25	50	3204	3185	-0.6%
	28	50	4768	4776	0.2%
	32	50	7238	7249	0.2%
	35	50	9292	9304	0.1%

Mo / 25µm Rh + 0,1mm Al

sasassa)	/lo/Rh 0,1	mm Al Ad	ded Filtra	tlon
Generato	r Settings	Measurements		
Set kVp	Set mAs	Ref. Dose µGy	XI Dose µGy	Tolerance *) 7,0%
23	50	1790	1785	-0.3%
25	50	2581	2594	0.5%
28	50	3928	3937	0,2%
32	50	6058	6055	-0.1%
35	50	7834	7859	0.3%

<sup>1)</sup> 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 (x = 2, which for a normal distribution provides a level of confidence of approximately 95%. (EA-4/02 (Expression of the Uncertainty of Measurement in Califoration) and ISO/EC Guide 91-3 2006 (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:	133957	Model:	Mammo Pro

#### Measurement Details, As Found:

Dose

W / 50µm Ag

W/Ag 0mm Al Added Filtration				
Generator	Settings	Measuremen	ts	
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Tolerance *) 7,5%
23	50	868.2	873.2	0.6%
25	50	1249	1266	1.4%
28	50	1870	1891	1.1%
32	50	2683	2689	0.2%
35	50	3286	3303	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	717.8	728.1	1.4%	
25	50	1057	1089	3.0%	
28	50	1610	1644	2.1%	
32	50	2320	2349	1.3%	
35	50	2873	2911	1.3%	

<sup>\*)</sup> 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 98-3:2908 (Guide to the Expression of Uncertainty in Measurement)). For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compilance with Specification".



# Arrival Check

#### Mammography W/Rh

Date of Arrival Check:	02/07/19	Product:	Xi
Serial Number:	133957	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	22.83	-0.2%	
25	50	24.90	24.94	0.2%	
28	50	27.87	28,09	0.8%	
32	50	31.91	31.83	-0.3%	
35	50	34.90	34.84	-0.2%	

W / 50µm Rh + 0,1mm Al

	W/Rh Paddle				
Generator	Settings	Measuremen	nts		
Set kVp	Set mAs	Ref. kVp	Xi kVp	Tolerance *) 2,8% or 0,9 kV	
23	50	22,88	22.78	-0.4%	
25	50	24.90	24.92	0.1%	
28	50	27.87	28.01	0.5%	
32	50	31.91	31.66	-0.8%	
35	50	34.90	34.89	0.0%	

Dose

W / 50µm Rh

	0mn	n Al Added I	Filtration	
Generator	Settings	Measurements		
Set kVp	SetmAs	Ref. Dose µGy	Xi Dose μGy	Tolerance *) 7,0%
23	50	771.1	768.7	-0.3%
25	50	1092	1093	0.1%
28	50	1522	1536	0.9%
32	50	2107	2113	0.3%
35	50	2541	2556	0.6%

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	639.8	644.8	0.8%
25	50	921.9	932.3	1.1%
28	50	1301	1319	1.4%
32	50	1816	1840	1.3%
35	50	2212	2227	0.7%

<sup>\*)</sup> 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:	02/13/19	Product:	Xi
Serial Number:		Model:	Mammo Pro

#### Measurement Details, As Left:

$\nu u$	n

Mo /25µm Rh + 2 mm Al

Mo/Rh 2mm Al Added Flitration					
Generator Settings Measurements					
Set kVp	Set mAs	Ref. kVp	XI kV	Deviation	
32	50	32,05	32,10	0.17%	
35	50	35,06	34.99	-0,22%	
38	50	38.02	37.95	-0,18%	

Dose

Mo /25µm Rh

	Mo /25µm Rh + 0,1mm A
Mo/Rh 0,1mm Al Added	Filtration

μGy

1785

2581

3946

6086

7895

Deviation

-0.04%

0.09%

0.80%

0.95%

1,30%

Generator Settings Measurements			ls	
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	50	2264	2257	-0.33%
25	50	3186	3178	-0,26%
28	50	4740	4768	0.60%
32	50	7208	7261	0.73%
35	50	9271	9343	0.77%

Mo	#25um	RЬ	+ 2	mm	ΑI

				IM KR + 2 MM AI
Albert Verbie	Mo/Rh	2mm Al Add	ed Filtratio	1
Generalor	erator Settings Measurements			
Set kVp	Set mAs	Ref. Dose µGy	Xì Dose µGy	Deviation
23	100	188.11	190.99	1.53%
25	100	339,83	346,85	2.07%
28	100	608.94	612.79	0.63%
32	50	521.33	520.04	-0,25%
35	50	724.09	718.90	-0.72%

#### HVL (Non-Accredited)

Mo / 50µm Rh

	Mo/Rh (	Omm Al Add	ed Filtratio	n 🚞 🗎
Generator	Settings	Measuremen	s	
Set kVp	SetmAs	Ref. HVL mm Al	XI HVL mm Al	Deviation
28	50	0.394	0.397	0.89%

Set kVp

23

25

28

32

35

Set mAs

50

50

50

50

50

Mo/Rh Specification: kV  $\pm$  2% or  $\pm$  0.5 kV, Dose  $\pm$  5% and HVL  $\pm$  5%

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

Ref. Dose

μGy

1785

2579

3915

6028

7794

# Certificate of Calibration

### Mammography W/Ag

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	133957	Model:	Mammo Pro

#### Measurement Details, As Left:

Dose

W / 50µm Ag

şirenakçı	W/Ag 0	mm Al Add	ed Filtration	
Generator	Settings	Measurements		
Set kVp	Set mAs	Ref. Dose	Xi Dose	Deviation
23	50	872.7	871.3	-0.2%
25	50	1254	1263	0.7%
28	50	1871	1857	-0.7%
32	50	2674	2637	-1.4%
35	50	3269	3252	-0.5%

W / 50µm Ag + 0,1mm Al

W/Ag 0,1mm Al Added Filtration					
Generator	Settings	Measuremen	ements		
Set kVp	Set mAs	Ref. Dose	XI Dose	Deviation	
23	50	719.7	722.2	0.3%	
25	50	1061	1077	1.6%	
28	50	1608	1615	0.5%	
32	50	2319	2316	-0.1%	
35	50	2866	2865	-0.1%	

W / 50µm Ag + 2mm Al

sayer Doğ	W/Ag 2	mm Al Adde	d Filtration	
Generator	Settings	Measurements		
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose µGy	Deviation
23	100	120.8	122.5	1.4%
25	50	119.5	119.0	-0.4%
28	50	235.8	235.7	-0.1%
32	50	394.2	394.6	0.1%
35	50	521.8	523.7	0.4%

HVL (Non-Accredited)

W / 50µm Ag

W/Ag 0mm Al Added Filtration					
Concenter Stattings Mocouroments					
Set kVp	Set mAs	Ref. HVL XI HVL Deviation			
28	50	0.555	0.562	1.3%	

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:	02/13/19	Product:	Xi
Serial Number:	133957	Model:	Mammo Pro

#### Measurement Details, As Left:

kVp

W / 50µm Rh

		W/Rh No Pa	ıddle	
Generator	Sellings	Measurements		
Set kVp	Set mAs	Ref. kVp	XI kV	Deviation
23	50	22.88	22.70	-0.8%
25	50	24.90	24.88	-0.1%
28	50	27.87	28.06	0.7%
32	50	31.91	31.67	-0.7%
35	50	34.90	34.87	-0.1%

W/	50µm	Rh+	0,1	mm	ļ

	W/Rh Paddle				
Generator	Settings	Measuremen	ts		
Set kVp	Set mAs	Ref, kVp	Xi kVρ	Deviation	
23	50	22.88	22.78	-0.4%	
25	50	24.90	24.85	-0.2%	
28	50	27.87	28.06	0.7%	
32	50	31.91	31.76	-0.5%	
35	50	34.90	34.88	-0.1%	

Dose

W / 50µm Rh

	0mr	n Al Added I	iltration		
Generalor	Settings	Measurement	asurements		
Set kVp	Set mAs	Ref. Dose µGy	XI Dose µGy	Deviation	
23	50	769.9	756.1	-1.8%	
25	50	1095	1076	-1.7%	
28	50	1520	1509	-0.7%	
32	50	2091	2082	-0.4%	
35	50	2531	2515	-0.6%	

W / 60µm Rh + 0,1mm Al

0,1mm Al Added Filtration					
Generator	Settings	Measurements			
Set kVp	SetmAs	Ref. Dose μGy	Xi Dose μGy	Deviation	
23	50	638.0	636.5	-0.2%	
25	50	923,8	918.2	-0.6%	
28	50	1296	1297	0.1%	
32	50	1809	1807	-0.1%	
35	50	2196	2195	0.0%	

W / 50µm Rh + 2mm Ai

2mm Al Added Filtration					
Generator	Settings	Measuremen	Measurements		
Sel kVp	Set mAs	Ref. Dose µGy	Xi Dose μGy	Deviation	
23	100	113.8	112.6	-1.0%	
25	100	206.3	206.3	0.0%	
28	50	164.2	161.5	-1.6%	
32	50	254.0	251.0	-1.2%	
35	50	335.5	327.3	-2.5%	

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	0.538	0.9%	

W/Rh No Paddie Specification: kV  $\pm 2\%$  or  $\pm 0.5$  kV, Dose  $\pm 5\%$  and HVL  $\pm 5\%$ 

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 Condition:

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

# Calibration Equipment

Date of Calibration(s):	02/13/19	Product:	Xi
Serial Number:		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 Manimomat 3000 SIN: 5853 Siemens P40 Mo W SIN: 533211	11/01/18	Slemens Mammomat 3000 S/N: 5853 Slemens P40 Mo W S/N: 533211	11/01/18
REFERENCE SYSTEM	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: W/Rh: kVp: <27kV 1%, >27 0,8% kVp: 0,8%

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

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 mmAp), Rh/Al and Mo/Al beam qualities. Unifors 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.

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

Tested by: Tanner Hogan, Adam Denney

Finalization Clerk

Approved by: A. Janus

RaySafe Inc.

a Fluke Biomedical Company 6045 Cochran RD, Cleveland, OH 44139-3303 Phone: 800.850.4608 FAX: 440.349.2307 customerservice.us@raysafe.com. vww.RaySafe.com



### CALIBRATION CERTIFICATE issued by an Accredited Calibration Laboratory

United States

	Product:	Xi
US Internal	Model:	Mammo Pro Plus
c/o Fluke Biomedical	Serial Number:	133957
6045 Cochran Rd	•	
ALLON DOLON OU	Manus MIAL Amiral Ch.	nde 0-4 00/07/40

Mammo W/Al Calibration Certificate: Calibration Equipment List

Date: 02/07/19

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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# Arrival Check

Xi Mammography W/Ai

Date of Arrival Check:	02 <b>/</b> 07/19	Product:	Xi
Serial Number:	133957	Model:	Mammo Pro Plus

#### Measurement Details, As Found:

-1 /	
KV.	n

W	0,7mm	IA!

14				**** 0,***,****
		W/Al No Pa	ıddle	
Generato	r Settings	Measureme	nts	
Set kVp	Set mAs	Ref. kVp	XI kV	Tolerance *) 2,6% or 0,7 kV
20	50	19.97	19.90	-0.4%
25	50	24.96	24.94	-0.1%
30	50	29.94	29.90	-0.1%
35	50	34.92	35,15	0.7%

#### W / 0,7mm Al + 0,1mm Al

		W/Al Pad	dle	elewice, President
Generato	r Settings	Measureme	ents	
Set kVp	Set mAs	Ref. kVp	Xi kVp	Tolerance *) 2,6% or 0,9 kV
20	50	19.97	19.95	-0.1%
25	50	24.96	24.96	0.0%
30	50	29.94	29.81	-0.4%
35	50	34.92	35.07	0.4%

#### Dose

W / 0,7mm Al

W/0	.7mm	Al+	0,1mm	Αl

	W/AI 0	mm Al Adde	d Filtration	
Generator	Settings	Measuremen	ils	
Set kVp	Set mAs	Ref. Dose µGy	XI Đose μGy	Tolerance *) 7,3%
20	50	1426	1422	-0.3%
25	50	3465	3499	1.0%
30	50	5928	6015	1.5%
35	50	8628	8841	2.5%
40	50	11450	11465	0.1%
45	50	14227	14181	-0.3%
49	50	16415	16362	-0.3%

				ini al + u,1mm al
	W/AI 0,1	mm: Al Add	ied Filtrati	on
Generato	r Settings	Measureme	ents	
Set kVp	Set mAs	Ref. Dose µGy	Xi Dose μGy	Tolerance *) 7,8%
20	50	1426	1422	-0.3%
25	50	3465	3499	1.0%
30	50	5928	6015	1.5%
35	50	8628	8841	2.5%
40	50	11450	11465	0.1%
45	50	14227	14181	-0.3%
49	50	16415	16362	-0.3%

<sup>\*)</sup> 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 W/AI

Date of Calibration:	02/07/19	Product:	ΧI
Serial Number:	133957	Model:	Mammo Pro Plus

#### Measurement Details, As Left:

kVp

W / 0,7mm Al

W/Al No Paddle					
Generato	Settings	Measuremer	nts		
Set kVp	Set mAs	Ref. kVp	XI kV -	Deviation	
20	50	19.97	19.94	-0.2%	
25	50	24.96	25.02	0.3%	
30	50	29.94	29.82	-0.4%	
35	50	34.92	35.06	0.4%	

W / 0.7mm	AI ÷	U.1mm	ΑI

		W/Ai Pad	dle	
Generato	r Settings	ents		
Set kVp	Set mAs	Ref. kVp	XI kVp	Deviation
20	50	19.97	19.86	-0.6%
25	50	24.96	24.97	0.1%
30	50	29.94	29.77	-0.6%
35	50	34.92	35.11	0.5%

Dose

W / 0,7mm A

nm Ai	
i de la composición dela composición de la composición de la composición dela composición dela composición dela composición de la composición de la composición de la composición dela composición de la composición dela c	

W.	/ 0.7mm	Al + 0.1mm Ai	

W/AI 0mm AI Added Filtration					
Generator	Settings	Measuremen	Measurements		
Set kVp	Set mAs	Ref. Dose μGy	,,,,,		
20	50	1902	1869	-1,7%	
25	50	4295	4303	0.2%	
30	50	7154	7139	-0.2%	
35	50	10194	10297	1,0%	
40	50	13284	13106	-1.3%	
45	50	16384	16108	-1.7%	
49	50	18795	18454	-1.8%	

	W/AI 0,1mm AI Added Filtration						
Generato	r Settings	Measureme	Measurements				
Set kVp	Set mAs	Ref. Dose µGy	XI Dose µGy	Deviation			
20	50	1429	1423	-0.4%			
25	50	3445	3474	0.9%			
30	50	5913	5970	1.0%			
35	50	8596	8772	2.0%			
40	50	11365	11331	-0.3%			
45	50	14142	14023	-0.8%			
49	50	16341	16200	-0.9%			

HVL (Non-Accredited)

W / 0,7mm Al

W/Al 0mm Al Added Filtration						
Generator Settings Measurements						
Set kVp	Set mAs	Ref. HVL mm Al	Xi HVL mm Al	Deviation		
30	50	0.454	0.452	-0.4%		

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

W/Al 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 Calibration:	02/07/19	Product;	Xi
Serial Number:	133957	Model:	Mammo Pro Plus

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

	Mammo Arrival Check	Mammo Calibration
GENERATOR	Hologic Selenia	Hologic Selenia
WAVEFORM TYPE	НЕ	HF
ANODE/FILTER	W/AI 0,7mm	W/AI 0,7mm
FIELD SIZE	24x29 cm	24x29 cm
FDD	70 cm	70 cm

	Mammo Arrival Check	Calibration Date	Mammo Calibration	Calibration Date
REFERENCE SYSTEM DOSE	RaySafe X2 S/N: 247597	4/25/2018	RaySafe X2 S/N: 247597	4/25/2018
REFERENCE SYSTEM <b>KV</b>	Hologic Selenia S/N: 28410072450RM Varian M-113T S/N: 82446-P7	5/28/2018	Hologic Selenia S/N: 28410072450RM Varian M-113T S/N: 82446-P7	5/28/2018
REFERENCE SYSTEM TIME	RaySafe X2 S/N: 247597	5/28/2018	RaySafe X2 S/N: 247597	5/28/2018

The expanded uncertainties for the presented deviations are:

kVp: 0,6 %

Dose: 2,3% (< 1 mm added Al-filtration) 2,8 % (> 1mm added Al-filtration)

Calibration Condition:

Ambient Temperature; 59-86% Relative Humidity; <80%

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/Al beam qualities. Unfors instruments certifies the W/Al beam quality measurements, made with this XI, to be accurate within its published specifications. XI is calibrated according to FDA MQSA requirements.

Unfors RaySafe calibration method; \*Calibration method for kV meters ACCR-0454\* and/or \*Calibration method for Air Kerma ACCR-

Tans

Tested by: Justin Johns

Approved by:

Stacel Torres Finalization Clerk

RaySafe Inc.

a Fluke Blomedical Company 6045 Cochran RD, Cleveland, OH 44199-3303 Phone: 800.850.4608 FAX: 440.349.2307 customerservice.us@raysafe.com. www.RaySafe.com



Certificate No.: 164572-20190213

## 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:	СТ
Serial Number:	164572

CT Arrival Check: Date: 02/13/19 CT Calibration Certificate: Date: 02/13/19

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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Certificate No.: 164572-20190213

### Arrival check Xi CT

Date of Arrival Check:	02/13/19	Product:	XI
Serial Number:	164572	Model:	CT

#### Measurement Details, As Found:

#### Dose

sandsanedis Santaniaci							
Generator settings					Measure	ments	
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	1511.4	1538.9	1.8%	10.7%
100	160	2,5+1,0	0.2	1107.7	1108.8	0.1%	10.7%
120	100	2,5+1,2	0.25	987.8	978.3	-1.0%	8.7%
150	80	2,5+2,0	0.3	1228.8	1202.3	-2.2%	10.7%

#### **Calibration Condition:**

Ambient Temperature (*F)	22,63 to 23,53
Atmospheric Pressure (kPa):	96,1 to 98,1
Relative Humidity:	<80 %RH

<sup>\*)</sup> 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 No.: 164572-20190213

# Certificate of Calibration

Xi CT

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	164572	Model:	СТ

#### Measurement Details, As Left:

#### Dose

Generalor Settings					Measurements	
Sel kVp	Set mA	Total Filtration mm Al	Total Filtration mm Cu	Ref. Dose µGy	Xì Dose µGy	Deviation
80	125	2.5	0	1513.4	1542.5	1.9%
100	160	2,5+1,0	0.2	1107.7	1108.0	0.0%
120	100	2,5+1,2	0.25	987.4	974.5	-1.3%
150	80	2,5+2,0	0.3	1226,8	1198.8	-2.3%

#### **Calibration Condition:**

Ambient Temperature ('F)	22,84 to 23,74
Almospheric Pressure (kPa):	96,1 to 98,1
Relative Humidity: <80 %RH	

CT Specification:
Uncertainty 6 %
(at reference point RQT9; 120 kV, 3.7 mm Ai and 0.25 mm Cu)
Energy dependence < 5 % (at 80 kV to 150 kV; RQA, RQR and RQT qualities)
Radial uniformity ± 2 %
Axial 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:	02/13/19	Product:	Xi
Serial Number:	164572	Model:	CŢ

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	НЕ
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 IGO/IEC Outle 90-9,2000, Outle 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:

Stacel Torres Finalization Clerk

RaySafe Inc.

a Fluke Biomedical Company 6045 Cochran RD, Cleveland, OH 44139-3303 Phone: 800.850.4608 FAX: 440.349.2307 customerservice.us@raysafe.com. www.RaySafe.com



### **Certificate of Calibration**

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

Product:	Xi
Model:	Light
Serial Number:	160504
Light Arrival Check:	Date: 02/13/19

Light Calibration Certificate:

Calibration Equipment List

Date: 02/13/19

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

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



# **Certificate of Calibration**

Xi Light Detector

Date of Calibration:	02/13/19	Product:	Xi
Serial Number:	160504	Model:	Light

#### Measurement Details, As Left:

#### Luminance

Measurements			
Ref. Value (cd/m²)	Xi Value (cd/m²)	Deviation	
4.990	4.937	-1.1%	
1000	994.9	-0.5%	
3002	2968	-1.2%	

#### Illuminance

Measurements	5	
Ref. Value (lux)	Xi Value (lux)	Deviation
200.3	199.9	-0.2%

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:	160504	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 Intregrating 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 b	py:		
	Inel Arslanovic		
	Calibration Engineer		
		RaySafe Inc.	

a Fluke Biomedical Company 6045 Cochran RD, Cleveland, OH 44139-3303 Phone: 800.850.4608 FAX: 440.349.2307 customerservice.us@raysafe.com. www.RaySafe.com



## 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:	Survey
Serial Number:	163193

Arrival check:

Date: 02/13/19

Date: 02/13/19

Calibration Equipment List

Calibration Certificate:

Your instrument has passed several strict test 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.

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



Certificate No.: 163193-20190213

Date of Calibration:	02/13/19	Product:	Xi	
Serial No:	163193	Model:	Survey	

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

### **Arrival check**

#### Dose Xi Survey Detector

Measurement Details, As Found:

	Genera	ator Settir	igs.		Measurement	S	Tolera	ance *)
kVp	mA	ms	Total Filtration	Reference µGy	Xi Survey μGy	Deviation	Min	Max
40	16	2000	4 mm Al + 0,2 mm Cu	15.4	15.1	-2.0%	-12.6%	12.6%
80	16	2000	4 mm Al + 2 mm Cu	17.6	17.6	0.2%	-12.6%	12.6%

# Calibration

#### Dose Xi Survey Detector

Measurement Details, As Left:

	Gener	ator Settir	ngs		Measurement	<b>S</b> paralagan para	Specil	ication
ΚVp	mΑ	ms	Total Filtration	Reference μ <b>G</b> y	Xi Survoy µ <b>G</b> y	Deviation	iviii	Max
40	16	2000	4 mm Al + 0,2 mm Cu	15.5	15.3	-1.1%	-10%	10%
80	16	2000	4 mm Al + 2 mm Cu	17.5	17.8	1.5%	-10%	10%

Xi Survey Specification: Dose ± 10% (R/F & Mam) 20% (Nucl. Med.) For further specification details, please refer to your Xi Survey Manual.

For further details regarding the arrival check tolerances, please refer to enclosed "Information on Assessment of Compliance with Specification".

<sup>\*)</sup> 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)).



# Calibration Equipment

Date of Calibration:	02/13/19	Product:	Xi
Serial No:	163193	Model:	Survey

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

	Conventional and R/F Arrival Check	Conventional and R/F Calibration
GENERATOR	CPI Indico 100	CPI indico 100
WAVEFORM TYPE	HF	НЕ
ANODE	W	W
FIELD SIZE	10 x 20 cm	10 x 20 cm
FDD	120 cm	120 cm

	Reference System	Calibration Date	Reference System	Calibration Date
DOSE	Unfors XI S/N: 211590	2018/09/03	Unfors X! S/N: 211690	9/3/2018

The expanded uncertainties for the presented deviations are: 2,6 % 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. Dose systems are calibrated by PTB. All dose reference systems are traceable to NIST and PTB.

RaySafe calibration method: "Calibration method for Air Kerma. ACCR-0453 ver. 3".

Calibration condition:

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

Tested by: Adam Denney

Approved by: Stacei Torres Finalization Clerk

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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:	191441

Arrival Check Calibration Certificate: Calibration Equipment List Dale 02/13/19 Dale 02/13/19

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.

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



Certificate No.: 191441-20190213

Date of Calibration:	02/13/19	Product:	Xi
Serial No:	191441	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:

	Genera	ator Settir	ıgs		Measurements	3	
kVp	mA	ms	Total Filtration	Reference μGγ	Xi µGy	Deviation	Tolerance *):
70	100	320	2,5 mm Al	855.32	857.16	0.22%	7.8%
100	80	320	2,5 mm Ai	1362.00	1386.93	1.83%	7.8%
120	80	320	2,5 mm Al	1865.49	1916.46	2.73%	7.8%

### Calibration

#### Dose, Unfors Xi Transparent Detector

Measurement Details, As Left:

	Generator Settings			Measurements			0
kVp	mA	ms	Total Filtration	Reference μGγ	Xi μGy	Deviation	Specification
70	100	320	2,5 mm Al	841.5	833.1	-1.01%	5%
100	80	320	2,5 mm Al	1335.5	1341.4	0.45%	5%
120	80	320	2,5 mm Al	1829.9	1848.9	1.04%	5%

<sup>\*)</sup> 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 Light Detector

Date of Arrival Check:	02/13/19	Product:	Xi
Serial Number:	160504	Model:	Light

Measurement Details, As Found:

#### Luminance

Measuremen	its	
Ref. Value (cd/m²)	Xi Value (cd/m²)	Tolerance *) 4,8%
4.990	5.127	2.7%
997.5	1027	3.0%

#### Illuminance

Measurement	S	
Ref. Value	Xi Value	Tolerance *)
(lux)	(lux)	5,0%
200.4	203.2	1.4%

Luminance measured with Xi setting at Luminance CRT

<sup>\*)</sup> 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))



# Calibration Equipment

Date of Calibration:	02/13/19	Product:	Xi
Serial No:		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	

	Reference System	Calibration Date	Reference System	Calibration Date
DOSE	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.

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

Calibration Condition:

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

Tested by: Adam Denney

Approved by:

y: J. Janus
Stacel Torres
Finalization Clerk

RaySafe Inc.