Radcal Corporation

Ref No: S117242

Service Report

Received: 08-Feb-16

The equipment was tested for conformance with Radcal specifications using applicable Conformance test procedures. These procedures include inspection, operation with an x-ray machine and electrical test. The results are summarized below:

Model Number	Serial Number	Description	Meets Mfr Spec	Spec limit (±)	Cal Date
9096	96-0115	Control Unit - Accu-Pro	Yes	Pass/Fail	16-Feb-16
9660	01-1053	Ion Chamber Converter	Yes	Pass/Fail	16-Feb-16
10X6-6	03-0368	Ion Chamber	Yes	4%	16-Feb-16
40X12-W	52-0159	Diagnostic kV Sensor	Yes	Pass/Fail	16-Feb-16
10X6-6M	04-0259	Ion Chamber	Yes	4%	16-Feb-16
40X9-MO	49-0347	Mammography kV Sensor	Yes	Pass/Fail	16-Feb-16

Service requested:

Converter Error, Zero is to large.
Perform conformance test, inspection and issue certificate.

Service performed:

Verified customers problem statement.
The 10x6-6 ion chamber cap was loose and cracked.
The chamber electrod was loose.
Replaced cap.
The 40X9-MO Mammographic kV Sensor was recalibrated for optimal performance.
The 10X6-6M ionization chamber was calibrated to meet the requirements of FDA-MQSA "Final rules for Quality Mammographic Standards".
Issued Report on Calibration 117242.
Issued Certificate of Conformance.

Parts Replaced

Part No	Quantity	Description	Unit cost	Ext cost
4001002-006	1	MP-CAP	$22.50	$22.50

426 W. Duarte Rd. Monrovia, CA 91016
Tel: (626) 357-7921 FAX: (626) 357-8863 email: service@radcal.com

Ref No: S117242

Certificate of Conformance

Issued to: Upstate Medical Physics
1290 Blossom Dr.
Victor, NY 14564

Equipment Description	Model	S/N
Control Unit - Accu-Pro	9096	96-0115
Ion Chamber Converter	9660	01-1053
Ion Chamber	10X6-6	03-0368
Ion Chamber	10X6-6M	04-0259

The equipment identified above has been calibrated and tested using Radcal calibration and acceptance procedure PP1102, Radcal Quality Manual PP1007, Radcal Policy and Procedure PP1038, PI1045, PI1055 and other related documents. The equipment has been found to conform in all respects. These test procedures are designed to ensure that the tested equipment meets or exceeds all aspects of Radcal's published product specifications and requirements. Radcal is an ACLASS accredited calibration lab that meets the requirements of ISO 17025 and ANSI/NCLS Z540-1, cert number AC-1553.

All measurements performed during the testing employ equipment traceable to NIST or another recognized National Laboratory such as Physikalisch-Technische Bundesansalt (PTB).

For additional information please refer to Radcal's Product note: "The Importance of Conformance Testing". Radcal recommends revalidation in 12 months.

Certificate Issue Date: 16-Feb-16

By: _____
Authorized Representative

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Service No: S117242

Certificate of Conformance

Issued To: Upstate Medical Physics
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Victor, NY 14564

Equipment Description	Model	S/N
Accu-kV Mammographic Sensor	40X9-MO	49-0347

The equipment identified above has been calibrated and tested using Radcal service acceptance procedure A4087133, Radcal Quality Manual PP1007, Radcal Calibration Program Policy and Procedure PP1038 and other related documents. These procedures are designed to ensure that the tested equipment meets or exceeds Radcal's specifications and the requirements of ANSI/NCLS Z540-1-1994. For additional information please refer to Radcal's Product Note: "The Importance of Conformance Testing"

All measurements performed during the testing employ equipment traceable to NIST or another recognized National Laboratory such as Physikalisch-Technische Bundesansalt (PTB).

Radcal recommends a recalibration interval of 12 months.

Certificate Issue Date: February 16, 2016

By: _____
Authorized Reviewer

Radcal Corporation
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Tel: (626) 357-7921
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Service No: S117242
Date: February 16, 2016

Certificate of Conformance

Measurement Test Conditions

A Lorad M-II Mammographic X-ray generator equipped with Mo target and a beryllium window x-ray tube was used as the source of the required x-ray beam. The generator ripple is less than 0.1 kV. A 30μm Mo filter was added to the beam. The Accu-kV sensor's long axis was aligned perpendicular to the tube anode-cathode axis for all measurments. The output of the generator was measured with a Radcal HV-1 High-Voltage Divider. The voltage divider output was recorded at a 7 kHz sampling rate by a 16-bit analog to digital converter and the results were averaged over 100 mS. All reported measurement results have an accuracy of better than ±1 % at the 95% confidence level.

Test Methods

The measurements were made in accordance with Radcal Test Procedure A4087133.

Limitations of Use:

See Manufacturer's specifications

Conditions of Measurement

Temperature: 23 °C
Humidity: 32%

Note: Corrections for environmental conditions are not required for this equipment

Measurement Results

AccukV 40X9-MO Mammographic Sensor Calibration

25-40 mA , 500 ms, 30 μm Mo total filtration, 30.5 cm target to detector

Invasive kV	Accu kV kVAvg	Error		Pass/ Fail
22.24 kV	22.40 kV	0.16 kV	0.72%	Pass
23.40 kV	23.50 kV	0.10 kV	0.43%	Pass
24.56 kV	24.60 kV	0.04 kV	0.16%	Pass
25.71 kV	25.80 kV	0.09 kV	0.35%	Pass
29.16 kV	29.40 kV	0.24 kV	0.82%	Pass
38.39 kV	38.50 kV	0.11 kV	0.29%	Pass

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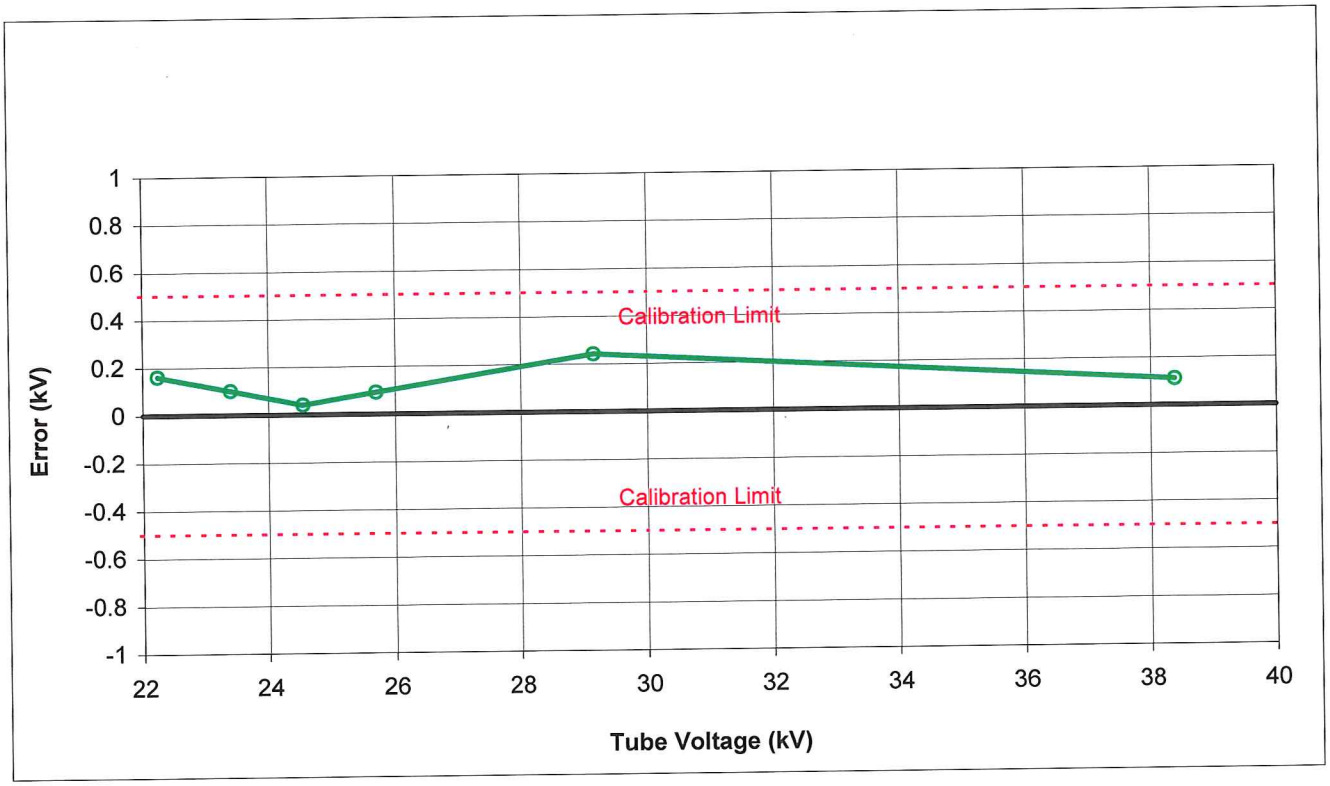
Date: February 16, 2016

AccukV 40X9-MO Mammographic Sensor 49-0347
Calibration Error (kV) vs. Tube Voltage (kV)
30 µm Mo Total Filtration



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Service No: S117242

Certificate of Conformance

Issued To: Upstate Medical Physics
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Victor, NY 14564

Equipment Description	Model	S/N
Accu-kV Diagnostic Sensor	40X12-W	52-0159

The equipment identified above has been calibrated and tested using Radcal calibration and acceptance procedure A4087132, Radcal Quality Manual PP1007, Radcal Calibration Program Policy and Procedure PP1038 and other related documents.These procedures are designed to ensure that the tested equipment meets or exceeds Radcal's specifications and the requirements of ANSI/NCLS Z540-1-1994.

All measurements performed during the testing employ equipment traceable to NIST or another recognized National Laboratory such as Physikalisch-Technische Bundesansalt (PTB).

Radcal recommends a recalibration interval of 12 months.

Certificate Issue Date: February 16, 2016

By: _____

Authorized Reviewer

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Service No: S117242
Date: February 16, 2016

Certificate of Conformance

Measurement Test Conditions

An Electromed EDEC-80 X-ray generator equipped with a Varian Model A192 tungsten target x-ray tube was used as the source of the required x-ray beam. The generator ripple is less than 0.5 kV. The X-ray Generator's filtration is set to produce a half value layer of 2.89 mmAl at 70kV. The output of the generator was measured by a Radcal Dynalyzer IIIU. The Dynalyzer outputs was recorded at a 7 kHz sampling rate by a 16-bit analog-to-digital converter and the results were averaged over 200mS. All reported measurement results have an accuracy of better than ± 1% at the 95% confidence level.

Test Methods

The measurements were made in accordance with Radcal Test Procedure A4087132

Limitations of Use:

See Manufacturer's specifications

Conditions of Measurement

Temperature: 23 °C
Humidity: 32%

Note: Corrections for environmental conditions are not required for this equipment

Measurement Results

AccukV 40X12-W Diagnostic Sensor calibration

EMED 1 Values 25 ma , 750 ms, 2.89 mmAl half value layer at 70kVp, 53 cm target to detector

Dynalyzer kV	Accu kV kVAvg	Error	Error %	Pass/Fail
41.1	41.0 kV	-0.10 kV	-0.2%	Pass
59.8	59.9 kV	0.15 kV	0.3%	Pass
70.0	69.7 kV	-0.28 kV	-0.4%	Pass
86.4	86.6 kV	0.16 kV	0.2%	Pass
97.8	97.7 kV	-0.08 kV	-0.1%	Pass
153.3	152.9 kV	-0.44 kV	-0.3%	Pass

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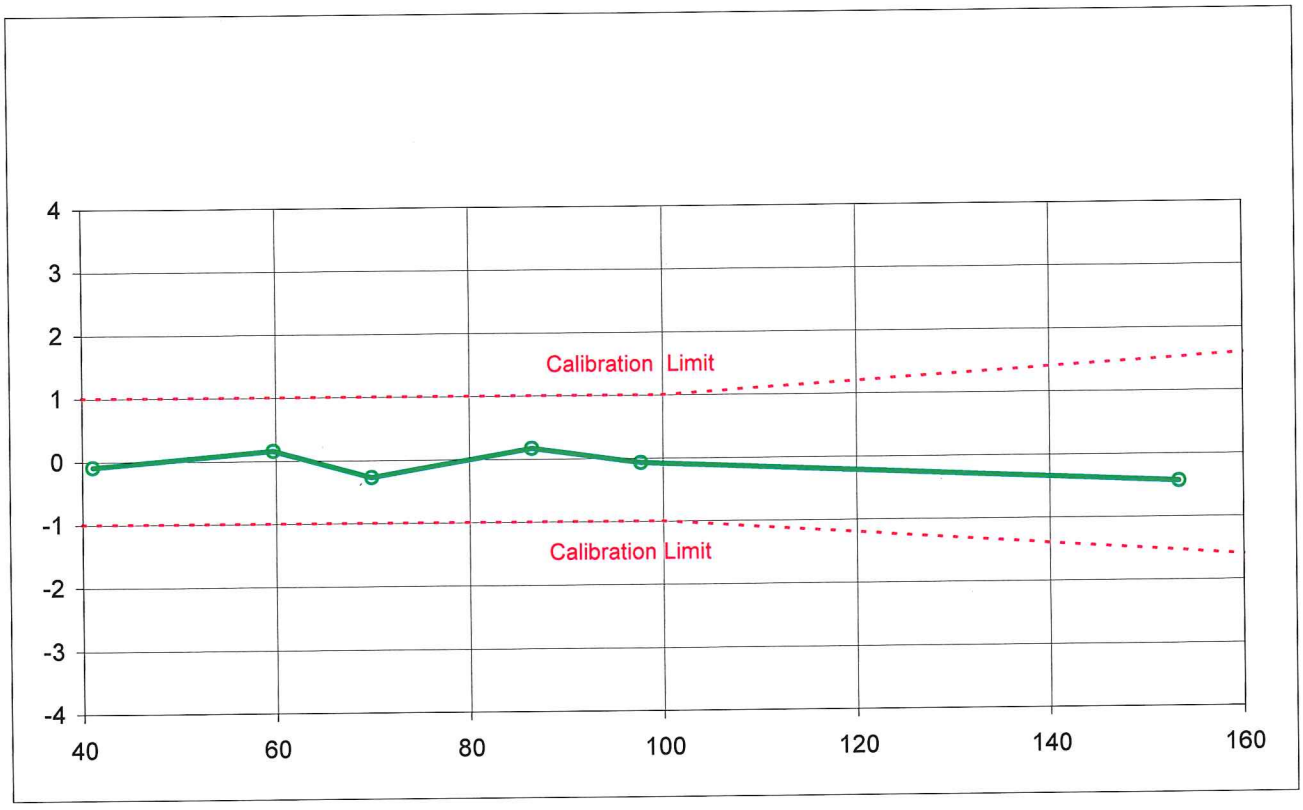
AccukV 40X12-W Diagnostic Sensor 52-0159
Calibration Error (kV) vs. Tube Voltage (kV)
2.89 mm Al HVL at 70kV



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Report No: 117242aCAL

MQSA(1) Certificate of Calibration

Issued To: Upstate Medical Physics
1290 Blossom Dr.
Victor, NY 14564

Equipment Description	Model	S/N	Asset No.
Control Unit - Accu-Pro	9096	96-0115	N/A
Ion Chamber	10X6-6M	04-0259	N/A
Ion Chamber Converter	9660	01-1053	N/A

Condition of Equipment As-Left:
In Tolerance

Remarks: Prior to calibration, the equipment was examined and found to be in good condition and performed in accordance with the manufacturer's specifications with the exceptions listed below:
1. None

The equipment identified above has been calibrated and tested using standard Radcal calibration and acceptance procedures in accordance with Radcal Quality Manual PP1007, 4600130 - CertCal - Mammo Chamber.XLT Rev:C and technical requirements contained in the customer's order. These procedures are designed to ensure that the tested equipment meets or exceeds the stated specifications and the requirements of ANSI/NCLS Z540-1-1994.
(1)See MQSA Advisory Note attached.

All measurements performed during the testing employ equipment traceable to NIST or another recognized National Laboratory such as Physikalisch-Technische Bundesansalt (PTB). All calibration results included with this certificate were recorded at the time of measurement and shall not imply anything about the instrument's future stability. This must be determined from previous historical data.

Calibration Date: 16 February 2016
Date of Report 16 February 2016
Interval, as defined by MQSA: 24 months after date of calibration
Calibration Due: 16 February 2018

Calibration Tech: AV

By: Authorized Reviewers
P. Sunde / E. Macintosh

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Report No: 117242aCAL

MQSA(1) Certificate of Calibration

Measurement Test Conditions

A Lorad M-IV Mammographic X-ray generator equipped with Tungsten target and a beryllium window x-ray tube was used as the source of the required mammographic x-ray beam. The generator ripple is less than 1 kV. Filters were added to produce the required beam (see data). The output of the generator was measured with a Radcal Dynalyzer invasive voltage divider. The HV-1 output was measured with an analog-to-digital converter with an uncertainty of ±0.1%. All reported kVp, mA and time measurement results have an uncertainty of better than ±1% at the 95% confidence level. Dose measurements were made using the substitution method and normalized with a reference mammographic dose diode. Reported dose and dose rate measurement results have an uncertainty of better than ±5% at the 95% confidence level.

Conditions of Measurement

Temperature: 22.7 °C
Pressure: 99.62 kPa
Humidity: 34%

NOTE: All dose measurements were normalized to 22°C, 101.3 kPa.
"CF" = correction factor and True Reading = CF x Reading
All exposures were made with the DUT oriented perpendicular to the beam.
The beam is collimated to not expose the chamber stem (if applicable).

Exposure Properties

ISO Beam	Added Filtration (mm Al)	First HVL (mm Al)	Homog. Coeff. hc	Set kV	Avg. Current mA	Avg. Time ms	Distance (Perp.)
M30	0.496	0.366	0.68	30	89	226	75 cm

Calibration Results

Exposure #	Standard Dose mR	DUT Dose mR	DUT CF
1	335.5	347.2	0.966
2	335.6	346.4	0.969
3	335.6	346.5	0.969
Avg.	**335.6**	**346.7**	0.968

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[1]MQSA Advisory Note

Date: 15 April 1999

Revision: 21 March 2014

Topic: FDA-MQSA "Final Rule for Quality Mammography Standards"

The FDA-MQSA "Final Rule for Quality Mammography Standards" (effective 28 April 1999), requires that all air kerma measuring instruments used by medical physicists in their annual survey of a mammography unit, must be calibrated at least once every two years, and each time it is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of ± 6% (95% confidence level) in the mammography energy range. Traceable to a national standard means an instrument is either calibrated at NIST or at a calibration laboratory that participates in a proficiency test with NIST at least every 2 years and the results of the proficiency test shows agreement within 3% of the national standard in the mammography energy range.

Radcal has met these requirements (ref: NIST Proficiency Report DG13027-14 dated 21 March 2014). The repetition of your calibration can wait until up to two years after the last calibration or until after the next repair, whichever comes first.

If your instrument was calibrated in Roentgens, air kerma is related to the exposure by the equation:

$$K = 2.58 \times 10^{-4} \cdot (W/e) \cdot X / (1-g)$$

Where:

K is air kerma in grays (Gy)
W/e is the mean energy per unit charge expended by electrons in dry air in Joules per coulomb (J/C); the value used at NIST is W/e = 33.97 J/C
X is the exposure in roentgens (R)
g is the fraction of the initial kinetic energy of secondary electrons dissipated in air through radiative processes; the value used at NIST is g = 0.00 for x-rays with energy less than 300 keV.