Radcal Corporation

Ref No: S116557

Service Report

Received: 02-Nov-15

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	96-0065	Control Unit - Accu-Pro	Yes	Pass/Fail	12-Nov-15
9660	01-1598	Ion Chamber Converter	Yes	Pass/Fail	12-Nov-15
10X6-6	03-0253	Ion Chamber	Yes	4%	12-Nov-15
40X12-W	52-0128	Diagnostic kV Sensor	Yes	Pass/Fail	12-Nov-15
10X6-6M	04-0254	Ion Chamber	Yes	4%	12-Nov-15
40X9-MO	49-0049	Mammography kV Sensor	Yes	Pass/Fail	12-Nov-15

Service requested:

Perform conformance test, inspection and issue certificate.

Service performed:

Upon receipt, the equipment met manufacturer's specifications.
The 10X6-6M ionization chamber was calibrated to meet the requirements of FDA-MQSA "Final rules for Quality Mammographic Standards".
Issued Report on Calibration 116557.
Issued Certificate of Conformance.

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

Ref No: S116557

Certificate of Conformance

Issued to: Upstate Medical Physics
1290 Blossom Drive
Victor, New York 14564

Equipment Description	Model	S/N
Control Unit - Accu-Pro	9096	96-0065
Ion Chamber Converter	9660	01-1598
Ion Chamber	10X6-6	03-0253
Ion Chamber	10X6-6M	04-0254

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: 12-Nov-15

By: _____
Authorized Representative

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

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Service No: S116557

Certificate of Conformance

Issued To: Upstate Medical Physics
1290 Blossom Drive
Victor, New York 14564

Equipment Description	Model	S/N
Accu-kV Diagnostic Sensor	40X12-W	52-0128

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: November 12, 2015

By: _____

Authorized Reviewer

Radcal Corporation
426 W. Duarte Rd.
Monrovia, CA 91016
Tel: (626) 357-7921
Fax: (626) 357-8863

Service No: S116557
Date: November 12, 2015

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: 35%

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	41.1 kV	-0.02 kV	0.0%	Pass
59.7	59.5 kV	-0.25 kV	-0.4%	Pass
70.0	69.7 kV	-0.26 kV	-0.4%	Pass
86.4	86.6 kV	0.18 kV	0.2%	Pass
97.8	98.0 kV	0.23 kV	0.2%	Pass
153.3	153.0 kV	-0.31 kV	-0.2%	Pass

Radcal Corporation
426 W. Duarte Rd.
Monrovia, CA 91016
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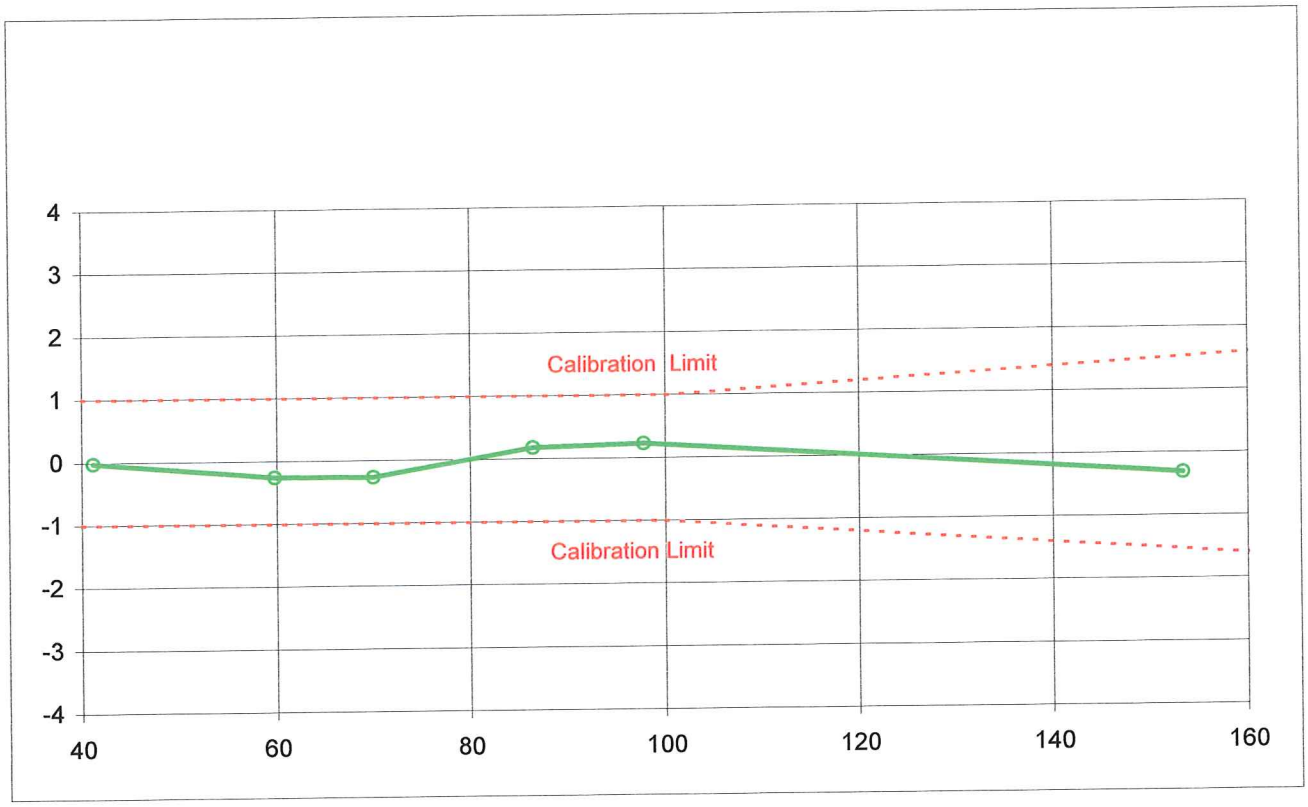
AccukV 40X12-W Diagnostic Sensor 52-0128
Calibration Error (kV) vs. Tube Voltage (kV)
2.89 mm Al HVL at 70kV



Radcal Corporation
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Monrovia, CA 91016
Tel: (626) 357-7921
Fax: (626) 357-8863

Service No: S116557

Certificate of Conformance

Issued To: Upstate Medical Physics
1290 Blossom Drive
Victor, New York 14564

Equipment Description	Model	S/N
Accu-kV Mammographic Sensor	40X9-MO	49-0049

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: November 12, 2015

By: _____
Authorized Reviewer

Radcal Corporation
426 W. Duarte Rd.
Monrovia, CA 91016
Tel: (626) 357-7921
Fax: (626) 357-8863

Service No: S116557
Date: November 12, 2015

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: 24 °C
Humidity: 34%

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
22.20 kV	22.30 kV	0.10 kV	0.45%	Pass
23.36 kV	23.40 kV	0.04 kV	0.17%	Pass
24.51 kV	24.50 kV	-0.01 kV	-0.04%	Pass
25.66 kV	25.50 kV	-0.16 kV	-0.62%	Pass
29.10 kV	28.90 kV	-0.20 kV	-0.69%	Pass
38.32 kV	38.60 kV	0.28 kV	0.73%	Pass

Radcal Corporation
426 W. Duarte Rd.
Monrovia, CA 91016
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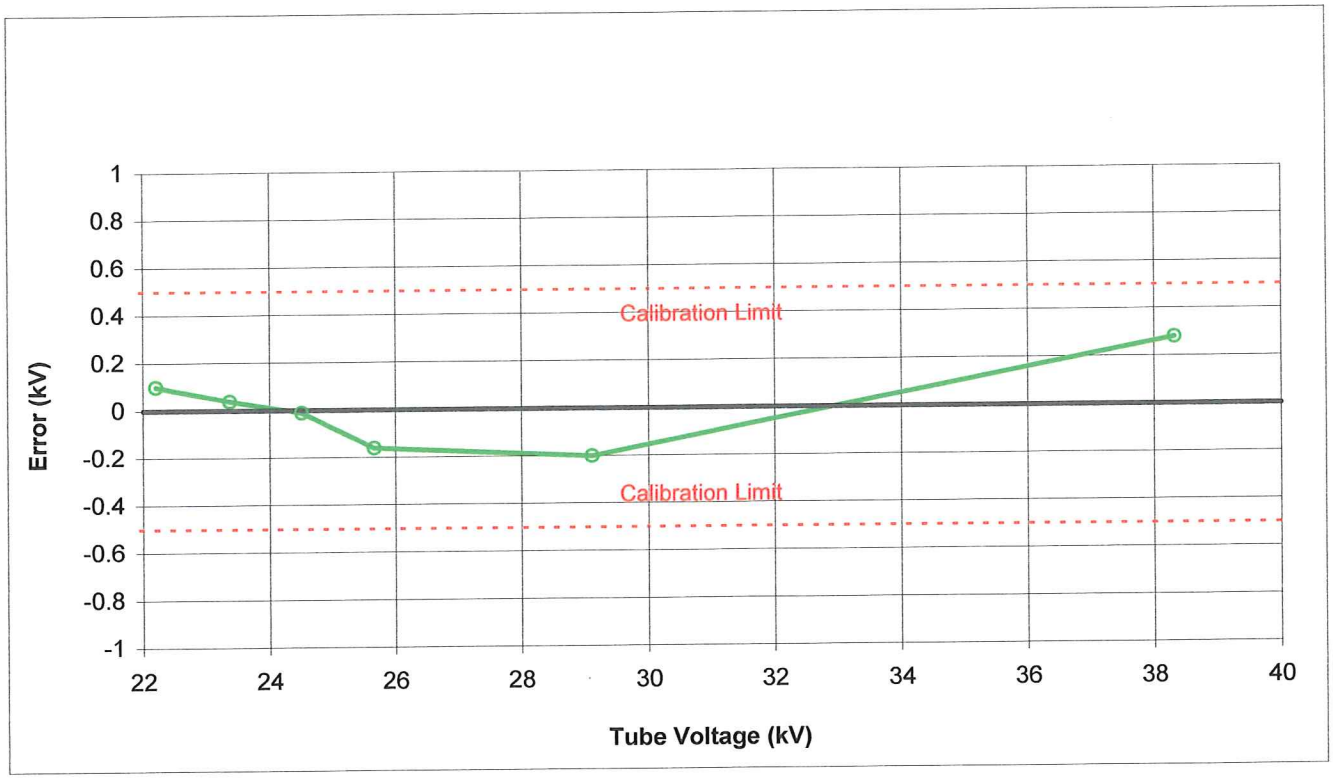
Fax: (626) 357-8863

Service No: S116557
Date: November 12, 2015

AccukV 40X9-MO Mammographic Sensor 49-0049
Calibration Error (kV) vs. Tube Voltage (kV)
30 µm Mo Total Filtration



Radcal® CORPORATION
426 WEST DUARTE ROAD
MONROVIA, CA 91016 - USA
TEL: 626.357.7921 FAX: 626.357.8863
EMAIL: service@radcal.com
WEB: www.radcal.com

Report No: 116557CAL

MQSA[(1)] Certificate of Calibration

Issued To: Upstate Medical Physics
1290 Blossom Drive
Victor, New York 14564

Equipment Description	Model	S/N	Asset No.
Control Unit - Accu-Pro	9096	96-0065	N/A
Ion Chamber	10X6-6M	04-0254	N/A
Ion Chamber Converter	9660	01-1598	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:B 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: 12 November 2015
Date of Report 12 November 2015
Interval, as defined by MQSA: 24 months after date of calibration
Calibration Due: 12 November 2017

Calibration Tech.: MB

By: Authorized Reviewers
P. Sunde / E. Macintosh

Radcal® CORPORATION
426 WEST DUARTE ROAD
MONROVIA, CA 91016 - USA
TEL: 626.357.7921 FAX: 626.357.8863
EMAIL: service@radcal.com
WEB: www.radcal.com

Report No: 116557CAL

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: 21.0 °C
Pressure: 100.52 kPa
Humidity: 27%

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	90	227	75 cm

Calibration Results

Exposure #	Standard Dose mR	DUT Dose mR	DUT CF
1	336.5	347.1	0.969
2	336.5	347.3	0.969
3	336.6	347.5	0.969
Avg.	**336.5**	**347.3**	0.969

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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.

Product Note

Topic: The Importance of Conformance Testing

High-quality dose-measurement instruments have evolved from rather simple devices to sophisticated measurement systems. They are no longer simple ion-chamber and solid-state instruments that are easy to characterize and calibrate in terms of charge and current. They have dynamic ranges exceeding 10,000,000 to one and may measure dose, dose rate, time, kVp and other parameters in a variety of ways. Many have direct computer access and provide automatic corrections for ambient conditions and other measurement parameters.

Owners of Radcal equipment have an additional benefit designed into their instruments — detector interchangeability. Radcal guarantees that its calibration specifications will be met when detectors are exchanged between compatible control units. Thus, detectors and control units are not calibrated as matched sets. Each component is tested and adjusted independently to meet its own specific requirements. The benefits of interchangeability can be enormous for users who own or have access to more than one Radcal instrument. Specialized detectors for CT, mammography, or scatter measurements can be shared freely thereby reducing calibration and system costs. When a detector or control unit requires service, only the faulty component needs to be returned for service if it is clear which component is faulty.

What is appropriate for a calibration of such equipment? Correction factors stating the deviation from a few standard values? Can you be sure that these correction factors are valid under your measurement conditions? Can you be confident that these correction factors are valid for the doses, dose-rates, and beam qualities you will use? Will your instrument properly perform the additional functions that may be present in your instrument such as timing and temperature and pressure correction?

Radcal believes that its customers should have full confidence that their instrument will meet all of its published specifications following service and calibration. This condition can only be satisfied when extensive tests, and adjustments if necessary, are performed in the same manner as when a new instrument is tested before delivery. These test procedures are designed to insure automatic detector recognition and interchangeability, full operation over the instrument's dynamic range, and proper operation of all special functions such as timing and temperature and pressure corrections. This then is the full meaning of Radcal's Certificate of Conformance. It is far more than the simple statement of a correction factor. It guarantees that your instrument will perform as stated in Radcal's published specifications.

426 West Duarte Road Monrovia, California 91016 USA T:(626)357-7921 F:(626)357-8863 www.radcal.com