*Radcal Corporation*

Ref No: S123253

## Service Report

Received: 23-Feb-18

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 |
|---|---|---|---|---|---|
| AGDM+ | 48-0693 | Accu-Gold Digitizer Module | Yes | Pass/Fail | 06-Mar-18 |
| AGNUGGET | 51-0193 | Accu-Gold Wifi Module | Yes | Pass/Fail | 06-Mar-18 |
| AGLS | 01-0175 | Accu-Gold Light Sensor | Yes | Pass/Fail | 06-Mar-18 |
| AGMS-DM+ | 43-0563 | Accu-Gold Multi-Sensor | Yes | Pass/Fail | 06-Mar-18 |

Service requested:

Perform conformance test, inspection and issue certificate.

Service performed:

Upon receipt, the equipment met manufacturer's specifications.
Added 3mm Wal and RhCu Calibration added to the AGMS-DM+ sensor.
Calibrated AGMS-DM+ for optimal performance.
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: S123253

# Certificate of Conformance

**Issued to:** Upstate Medical Physics
1290 Blossom Drive
Victor, Ny 14564

| Equipment Description | Model | S/N |
|---|---|---|
| Accu-Gold Digitizer Module | AGDM+ | 48-0693 |
| Accu-Gold Wifi Module | AGNUGGET | 51-0193 |
| Accu-Gold Light Sensor | AGLS | 01-0175 |
| Accu-Gold Multi-Sensor | AGMS-DM+ | 43-0563 |

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 06-Mar-18

By: Sonya Gruff
Authorized Representative

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**Report No:** 123253MAL

# MQSA[(1)] Certificate of Calibration

**Issued To:** Upstate Medical Physics
1290 Blossom Drive
Victor, Ny 14564

| Equipment Description | Model | S/N | Asset No. |
|---|---|---|---|
| Accu-Gold Digitizer Module | AGDM+ | 48-0693 | N/A |
| Accu-Gold Multi-Sensor | AGMS-DM+ | 43-0563 | 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, 4600131 - CertCal - Mammo Sensor.XLT Rev:E 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: 6 March 2018
Date of Report 6 March 2018
Interval, as defined by MQSA: 24 months after date of calibration
Calibration Due: 6 March 2020

Calibration Tech.: _____
AV

By: _____
Authorized Reviewers
E. Macintosh / M. Bryant

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**Report No:** 123253MAL

# MQSA[(1)] Certificate of Calibration

### Measurement Test Conditions

A Lorad M-II Mammographic X-ray generator equipped with Molybdenum 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: 23.3 °C
Pressure: 100.53 kPa
Humidity: 22%

**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).

All Multi-Sensor readings were captured with: Accu-Gold 2.40.2

### Exposure Properties

| ISO Beam | Added Filtration (µm Mo) | First HVL (mm Al) | Set kV | Avg. Current mA | Avg. Time ms | Distance (Perp.) |
|---|---|---|---|---|---|---|
| **RQR-M-3** | 32.6 | 0.361 | 30.4 | 28.0 | 406 | 48 cm |

### Calibration Results

| Exposure # | Standard Dose mGy | DUT Dose mGy | DUT CF |
|---|---|---|---|
| 1 | 3.174 | 3.149 | 1.008 |
| 2 | 3.173 | 3.149 | 1.008 |
| 3 | 3.174 | 3.150 | 1.008 |
| Avg. | **3.174** | **3.149** | 1.008 |

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# [1]MQSA Advisory Note

**Date:** 15 April 1999

**Revision:** 20 April 2016

**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 DG13213-16 dated 01 April 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.