



Certificate of Conformance

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

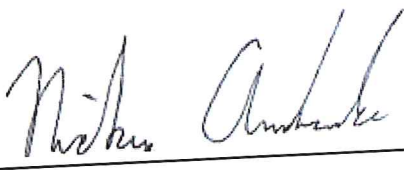
<u>Equipment Description</u>	<u>Model</u>	<u>S/N</u>
Accu-Gold Digitizer Module	AGDM+	48-0694
Accu-Gold Wifi Module	AGNUGGET	51-0188
Accu-Gold Light Sensor	AGLS	01-0177
Accu-Gold Multi-Sensor	AGMS-DM+	43-0549

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/NCLZ 540-1, cert number AC-1553.

All measurements performed during the testing employ equipment traceable to NIST or another recognized National Laboratory such as Physikalisch-Technische Bundesanstalt (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-May-18

By: 
Authorized Representative

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+	48-0694	Accu-Gold Digitizer Module	Yes	Pass/Fail	16-May-18
AGNUGGET	51-0188	Accu-Gold Wifi Module	Yes	Pass/Fail	16-May-18
AGLS	01-0177	Accu-Gold Light Sensor	Yes	Pass/Fail	16-May-18
AGMS-DM+	43-0549	Accu-Gold Multi-Sensor	Yes	Pass/Fail	16-May-18

Service requested:

Perform conformance test, inspection and issue certificate.

Service performed:

Upon receipt, the equipment met manufacturer's specifications.
The AGMS-DM+ sensor was calibrated to meet the requirements of FDA-MQSA "Final rules for Quality Mammographic Standards".
Issued Report on Calibration 123731.
Issued Certificate of Conformance.

Report No: 123731MAL

MQSA⁽¹⁾ Certificate of Calibration

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Equipment Description	Model	S/N	Asset No.
Accu-Gold Digitizer Module	AGDM+	48-0694	N/A
Accu-Gold Multi-Sensor	AGMS-DM+	43-0549	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/NCLC 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 Bundesanstalt (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 May 2018
 Date of Report: 16 May 2018
 Interval, as defined by MQSA: 24 months after date of calibration
 Calibration Due: 16 May 2020

Calibration Tech: 
 AV

By: 
 Authorized Reviewers
 E. Macintosh / M. Bryant

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 $\pm 0.1\%$. All reported kVp, mA and time measurement results have an uncertainty of better than $\pm 1\%$ 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 $\pm 5\%$ at the 95% confidence level.

Conditions of Measurement

Temperature: 24.3 °C
 Pressure: 100.10 kPa
 Humidity: 29%

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	DUT	DUT CF
	Dose mGy	Dose mGy	
1	3.181	3.137	1.014
2	3.174	3.138	1.011
3	3.172	3.137	1.011

Avg.	3.176	3.137	1.012
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