

Service Report

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	40-0201	Accu-Gold Digitizer Module	Yes	Pass/Fail	09-Aug-17
AGNUGGET	51-0194	Accu-Gold Wifi Module	Yes	Pass/Fail	09-Aug-17
AGLS	01-0127	Accu-Gold Light Sensor	Yes	Pass/Fail	09-Aug-17
AGMS-D	41-0179	Accu-Gold Multi-Sensor	Yes	Pass/Fail	09-Aug-17
AGMS-M	42-0113	Accu-Gold Multi-Sensor	Yes	Pass/Fail	09-Aug-17

Service requested:

Perform conformance test, inspection and issue certificate.

Service performed:

Upon receipt, the equipment met manufacturer's specifications. The AGMS-M sensor was calibrated to meet the requirements of FDA-MQSA "Final rules for Quality Mammographic Standards".
Issued Report on Calibration 121915.
Issued Certificate of Conformance.



Certificate of Conformance

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

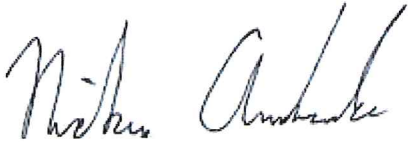
<u>Equipment Description</u>	<u>Model</u>	<u>S/N</u>
Accu-Gold Digitizer Module	AGDM	40-0201
Accu-Gold Wifi Module	AGNUGGET	51-0194
Accu-Gold Multi-Sensor	AGMS-D	41-0179
Accu-Gold Light Sensor	AGLS	01-0127
Accu-Gold Multi-Sensor	AGMS-M	42-0113

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 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 09-Aug-17

By: 
Authorized Representative

MQSA⁽¹⁾ Certificate of Calibration

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1290 Blossom Dr.
Victor, NY 14564

Equipment Description	Model	S/N	Asset No.
Accu-Gold Digitizer Module	AGDM	40-0201	N/A
Accu-Gold Multi-Sensor	AGMS-M	42-0113	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:D 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 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: 9 August 2017

Date of Report 9 August 2017

Interval, as defined by MQSA: 24 months after date of calibration

Calibration Due: 9 August 2019

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 ±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: 24.9 °C
 Pressure: 100.00 kPa
 Humidity: 36%

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 2.39.4

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	30.3	28.0	406	48 cm

Calibration Results

Exposure #	Standard	DUT	DUT CF
	Dose mGy	Dose mGy	
1	3.187	3.161	1.008
2	3.181	3.160	1.007
3	3.182	3.163	1.006
Avg.	3.183	3.161	1.007

⁽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 $\pm 6\%$ (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.

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