ION LABS QUALITY FIRST	Standard Operating Procedure **Verification of Digital Temperature and Humidity Recording Devices**	**SOP Number** **G-206**	**Revision** **3**
		Effective Date 06/11/19	**Page** **Page 1 of 4**

Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
05/08/19	05-09-19	05/15/19
Title: Analytical Development Manager	**Title: QC Laboratory Supervisor**	**Title: QC Laboratory Director**

1.0 Purpose

Most digital temperature and humidity recording devices do not allow true calibration since the readings cannot be altered to match a standard device. Therefore, the readings of each device can be verified against a single device whose performance characteristics are certified against a NIST traceable standard.

2.0 Scope

This procedure can be applied to any temperature, humidity, or combination recording device. This procedure is not intended for non-recording temperature and humidity devices.

3.0 Responsibility

3.1 The QC Chemists are responsible for the application of and compliance to this procedure.

3.2 The QC Laboratory Management is responsible for the execution of and compliance to this procedure.

3.3 The QC Laboratory Management is responsible for keeping the SOP current with latest Ion Labs practices.

4.0 Definitions

4.1 **QC**- Quality Control

°C – Degrees Celsius

4.2 **RH** – Relative Humidity

4.3 **°F** – Degrees Fahrenheit

5.0 References

5.1 G-201-F2, Form, Calibration Certificate

5.2 G-201, SOP, Calibration Program

6.0 Specifications

6.1 TP125- Temperature and Humidity Data Logger, Digital

6.1.1	Operating RH conditions:	0-95% RH non-condensing
6.1.2	Operating Temp. Range:	-10 to 176°F (-25 to 80°C)
6.1.3	Battery life:	Up to 1 year
6.1.4	Battery Type:	CR2450
6.1.5	Download Cable:	USB mini
6.1.6	Minimum Software Ver.:	10
6.1.7	Data Capacity:	32,000 (16,000 per channel)
6.1.8	RH Accuracy:	+/-2%- 0 to 60%; +/-3%- 60 to 95%
6.1.9	Temperature Accuracy:	+/- 0.8°F- 20 to 120°F, +/-1.8°F Remaining
		+/-0.44°C -7 to 49°C; +/-1.0°C Remaining

6.2 SP125- Temperature Data Logger, Digital

6.2.1	Operating RH conditions:	0-95% RH non-condensing
6.2.2	Operating Temp. Range:	-10 to 176°F (-25 to 80°C)
6.2.3	Battery life:	Up to 1 year
6.2.4	Battery Type:	CR2450
6.2.5	Download Cable:	USB mini
6.2.6	Minimum Software Ver.:	10
6.2.7	Data Capacity:	32,000
6.2.8	Temperature Accuracy:	+/- 0.8°F- 20 to 120°F, +/-1.8°F Remaining
		/-0.44°C -7 to 49°C; +/-1.0°C Remaining

6.3 Other Data loggers with similar or better capabilities can be purchased and used. These types of devices will be added to this SOP as they become active.

7.0 Procedure

7.1 Every year before any verification procedure is performed a fresh battery will be installed into the data logger. If the data sampling is one minute or less the battery will need to be replaced at six month intervals. Experimental evidence shows that batteries have been lasting much shorter than 1 year. Batteries will be changed at least every two months to ensure they do not cause loss of data.

7.2 A temperature and humidity device calibrated against a NIST traceable standard will be used as a verification standard.

7.3 The calibration and certification of the temperature/humidity reference standard must be a performed by an outside laboratory or by the instrument manufacturer.

7.4 Calibration verification will be documented using Form G-201-F2 in accordance with SOP G-201.

7.5 A single point verification will be performed using a controlled environment such as an incubation chamber or refrigerator. The controlled environment should be set to 35°C +/- 5°C with environmental humidity or at a temperature within the refrigeration range of 4 to 8°C. Calibration of humidity should not be performed at refrigeration temperatures unless the humidity is controlled in the test environment.

7.6 Both the internal reference standard and the digital recording device(s) must be fully equilibrated to the environment before the verification is initiated. The data range used in the performance verification should be clearly marked on the output graph.

7.7 When the internal reference standard stabilizes, document the temperature and humidity reading and the time the verification is started and at multiple time intervals if the verification is performed for a specific time period (ex. Every 10 minutes for a 1 hour verification interval). The chamber must remain sealed during the verification process. For large climate controlled chambers multiple standard references should be used for the purpose of verifying the uniformity of the space used for the calibration.

7.8 When the data collection is complete compare the device readings to the internal standard readings at similar time points and compare results to the specifications for that device.

7.9 The specification for the verification is +/-2°C and +/- 4% humidity. The operation range for the device is -23 to 80°C and 0 to 95% humidity.

7.10 If the device is within the specified range at all monitoring points the unit is verified and a calibration sticker can be affixed to the unit before returning to service. Generate a report and add to the calibration log.

7.11 If the device fails the unit must be removed from service and replaced. Generate a report and add to the calibration log.

7.12 The calibration is good for 12 months.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	04/26/10	New	-	-
1	03/07/13	Updated SOP format and SOP number.	13-131	B. Johns
2	01/27/16	Updated SOP format. Removed G-206-F1. Added G201-F2 and SOP G-201. Required NIST certified internal standards. Changed to single point calibration in a tightly controlled environment. Introduced specifications. Adjusted SOP title. Updated responsibilities.	15-1146	R. Casabianca
3	04/08/19	Scheduled review: Updated battery requirement	19-0235	J. Maignan