TEMPERATURE MONITORING CALIBRATION RECORDS

TEMPERATURE MONITORING CALIBRATIO

Polar Dynamics Robotics, Inc.

Document Reference: TMC-2023-Q4

Last Updated: December 31, 2023

1. PURPOSE AND SCOPE

1. This document establishes the official record of temperature monito

2. These records cover all temperature monitoring systems installed i

2. REGULATORY COMPLIANCE

1. All calibration procedures documented herein comply with:

- ISO/IEC 17025:2017 General requirements for testing and calibration
- NIST Handbook 150-2G Technical Requirements for Temperature Ca
- FDA 21 CFR Part 11 for electronic systems in regulated environments
- ASTM E2877 Standard Guide for Digital Contact Thermometers

3. CALIBRATION EQUIPMENT AND STANDARDS

1. Primary Reference Standards:

Fluke 1594A Super-Thermometer (Serial: ST-2023-445)

- Isotech SPRT 670 (Serial: SPRT-2023-112)

- MicroK 70 Precision Thermometry Bridge (Serial: MTB-2023-089)

2. Secondary Working Standards:

- Precision platinum resistance thermometers (PPRTs)

- Digital temperature indicators

- Calibrated temperature probes

4. CALIBRATION PROCEDURES

1. Frequency of Calibration:

- Primary standards: Annual calibration by accredited external laborato

- Secondary standards: Quarterly verification against primary standards

- Production units: Pre-deployment and quarterly thereafter

2. Calibration Method:

a) Zero-point verification at 0 C using triple-point cell

b) Three-point calibration at -40 C, -20 C, and 0 C

c) Linearity verification across operating range

d) Stability testing at -30 C for 24 hours

5. CALIBRATION RECORDS

1. Primary Standards Calibration:

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Last calibration date: October 15, 2023

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Calibration provider: MetroCal Laboratories (ISO 17025 Accredited)

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Certification numbers: MC-2023-4456, MC-2023-4457, MC-2023-445

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Next scheduled calibration: October 15, 2024

2. Production Unit Calibration Summary:

Total units calibrated: 847

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Pass rate: 99.4%

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Units requiring adjustment: 28

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Units rejected: 5

6. MEASUREMENT UNCERTAINTY

1. Documented measurement uncertainty for production units:

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Range -40 C to 0 C: 0.1 C

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Resolution: 0.01 C

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Stability: 0.05 C/year

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Combined expanded uncertainty (k=2): 0.15 C

7. QUALITY CONTROL MEASURES

1. Environmental Controls:

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Calibration laboratory temperature: 20 C 1 C

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Relative humidity: 45% 5%

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Air pressure: 101.3 kPa 0.5 kPa

2. Personnel Qualifications:

- Lead Metrologist: ISO 17025 certified
- Calibration Technicians: Minimum Level II certification
- Annual competency assessments documented

8. NONCONFORMANCE MANAGEMENT

1. Out-of-tolerance conditions detected: 12
2. Corrective actions implemented: 12
3. Preventive actions identified: 4
4. Impact assessments completed: 12

9. CERTIFICATION

The undersigned hereby certifies that all calibration procedures and re
documented herein are accurate and complete, performed in accorda
applicable standards and procedures, and maintain traceability to nati
standards.

Certified by:

/s/ Dr. Marcus Chen

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Dr. Marcus Chen

Chief Technology Officer

Date: December 31, 2023

/s/ Jennifer Wong

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Jennifer Wong

Quality Assurance Director

Date: December 31, 2023

10. DOCUMENT CONTROL

Document Owner: Quality Assurance Department

Version: 4.2

Review Cycle: Quarterly

Next Review Date: March 31, 2024

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