Temperature Control System Validation Report

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Date: December 15, 2023

Location: Polar Dynamics Robotics Manufacturing Facility

Address: 2850 Arctic Way, Dover, Delaware 19901

1. Executive Summary

This validation report documents the comprehensive testing and verification of the Temperature Control System (TCS) implemented in the IceNav(TM) Series 3000 Autonomous Mobile Robots manufactured by Polar Dynamics Robotics, Inc. The validation process was conducted in accordance with FDA 21 CFR Part 11, GAMP 5 guidelines, and ISO/IEC 17025:2017 standards.

2. System Description

1 The TCS consists of:

- Proprietary CryoCore(TM) thermal management unit (Model TC-3000)
- Dual redundant temperature sensors (Precision: 0.1 C)
- Environmental monitoring system with 16 distributed sensor nodes
- Adaptive thermal regulation software (Version 4.2.1)
- Emergency thermal shutdown protocol system

2 Operating Parameters:

- Temperature Range: -40 C to +25 C
- Humidity Range: 10% to 95% RH
- Response Time: <2.5 seconds
- Control Accuracy: 0.5 C

3. Validation Objectives

1 Primary Objectives:

- Verify system performance across specified temperature range
- Validate thermal management system reliability
- Confirm accuracy of temperature monitoring and control

- Evaluate system response to environmental variations
- Assess compliance with regulatory requirements

2 Critical Quality Attributes:

- Temperature stability
- System recovery time
- Sensor accuracy
- Control system precision
- Fail-safe operation

4. Test Protocols and Results

1 Installation Qualification (IQ)

- System components verified against specifications
- Calibration certificates validated for all sensors
- Software version confirmation completed
- Documentation review completed successfully

2 Operational Qualification (OQ)

- Temperature mapping conducted across 27 points
- Control system response tested under varying loads
- Power failure recovery validated
- Alarm systems verified at all setpoints

3 Performance Qualification (PQ)

Results from 168-hour continuous operation test:

- Temperature Deviation: 0.3 C (within 0.5 C specification)
- Recovery Time: 1.8 minutes (meets <2.5 minute requirement)
- System Uptime: 99.98%
- Zero critical failures recorded

5. Test Data Analysis

1 Statistical Analysis

- Mean temperature deviation: 0.27 C
- Standard deviation: 0.08 C
- Confidence interval (95%): 0.15 C
- Sample size: 10,080 data points

2 Deviation Investigation

All deviations were documented and investigated:

- Minor deviation #MD-2023-112: Temperature spike during power transfer
- Resolution: Backup power engagement timing adjusted
- Impact Assessment: No effect on product quality

6. Compliance Assessment

1 Regulatory Requirements

System meets or exceeds:

- FDA 21 CFR Part 11
- EU GMP Annex 11
- ISO 13485:2016
- GAMP 5 Guidelines

2 Documentation Review

- Standard Operating Procedures verified
- Calibration protocols confirmed
- Training records validated
- Change control procedures assessed

7. Risk Assessment

1 Critical Risks Evaluated:

- Temperature excursion probability: LOW
- Sensor failure impact: MEDIUM (mitigated by redundancy)
- Control system malfunction: LOW
- Power failure impact: LOW (redundant systems in place)

2 Risk Mitigation Strategies

- Implemented dual redundant sensors
- Established automated alert system
- Created emergency response protocols
- Developed contingency procedures

8. Conclusions and Recommendations

1 Validation Status

The Temperature Control System has been thoroughly tested and is deemed VALIDATED for production use in the IceNav(TM) Series 3000 AMRs.

2 Recommendations

- Implement quarterly performance reviews
- Conduct annual revalidation
- Update SOPs to reflect current best practices
- Enhance preventive maintenance schedule

9. Approval Signatures

VALIDATED BY:

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Date: December 15, 2023

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## 10. Document Control

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