

COLD CHAIN COMPLIANCE AUDIT REPORT 2023

Polar Dynamics Robotics, Inc.

Prepared: December 15, 2023

Report Reference: CCR-2023-PDR-001

1. EXECUTIVE SUMMARY

This Cold Chain Compliance Audit Report documents the comprehensive evaluation of Polar Dynamics Robotics, Inc.'s ("PDR") compliance with applicable cold chain regulations, standards, and best practices for the period January 1, 2023 through December 1, 2023. The audit focused on PDR's autonomous mobile robot (AMR) systems operating in temperature-controlled environments and their adherence to FDA 21 CFR Part 11, FSMA requirements, and relevant ISO standards.

2. AUDIT SCOPE AND METHODOLOGY

1 Primary Audit Areas:

- IceNav(TM) AI navigation system temperature monitoring capabilities
- Cold-resistant actuator compliance with FDA requirements
- Thermal management system performance validation
- Data logging and electronic records compliance
- Standard Operating Procedures (SOPs) for cold chain operations
- Quality Management System (QMS) documentation
- Training and qualification programs

2 Audit Standards Applied:

- FDA 21 CFR Part 11
- ISO 13485:2016 Medical Devices QMS
- FSMA Preventive Controls Rule
- GAMP 5 Guidelines
- GDP Guidelines (WHO Technical Report Series No. 961)

3. KEY FINDINGS

1 Compliance Status Summary

Category	Status	Risk Level
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Temperature Monitoring	Compliant	Low
Data Integrity	Compliant	Low
System Validation	Partial Compliance	Medium
Documentation	Compliant	Low
Training	Compliant	Low

2 Major Observations

2.1 Strengths:

- Robust temperature mapping protocols for AMR operation zones
- Comprehensive electronic record keeping system
- Advanced data encryption meeting 21 CFR Part 11 requirements
- Well-documented calibration procedures
- Effective change control management

2.2 Areas for Improvement:

- System validation documentation requires additional detail for -40 C operations
- Backup power system testing protocols need enhancement
- Emergency response procedures require updating for new IceNav(TM) 4.0 features

4. DETAILED COMPLIANCE ASSESSMENT

1 Temperature Monitoring Systems

The IceNav(TM) platform demonstrates compliance with temperature monitoring requirements through:

- Real-time temperature tracking with 0.1 C accuracy
- Automated alerts for temperature excursions
- Redundant sensor systems with fail-safe protocols
- 21 CFR Part 11 compliant audit trails
- Validated data storage and retrieval systems

2 Quality Management System

PDR's QMS meets ISO 13485:2016 requirements with:

- Documented quality manual (QM-2023-V3)
- Risk management procedures (RM-SOP-2023-12)
- Complaint handling system (CHS-2023-V2)
- CAPA management program (CAPA-SOP-2023-08)
- Equipment qualification protocols (EQ-SOP-2023-15)

5. VALIDATION AND QUALIFICATION

1 System Validation Status

All critical systems have undergone validation:

- IceNav(TM) 4.0 platform (VAL-IN-2023-001)
- Temperature monitoring systems (VAL-TM-2023-002)
- Data logging systems (VAL-DL-2023-003)
- Emergency backup systems (VAL-EB-2023-004)

2 Outstanding Validation Items

The following require additional validation:

- Extended operation protocols for -40 C environments
- New battery management system for Arctic-grade units
- Updated emergency stop protocols for multi-robot configurations

6. RISK ASSESSMENT

1 Critical Risk Areas:

- Temperature excursion management
- Data integrity maintenance
- System redundancy
- Emergency response capabilities
- Power failure protocols

2 Risk Mitigation Strategies:

- Implementation of triple-redundant temperature monitoring

- Enhanced backup power systems
- Automated failover protocols
- Regular validation testing
- Comprehensive staff training program

7. CORRECTIVE ACTIONS

1 Required Actions:

Finding	Action Required	Due Date	Priority
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VAL-2023-01	Complete -40 C validation	03/31/2024	High
DOC-2023-02	Update emergency procedures	02/28/2024	Medium
TRN-2023-03	Enhance operator training	01/31/2024	Medium

2 Recommended Improvements:

- Implement enhanced temperature mapping protocols
- Upgrade data backup systems
- Expand validation documentation
- Enhance staff training program
- Improve change control procedures

8. COMPLIANCE CERTIFICATION

Based on our comprehensive audit, Polar Dynamics Robotics, Inc.'s cold chain management systems are deemed substantially compliant with applicable regulations and standards, subject to the completion of identified corrective actions.

9. AUDIT TEAM AND METHODOLOGY

1 Audit Team:

- Lead Auditor: Dr. Margaret Chen, CQA
- Technical Specialist: James Wilson, P.E.
- Quality Systems Auditor: Sarah Thompson, RAC
- Validation Specialist: Dr. Robert Kumar

2 Audit Period:

- November 1-30, 2023

10. DISCLAIMERS AND LIMITATIONS

This report is confidential and intended solely for the use of Polar Dynamics Robotics, Inc. The findings represent conditions observed during the audit period and may not reflect subsequent changes. This report shall not be reproduced except in full, without written approval of the audit team.

11. AUTHORIZATION

Prepared by:

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License: CQA #45789

Date: December 15, 2023

Reviewed and Approved by:

Katherine Wells

Chief Financial Officer

Polar Dynamics Robotics, Inc.

Date: December 18, 2023

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