

COLD CHAIN MANAGEMENT POLICY

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Polar Dynamics Robotics, Inc.

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1. PURPOSE AND SCOPE

1. This Cold Chain Management Policy ("Policy") establishes the requ

2. This Policy applies to all Company employees, contractors, and au

2. DEFINITIONS

1. "Cold Chain" refers to the temperature-controlled supply chain proc
2. "BlueCore(TM) System" means the Company's proprietary cold-res
3. "Temperature Excursion" refers to any deviation from prescribed te
4. "Critical Control Points" (CCPs) are specific points, procedures, or c

3. TEMPERATURE MONITORING AND CONTROL

1. Automated Monitoring Systems

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All BlueCore(TM)-enabled robots must maintain continuous temperature

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Minimum sensor calibration frequency: Every 90 days

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Required accuracy range: 0.5 C

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Data logging intervals: Every 300 seconds during operation

2. Temperature Ranges

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Ultra-low temperature: -40 C to -20 C

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Deep freeze: -25 C to -15 C

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Standard refrigeration: +2 C to +8 C

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Cool storage: +8 C to +15 C

3. Alert Parameters

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Primary alert threshold: 1 C from specified range

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Critical alert threshold: 2 C from specified range

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Maximum response time: 15 minutes for critical alerts

4. OPERATIONAL REQUIREMENTS

1. Pre-Operation Verification

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System diagnostics check

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Temperature sensor calibration verification

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Power system cold-rating confirmation

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Navigation system cold-environment parameters

2. During Operation

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Continuous monitoring of environmental conditions

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Real-time temperature mapping

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Automated adjustment of operating parameters

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Documentation of all temperature excursions

3. Post-Operation

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Performance data analysis

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Temperature log review

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System integrity verification

-

Maintenance requirement assessment

5. QUALITY ASSURANCE

1. Documentation Requirements

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Temperature monitoring records

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Calibration certificates

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Maintenance logs

-

Incident reports

-

Training records

2. Audit Procedures

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Quarterly internal audits

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Annual third-party verification

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Random spot checks

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System performance reviews

6. TRAINING AND QUALIFICATION

1. Required Training

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Cold chain management principles

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BlueCore(TM) system operation

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Emergency response procedures

-

Temperature monitoring protocols

2. Qualification Requirements

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Initial certification

-

Annual recertification

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Performance assessment

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Compliance verification

7. INCIDENT MANAGEMENT

1. Response Procedures

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Immediate assessment of temperature excursion

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Implementation of corrective actions

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Documentation of incident details

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Root cause analysis

2. Reporting Requirements

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Internal notification within 1 hour

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Customer notification as required

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Regulatory reporting if applicable

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Corrective action documentation

8. COMPLIANCE AND REVIEW

1. Regulatory Compliance

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FDA 21 CFR Part 11

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EU GDP Guidelines

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ISO 9001:2015

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GAMP 5 -

2. Policy Review

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Annual policy review

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Update based on regulatory changes

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Integration of technological advances

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Stakeholder feedback incorporation

9. RESPONSIBILITY AND AUTHORITY

1. The Chief Technology Officer maintains overall responsibility for the

2. The Quality Assurance Department ensures compliance with this P
3. The Operations Department implements and monitors adherence to

10. REVISION HISTORY

Version	Date	Description	Approved By
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0	2023-01-15	Initial Release	M. Chen
0	2024-01-15	Updated for BlueCore(TM) 2.0	M. Chen

APPROVAL

Approved by:

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Marcus Chen

Chief Technology Officer

Date: January 15, 2024

Sarah Nordstrom

Chief Operating Officer

Date: January 15, 2024

