

QUALITY ASSURANCE STANDARDS

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COLD CHAIN ROBOTICS SYSTEMS AND OPERATI

Polar Dynamics Robotics, Inc.

Document No. QA-2023-114

Effective Date: January 15, 2024

1. PURPOSE AND SCOPE

1. This Quality Assurance Standards document ("Standards") establis

2. These Standards apply to all Company facilities, personnel, contractors, and subcontractors.

2. DEFINITIONS

1. "BlueCore(TM) System" means the Company's proprietary cold-resistance system.
2. "Cold Chain Environment" means any controlled temperature environment.
3. "Critical Component" means any system element essential to maintaining the Cold Chain Environment.
4. "Quality Event" means any deviation from specified performance parameters.

3. QUALITY MANAGEMENT SYSTEM

1. The Company shall maintain ISO 9001:2015 certification for all manufacturing facilities.

2. Quality control procedures shall comply with:

a) ANSI/RIA R15.06-2012 Industrial Robot Safety Standards

b) IEC 61496-1:2020 Safety of Machinery

c) FDA 21 CFR Part 11 (where applicable for pharmaceutical applications)

3. All quality records shall be maintained for a minimum of seven (7) years.

4. COLD ENVIRONMENT TESTING REQUIREMENTS

1. Pre-Production Testing

a) All prototype units shall undergo minimum 500 hours of continuous operation at -30 C

b) Navigation accuracy testing at specified temperature intervals

c) Power system endurance verification under maximum load conditions

d) Impact resistance validation at cold temperature extremes

2. Production Unit Testing

a) 100% functional testing of all BlueCore(TM) components

b) Minimum 48-hour cold chamber testing for each unit

c) Thermal cycling between ambient and -40 C (5 cycles minimum)

d) Verification of all sensor systems and safety features

5. COMPONENT SPECIFICATIONS

1. Critical Components must meet or exceed:

a) Operating temperature range: -40 C to +50 C

b) IP65 environmental protection rating

c) Mean Time Between Failures (MTBF) 50,000 hours

d) Impact resistance: IK08 rating minimum

2. Supplier Quality Requirements

a) ISO 9001:2015 certification required

b) Component traceability documentation

c) Material certificates for cold-rated components

d) First Article Inspection reports

6. QUALITY CONTROL PROCEDURES

1. Incoming Inspection

a) Visual inspection of all components

b) Dimensional verification

c) Documentation review

d) Cold resistance validation

2. In-Process Quality Control

a) Assembly verification at designated control points

b) Torque verification of critical fasteners

c) Electronic systems testing

d) Software validation

3. Final Inspection

a) Full functional testing

b) Safety system verification

c) Performance validation

d) Documentation completeness

7. NONCONFORMANCE MANAGEMENT

1. All quality events shall be documented in the Company's Quality Management System.
2. Corrective and Preventive Action (CAPA) procedures shall be implemented.
3. Monthly quality metrics reporting to senior management is required.

8. CONTINUOUS IMPROVEMENT

1. Quality metrics shall be reviewed quarterly by the Quality Steering Committee.
2. Annual audit of quality systems and procedures is required.
3. Employee training on quality standards must be conducted semi-annually.

9. COMPLIANCE AND ENFORCEMENT

1. Compliance with these Standards is mandatory for all Company personnel.
2. Violations may result in disciplinary action up to and including termination.

10. AMENDMENTS AND UPDATES

1. These Standards shall be reviewed annually and updated as necessary.
2. All amendments require approval from the Chief Quality Officer and the Board of Directors.

AUTHORIZATION

APPROVED AND ADOPTED this 15th day of January, 2024.

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