TECHNICAL REQUIREMENTS - POLARPHARM STORAGE

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Classification: Confidential

1. PURPOSE AND SCOPE

1. This Technical Requirements document ("Requirements") establishes the mandatory specifications for Polar Dynamics Robotics, Inc. ("Company") autonomous mobile robot systems ("AMR Systems") deployed in pharmaceutical storage environments ("PolarPharm Storage") operating at temperatures between -30 C and +25 C.

2. These Requirements apply to all Company AMR Systems installed or operated within GMP-certified pharmaceutical storage facilities, including but not limited to controlled room temperature (CRT), refrigerated, and frozen storage zones.

2. DEFINITIONS

1. "Cold Chain Compliance" means adherence to GDP (Good Distribution Practice) and GMP (Good Manufacturing Practice) guidelines for pharmaceutical storage and handling.

2. "IceNav(TM) System" refers to Company's proprietary cold-environment navigation and operation platform.

3. "Thermal Management System" means Company's integrated temperature control and monitoring system for AMR operation in cold environments.

3. TECHNICAL SPECIFICATIONS

1. Temperature Operating Range

- Primary operating range: -30 C to +25 C
- Maximum exposure duration at -30 C: 12 continuous hours
- Temperature transition tolerance: 0.5 C per minute
- Thermal shock resistance: Compliant with IEC 60068-2-14

2. Navigation and Positioning

- IceNav(TM) System accuracy: 15mm in all operating conditions
- SLAM mapping resolution: 1cm at -30 C
- Position update frequency: 100Hz minimum
- Anti-condensation sensors: Grade 316L stainless steel

3. Power and Battery Systems

- Cold-rated lithium iron phosphate (LiFePO4) cells
- Minimum runtime at -30 C: 8 hours
- Charging temperature range: 0 C to +40 C
- Battery management system: UL 1642 certified

4. COMPLIANCE REQUIREMENTS

1. Regulatory Standards

- FDA 21 CFR Part 11 compliance for electronic systems
- EU GMP Annex 11 compliance
- ISO 13485:2016 Medical devices QMS requirements
- IEC 60529 IP54 rating minimum

2. Documentation Requirements

- Installation Qualification (IQ) protocols
- Operational Qualification (OQ) protocols
- Performance Qualification (PQ) protocols
- Calibration certificates for all measuring devices

5. SAFETY AND MONITORING

1. Safety Systems

- Emergency stop functionality: Response time <100ms
- Automatic shutdown on critical sensor failure
- Redundant temperature monitoring
- Anti-collision system with 360 coverage

2. Environmental Monitoring

- Temperature logging frequency: Every 60 seconds
- Humidity monitoring range: 0-95% RH
- Particle detection capability: 0.5 m
- Data retention period: Minimum 12 months

6. MAINTENANCE AND CALIBRATION

1. Scheduled Maintenance

- Primary inspection interval: 90 days
- Thermal system calibration: 180 days
- Navigation system calibration: 365 days
- Battery system inspection: 90 days

2. Calibration Standards

- Temperature sensors: NIST traceable
- Position sensors: ISO 17025 certified
- Humidity sensors: 2% RH accuracy
- Pressure sensors: 0.1% full scale

7. DATA MANAGEMENT AND SECURITY

1. Data Collection

- Operating parameters logged at 1Hz minimum
- Environmental conditions recorded every 60 seconds
- System events logged in real-time
- Audit trail maintenance: 5-year retention

2. Security Requirements

- 256-bit AES encryption for all stored data
- Role-based access control
- Automated backup every 24 hours
- Secure remote access via VPN only

8. WARRANTY AND SUPPORT

1. The Company warrants compliance with these Requirements for a period of twenty-four (24) months from the date of installation, subject to proper maintenance and operation.

2. Technical support shall be available 24/7/365 with maximum response time of 2 hours for critical issues.

9. MODIFICATIONS AND UPDATES

1. These Requirements may be modified only by written agreement between Company and customer.

2. Software updates affecting compliance-related functionality require validation prior to implementation.

APPROVAL AND EXECUTION

IN WITNESS WHEREOF, the undersigned has executed these Technical Requirements as of the Effective Date.

POLAR DYNAMICS ROBOTICS, INC.

By:

Name: Dr. James Barrett

Title: Chief Robotics Officer

Date: January 15, 2024