

FDA 21 CFR Part 11 Validation Package

Pharmaceutical Operations Division

Polar Dynamics Robotics, Inc.

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1. Purpose and Scope

1 This validation package documents the compliance of Polar Dynamics Robotics, Inc.'s ("PDR") IceNav(TM) Autonomous Mobile Robot System with FDA 21 CFR Part 11 requirements for electronic records and electronic signatures in pharmaceutical operations environments.

2 This validation applies specifically to the following system components:

- IceNav(TM) Control Software v4.2
- TempTrack(TM) Environmental Monitoring Module v2.1
- PharmaSafe(TM) Data Logging System v3.0
- SecureSign(TM) Electronic Authentication Platform v2.4

2. System Description

1 The IceNav(TM) system is designed to operate in controlled pharmaceutical environments, maintaining compliance with GMP requirements while executing autonomous material handling operations in temperature-controlled facilities.

2 Electronic records generated and maintained by the system include:

- Environmental condition logs
- Robot movement and operation records
- Material handling transaction data
- User authentication and access logs
- System configuration changes
- Calibration and maintenance records

3. Part 11 Controls Implementation

1 System Access Controls

- Unique user identification requirements
- Role-based access control (RBAC) implementation
- Biometric authentication integration
- Automatic terminal timeout after 15 minutes
- Failed login attempt limitations (3 attempts)

2 Audit Trail Features

- Automated, computer-generated timestamps
- Original and modified record retention
- User identification for all actions
- Reason for change documentation
- Sequential record generation

3 Electronic Signature Components

- Two-distinct identification components
- Username and biometric or password combination
- Non-reusable password requirements
- Periodic password expiration (90 days)
- Loss management procedures

4. Validation Testing Protocol

1 Installation Qualification (IQ)

- Hardware component verification
- Software installation confirmation
- Network connectivity validation
- Environmental controls verification
- Security system implementation

2 Operational Qualification (OQ)

- User access control testing
- Electronic signature verification

- Audit trail functionality
- Data backup and recovery
- System security features

3 Performance Qualification (PQ)

- Temperature mapping validation
- Movement precision verification
- Data integrity testing
- Long-term stability assessment
- Error handling verification

5. Security Measures

1 Data Integrity Controls

- SHA-256 encryption for data at rest
- TLS 1.3 encryption for data in transit
- Automated backup systems
- Record change control procedures
- Data archival protocols

2 System Security

- Network segmentation
- Firewall implementation
- Intrusion detection systems
- Regular security audits
- Vulnerability assessments

6. Documentation Requirements

1 Standard Operating Procedures

- User access management
- System maintenance
- Data backup and recovery
- Change control procedures

- Security incident response

2 Training Requirements

- Initial user training
- Annual refresher courses
- Security awareness training
- Documentation practices
- Compliance updates

7. Compliance Declaration

1 Based on comprehensive validation testing and documentation, the IceNav(TM) system meets all applicable requirements of 21 CFR Part 11 for:

- System validation
- Record generation and maintenance
- Electronic signature implementation
- Access controls
- Audit trail functionality

8. Certification

The undersigned hereby certify that this validation package accurately represents the Part 11 compliance status of the IceNav(TM) system:

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9. Document Control

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