

STANDARD OPERATING PROCEDURE

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CLEANING AND SANITIZATION PROTOCOL FOR A

Document No.: SOP-CS-2024-001

Effective Date: January 15, 2024

Version: 3.0

Department: Operations

Approved By: Sarah Nordstrom, COO

1. PURPOSE

This Standard Operating Procedure (SOP) establishes the requirements and procedures for cleaning and sanitizing Polar Dynamics Robotics, Inc. ("Company") autonomous mobile robots (AMRs) operating in temperature-controlled environments, ensuring compliance with FDA 21 CFR Part 110, ISO 14644, and applicable GMP requirements.

2. SCOPE

- 1 This SOP applies to all BlueCore(TM)-enabled AMRs deployed in controlled environments.
- 2 This procedure covers routine cleaning, deep sanitization, and emergency decontamination procedures.

3. RESPONSIBILITIES

- 1 Operations Personnel
 - Execute routine cleaning procedures

- - 2 -

Document cleaning activities

-

Report cleaning-related issues

2 Quality Assurance

-

Monitor compliance with cleaning protocols

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Conduct periodic audits

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Maintain cleaning validation records

3 Technical Support

-

Provide specialized cleaning guidance for sensitive components

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Perform post-cleaning system checks

4. MATERIALS AND EQUIPMENT

1 Approved Cleaning Agents

-

Non-ionic surfactant solution (P/N: CLN-001)

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Industrial-grade sanitizer (P/N: SAN-002)

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Anti-static electronic cleaner (P/N: ELC-003)

2 Required Equipment

-

Clean-room grade wipes

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HEPA-filtered vacuum system

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Electrostatic sprayer

-

Personal protective equipment (PPE)

5. CLEANING PROCEDURES

1 Pre-Cleaning Preparation

- a) Power down AMR following shutdown procedure SOP-OP-2023-00
- b) Remove detachable components per maintenance manual MM-202
- c) Don appropriate PPE

2 External Surface Cleaning

a) Apply approved cleaning solution using electrostatic sprayer

b) Wipe surfaces with clean-room grade wipes

c) Pay special attention to:

-

Sensor arrays

-

Navigation cameras

-

Articulation points

-

Charging contacts

3 Internal Component Cleaning

a) Remove access panels following safety protocol SP-2023-002

- b) Use anti-static cleaner on electronic components
- c) Vacuum debris using HEPA-filtered system
- d) Clean internal sensors and cooling systems

4 Sanitization

- a) Apply approved sanitizer to all food-contact surfaces
- b) Allow proper dwell time per manufacturer specifications
- c) Wipe dry with clean, lint-free cloths

6. FREQUENCY AND SCHEDULING

1 Routine Cleaning: Daily

-

Basic external cleaning

-

Sensor array maintenance

-

Charging contact cleaning

2 Deep Cleaning: Weekly

-

Complete external/internal cleaning

-

Full sanitization protocol

-

System inspection

3 Emergency Cleaning

-

Following spills or contamination events

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After maintenance procedures

-

Upon transfer between different operating environments

7. DOCUMENTATION

1 Required Records

-

Cleaning logs

-

Sanitization verification

-

Material usage tracking

-

Non-conformance reports

2 Documentation Procedures

- a) Complete cleaning log form CLN-LOG-2024
- b) Record all cleaning materials used
- c) Note any observations or issues
- d) Obtain supervisor verification

8. QUALITY CONTROL

1 Verification Methods

-

ATP testing of critical surfaces

-

Visual inspection

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Performance validation

-

Environmental monitoring

2 Acceptance Criteria

-

ATP readings < 150 RLU

-

No visible residue

-

Full sensor functionality

-

Proper system operation

9. HEALTH AND SAFETY

1 Required PPE

-

Chemical-resistant gloves

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Safety glasses

-

Clean room suits when required

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Cold-environment protection where applicable

2 Safety Precautions

-

Ensure proper ventilation

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Follow chemical handling procedures

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Observe cold-room safety protocols

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Maintain electrical safety standards

10. REVISION HISTORY

Version 3.0 - January 15, 2024

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Updated for BlueCore(TM) Generation 3 systems

-

Added cold-environment specifications

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Revised cleaning agent requirements

11. APPROVALS

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12. DISCLAIMER

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