Work Instruction (WI) for Bug Tracking

- **WI Number**: SOP-003-01

- **Title**: Bug Tracking Procedure for Infusion Pump Software

- **Version**: 1.0

- **Effective Date**: 15-Oct-2024

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1. Purpose

This Work Instruction outlines the process for tracking and managing software bugs identified during the software development life cycle (SDLC) of infusion pump software, ensuring compliance with IEC 62304.

2. Scope

This WI applies to all software development and testing teams involved in the development of infusion pump software at [Company Name].

3. Responsibilities

- **Software Development Team**: Responsible for fixing bugs and documenting resolutions.

- **QA Team**: Responsible for identifying, logging, and verifying bug fixes.

- **Project Manager**: Monitors the bug tracking process and resolves any issues.

4. Definitions

- **Bug**: An error, flaw, or unintended behavior in software that produces incorrect or unexpected results.

- **Bug Tracking System**: A tool used to report, track, and manage software bugs.

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5. Procedure

5.1 Bug Identification

Objective: Identify bugs during testing and user feedback.

Procedure:

1. During testing, document any anomalies or failures.

2. Gather feedback from users and stakeholders about software performance.

3. Classify the identified issues based on severity (critical, major, minor).

Key Decisions:

- Determine the priority level for addressing each identified bug.

Exit Criteria:

- Comprehensive list of identified bugs documented.

5.2 Bug Logging

Objective: Log identified bugs into the bug tracking system.

Procedure:

1. Open a new entry in the bug tracking system for each identified bug.

2. Include detailed information in the bug report, such as:

   o Description of the bug

   o Steps to reproduce

   o Severity and priority levels

   o Environment details (e.g., OS version, hardware specifics)

   o Date and time of identification

   o Reporter's name

Key Decisions:

- Validate the completeness of each bug report before logging.

Exit Criteria:

- All identified bugs logged in the bug tracking system.

5.3 Bug Triage

Objective: Review and prioritize logged bugs.

Procedure:

1. Conduct regular bug triage meetings with the development and QA teams.

2. Review each logged bug for accuracy and completeness.

3. Assign severity and priority to each bug based on impact and urgency.

Key Decisions:

- Confirm the assigned priority and ownership for each bug.

Exit Criteria:

- Prioritized list of bugs, ready for resolution.

5.4 Bug Resolution

Objective: Fix logged bugs based on priority.

Procedure:

1. Development team addresses bugs according to their assigned priority.

2. Document the resolution for each bug, including:

   o Code changes made

   o Testing conducted post-fix

   o Verification of bug resolution

Key Decisions:

- Confirm readiness for retesting after bug fixes.

Exit Criteria:

- Documented resolution for each bug and status updated in the bug tracking system.

5.5 Bug Verification

Objective: Verify the fixes for logged bugs.

Procedure:

1. QA team conducts verification testing for fixed bugs.

2. Update the bug tracking system with verification results (passed/failed).

3. Reopen bugs if verification fails, document reasons for failure.

Key Decisions:

- Confirm that the bug is resolved based on verification results.

Exit Criteria:

- All fixed bugs verified and status updated in the tracking system.

5.6 Reporting

Objective: Generate reports on bug tracking metrics.

Procedure:

1. Regularly generate reports on logged bugs, fixed bugs, and outstanding issues.

2. Share bug tracking metrics with the project team and stakeholders.

Key Decisions:

- Determine the frequency of bug tracking reports based on project timelines.

Exit Criteria:

- Bug tracking metrics reported to stakeholders.

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6. References

- IEC 62304 (Medical Device Software – Software Life Cycle Processes)

- Bug Tracking System User Guide

- Software Development Life Cycle SOP (SOP-SDLC-001)

7. Revision History

Version	Date	Description of Changes	Author
01	15-Oct-2024	Initial release	Raj Solai