

Tytonyx

510(K) Device Readiness Report

Project: XXX 001

Executive Summary - XXX 001

What we did

TytoNyx prepared a 510(k) Device Readiness report for XXX 001, reviewing against current FDA guidance and relevant standards.

What we found

31+ deficiencies that would trigger an FDA Refuse to Accept (RTA) hold or multiple rounds of additional information (AI) requests.

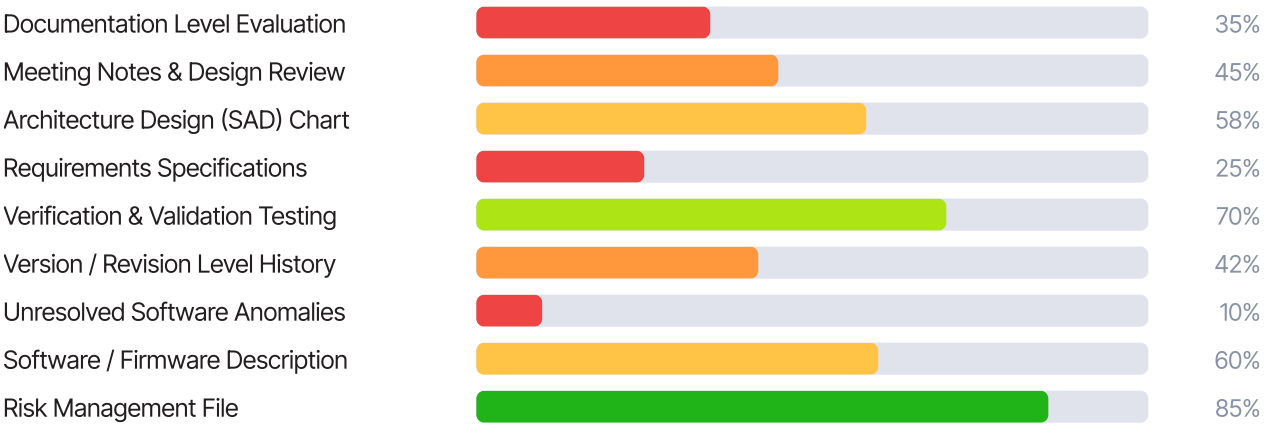
Recurrent issues: findings were concentrated in documentation level evaluation, meeting notes and design review implementation, system and software architecture design (SAD) chart, and software requirements specifications.

Documented compliances in key areas (software testing as part of verification & validation and system and software architecture design (SAD) chart), confirming where remediation can remain targeted.

Why it matters

Unaddressed, these deficiencies would likely add 2-3 months and 6-figure costs to clearance, and could expose the device to recall risk after launch. Early detection allows teams to address issues before the FDA identifies them.

Level of Completion



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Audit specifications and assumptions

Medical Device Classification

The product is a medical device requiring 510(k) clearance according to FDA classification guidelines.

User Input Assumptions

It is assumed that the user has correctly identified and completed the following information:

- Classification / Medical Specialty
- Classification / Regulation
- Classification / Product Code

Guidance Compliance

The audit follows the Electronic Submission Template for Medical Device 510(k) Submissions guidance and related references. Specifically, the audit assists in:

> *"preparation of the electronic submission template for 510(k)s that enable submission of the 510(k) electronic submission solely in electronic format. The electronic submission template includes the information and guided prompts FDA believes will best facilitate the collection and assembly of the necessary elements of a 'complete' submission, as required by regulation or essential to FDA's substantive review of the 510(k) submission."*

Regulatory Compliance and Consistency Check

The audit assesses regulatory compliance, consistency, and adherence to FDA requirements.

Scope of Audit

The audit does not check for the correctness of verification and validation outputs.

Section 1: Indications for Use

Audit instructions

- Indications for Use must describe the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
- Indications for Use must be identical across all documents. All documents and all formulation discrepancies must be reported.

Our audit findings reveal significant discrepancies and inconsistencies in the Indications for Use statements across multiple documents. Below are the detailed deficiencies identified:

1.1 Inconsistency in Patient Population Age

Deficiency

There is a significant inconsistency in the specified minimum patient age across the documents. Some documents state "at least 16 years of age," while others state "at least 3 years of age." This discrepancy may lead to confusion regarding the intended patient population and must be rectified to ensure compliance.

DOCUMENTS INDICATING "AT LEAST 16 YEARS OF AGE":

> **STATEMENT:**
>
> *"XXX 001 is intended for use by trained/qualified* [redacted] *or physicians on adult and pediatric subjects at least 16 years of age for* [redacted]*. It does not diagnose, treat, or prevent any disease states. Diagnosis and treatment are the responsibility of a licensed clinician."*

Reference: *XXX 001 FDA Predicate Device Evaluation.pdf*; Section: Device Intended Application; Page: 2

STATEMENT:

"XXX 001 is intended for use by trained/qualified [redacted] or physicians on adult and pediatric subjects at least 16 years of age for [redacted]. It does not diagnose, treat, or prevent any disease states. Diagnosis and treatment are the responsibility of a licensed clinician."

Reference: *XXX 001 Design Development Plan.pdf*; Section: Device Intended Application; Page: 2

STATEMENT:

"XXX 001 is intended for use by trained/qualified [redacted] or physicians on adult and pediatric subjects at least 16 years of age for [redacted]. It does not diagnose, treat, or prevent any disease states. Diagnosis and treatment are the responsibility of a licensed clinician."

Reference: *XXX 001 Software Description Rev B.pdf*; Section: XXX 001 Software Description > Software Operations; Pages: 1, 2

STATEMENT:

"The intended use of the XXX 001 software is for trained/qualified [redacted] or physicians to visualize [redacted]. It is intended for both adult and pediatric patients at least 16 years of age."

Reference: *XXX 001 About Page Labeling Rev A.pdf*; Page: 1

DOCUMENTS INDICATING "AT LEAST 3 YEARS OF AGE":

STATEMENT:

"The intended use of the XXX 001 device is for visualization of [redacted]. It is intended for use by trained [redacted] or physicians on adult and pediatric subjects at least 3 years of age. The device is not intended to diagnose, treat, prevent, cure, or mitigate any disease or condition, nor is it intended to be implanted or in contact with patients."

Reference: *XXX 001 Risk Management Plan & Report Rev A - signed.pdf*; Section: Appendix 2: Product Characteristics; Pages: 9, 10, 11

STATEMENT:

"The intended use of the XXX 001 device is for visualization of [redacted]. It is intended for use by trained [redacted] or physicians on adult and pediatric subjects at least 3 years of age. The device is not intended to diagnose, treat, prevent, cure, or mitigate any disease or condition."

Reference: *XXX 001 User Requirements Rev B - signed.pdf*; Section: User Requirements; Page: 4

1.2 Variations in Device Description

Deficiency

The descriptions of the device's functionality are not absolutely identical across all documents. Phrases such as "visualizing brain function," "visualize human brain function by fusing EEG information with images of an idealized head model and MRI image," "visualization of human brain function by fusing EEG information with images of an atlas head model and MRI image," and "visualizes cortex projections of human brain activity on high-resolution 2D and 3D head models" are used interchangeably. This variation in wording does not meet the requirement for absolute identity and must be standardized.

DIFFERENT PHRASING OF DEVICE FUNCTIONALITY:

STATEMENT:

"... for visualizing brain function."

Reference: *XXX 001 FDA Predicate Device Evaluation Rev A - signed.pdf*

STATEMENT:

"... to visualize human brain function by fusing EEG information with images of an idealized head model and MRI image."

Reference: *XXX 001 About Page Labeling Rev A.pdf*

> **STATEMENT:**
>
> *"... for visualization of human brain function by fusing EEG information with images of an atlas head model and MRI image."*

Reference: *XXX 001 Risk Management Plan & Report Rev A - signed.pdf*, Page: 3

> **STATEMENT:**
>
> *"It estimates and visualizes cortex projections of human brain activity on high-resolution 2D and 3D head models."*

Reference: *XXX 001 Software Architecture and Detail Design.pdf*, Section: 4 Software Description, Pages: 5, 6

1.3 Inconsistent Statements Regarding Diagnostic Capabilities

Deficiency

Not all documents consistently state that the device is not intended to diagnose, treat, prevent, cure, or mitigate any disease or condition. The absence of this statement in XXX 001 About Page Labeling Rev A.pdf constitutes a discrepancy that needs to be addressed to maintain consistency across all documents.

DOCUMENTS STATING THE DEVICE DOES NOT DIAGNOSE OR TREAT DISEASES:

> **STATEMENT:**
>
> *"It does not diagnose, treat, or prevent any disease states. Diagnosis and treatment are the responsibility of a licensed clinician."*

Reference: *XXX 001 FDA Predicate Device Evaluation Rev A - signed.pdf*

> **STATEMENT:**
>
> *"XXX 001 does not treat or diagnose any disease states. Diagnosis and treatment are the responsibility of a licensed clinician and not XXX 001 (the device)."*

Reference: *XXX 001 Software Architecture and Detail Design.pdf*

> **STATEMENT:**
>
> *"The device is not intended to diagnose, treat, prevent, cure, or mitigate any disease or condition, nor is it intended to be implanted or in contact with patients."*

Reference: *XXX 001 Risk Management Plan & Report Rev A - signed.pdf*

DOCUMENT WITHOUT EXPLICIT STATEMENT ON DIAGNOSTIC CAPABILITIES:

> **STATEMENT:**
>
> *[No explicit statement regarding diagnostic, treatment, prevention, cure, or mitigation capabilities.]*

Reference: *XXX 001 About Page Labeling Rev A.pdf*

1.4 Inconsistencies in Terminology and Professional Titles

Deficiency

The inconsistency in user descriptions ("trained/qualified [redacted] or physicians" vs. "trained [redacted] or physicians") may lead to ambiguity regarding the qualifications required to operate the device. This discrepancy violates the requirement for absolutely identical Indications for Use statements.

VARIATIONS IN DESCRIBING USERS:

> **STATEMENT:**
>
> *"Trained/qualified [redacted] or physicians"*

Reference: *XXX 001 FDA Predicate Device Evaluation Rev A - signed.pdf*, *XXX 001 Software Description Rev B.pdf*

> **STATEMENT:**
>
> *"Trained [redacted] or physicians"*

Reference: *XXX 001 Risk Management Plan & Report Rev A - signed.pdf*, *XXX 001 User Requirements Rev B - signed.pdf*

Conclusion and Required Actions

To achieve compliance with the audit instructions and FDA requirements, the following actions must be taken:

1. **Standardize the Indications for Use Statement:**
   Develop a single, precise Indications for Use statement. Ensure the statement includes:
   - A consistent description of the device's functionality.
   - A clear and uniform patient population age.
   - Explicit statements regarding the device's diagnostic, treatment, prevention, cure, or mitigation capabilities.
   - Consistent terminology for users and device naming.
2. **Update All Documents:**
   Replace the current Indications for Use statements in all documents with the standardized version.
   Verify that the wording is absolutely identical across all documents, including punctuation and symbols.

Section 2: Software Documentation Level

Audit instructions

- A statement should be provided indicating the Documentation Level for the device and a description of the rationale for such Documentation Level. The rationale should account for the device's intended use, and include references, where appropriate, from the submission documentation (such as Risk Management File, Software / Firmware Description, etc.) to support the indicated Documentation Level.

The audit of the Software Documentation Level for the XXX 001 device has identified several deficiencies that need to be addressed to achieve full compliance with the audit instructions and regulatory requirements.

2.1 Inadequate Rationale for Documentation Level Classification

Deficiency

The submission lacks a detailed rationale accounting for the device's intended use to support the declared Documentation Level. The rationale provided does not include references from the submission documentation (such as Risk Management File, Software Description) to substantiate the indicated Documentation Level.

Evidence

STATEMENT:

"The device is intended to compute electrical source distributions based on high-density EEG recordings. It uses EEG and MRI-derived information to estimate and visualize cortex projections of human brain activity on high-resolution 2D and 3D head models. The document states that a failure or latent flaw of the device software function would not present a hazardous situation with probable risk of death or serious injury prior to the implementation of risk control measures. The outcome is categorized as Basic Documentation Level."

Reference: *"XXX 001 Document Level Evaluation Rev A.pdf"*, Section: Document Level Evaluation, Page: 1

Why This Is a Deficiency

The rationale does not thoroughly account for the device's intended use and its potential risks in justifying the Basic Documentation Level. It lacks specific references to other submission documents, such as the Risk Management File or Software Description, that would support the classification. Without a comprehensive rationale and supporting evidence, it is unclear whether the chosen Documentation Level is appropriate for the device's risk profile and intended use.

How to Fix

1. **Provide a Detailed Rationale:**
   Expand the rationale to thoroughly explain how the device's intended use, operational environment, and risk assessment justify the Basic Documentation Level.

2. **Include Supporting References:**
   Reference relevant sections from the submission documentation that support the classification. For example:

   - **Risk Management File:**
     Cite specific risk assessments that demonstrate the device does not pose a probable risk of death or serious injury.

     Reference: *"XXX 001 Risk Management Plan & Report Rev A - signed.pdf"*, Appendix 2: Product Characteristics, Page IDs: [9-11]

   - **Software Description:**
     Highlight how the software operates and any built-in safety features.

     Reference: *"XXX 001 Software Description Rev B.pdf"*, Section: Significant Software Features and Functions, Page IDs: [1]

3. **Justify with Intended Use:**
   Explain how the device's non-invasive nature and use by trained professionals in controlled environments reduce potential risks.

EXAMPLE OF AN IMPROVED RATIONALE:

"XXX 001 is a non-invasive, software-only device intended for use by trained EEG technologists or physicians in clinical settings. As detailed in the Risk Management File (Reference: 'XXX 001 Risk Management Plan & Report Rev A - signed.pdf', Appendix 2: Product Characteristics, Page IDs: [9-11]), the device processes previously recorded EEG data and does not interact directly with patients. Failure of the device would not result in a hazardous situation with probable risk of death or serious injury. Therefore, in accordance with the risk assessments and the device's intended use, a Basic Documentation Level is appropriate."

2.2 Inconsistency in Safety Classification and Documentation Level Across Documents

Deficiency

There are inconsistencies in the submission regarding the device's safety classification and Level of Concern. Different documents classify the device as having a 'Moderate Level of Concern', being a 'Class B' medical device, and requiring a 'Basic Documentation Level' without reconciling these classifications.

Evidence

BASIC DOCUMENTATION LEVEL:

"The outcome is categorized as Basic Documentation Level."

Reference: *"XXX 001 Document Level Evaluation Rev A.pdf"*, Section: Document Level Evaluation, Page: 1

> **MODERATE LEVEL OF CONCERN AND CLASS B CLASSIFICATION:**
>
> *"The XXX 001 is classified as a class-B medical device according to IEC-62304, with a moderate level of concern."*
>
> **Reference:** *"XXX 001 Software Development Plan Rev D - signed.pdf"*, Section: Product Description, Page: 7

> **LEVEL OF CONCERN DEFINITIONS:**
>
> *"The document outlines the Level of Concern (LOC) for software documentation, categorizing it into Major, Moderate, and Minor concerns."*
>
> **Reference:** *"XXX 001 Software Development Plan Rev D - signed.pdf"*, Section: Appendix, Page: 17

Why This is a Deficiency

Inconsistent classifications can lead to confusion about the appropriate Documentation Level and may result in inadequate documentation for the device's risk profile. A 'Moderate Level of Concern' typically requires more comprehensive documentation than a 'Basic Documentation Level'. The submission does not reconcile these differences or explain how they collectively support the chosen Documentation Level, which may lead to non-compliance with regulatory expectations.

How to Fix

1. **Ensure Consistent Classification:**
   Review all submission documents to align the device's safety classification and Level of Concern consistently.
2. **Reconcile Classifications:**
   Provide a clear explanation reconciling the device's IEC 62304 safety class (Class B), the Level of Concern (Moderate), and the chosen Documentation Level (Basic).
3. **Adjust Documentation Level if Necessary:**
   If the device's risk profile aligns with a Moderate Level of Concern, consider adjusting the Documentation Level accordingly (e.g., to Moderate or Enhanced).
4. **Update the Rationale:**
   Revise the Documentation Level rationale to reflect consistent classifications, supporting it with references to submission documents.

EXAMPLE OF RECONCILIATION:

"While the XXX 001 device is classified as Class B under IEC 62304 due to its software safety considerations (Reference: 'XXX 001 Software Development Plan Rev D - signed.pdf', Section: Product Description, Page IDs: [7]), its intended use and risk assessments indicate that failures would not result in serious injury or death. As outlined in the Risk Management File (Reference: 'XXX 001 Risk Management Plan & Report Rev A - signed.pdf', Page IDs: [7-8]), the residual risks are acceptable and well controlled. Therefore, despite the software's Moderate Level of Concern, the overall risk profile justifies a Basic Documentation Level."

5. **Align Documentation Requirements:**
   If maintaining a Basic Documentation Level, ensure that all required documentation for the device's Level of Concern and safety classification is still provided to meet regulatory requirements.

By addressing these deficiencies, the submission will provide a clear and substantiated rationale for the Documentation Level, ensuring compliance with the audit instructions and regulatory expectations.

Section 3: Software Requirements Specifications (SRS)

Audit instructions

- The SRS documentation should describe the needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (e.g. risk management file, software design specification, system and software architecture design (SAD) chart, software testing).
- The SRS documents the requirements for the software which typically specifies the following: inputs and outputs, functions that the software will perform, hardware, performance, interfaces, user interaction, error definition and handling, intended operating environment, safety related requirements derived from a risk assessment (hazard analysis) and all ranges, limits, defaults, and specific values that the software will accept.

The audit of the Software Requirements Specifications (SRS) for the XXX 001 device has identified several critical deficiencies that need to be addressed to achieve full compliance with the audit instructions and regulatory requirements. Below are the detailed findings, supported by evidence from the provided documentation, along with actionable recommendations for remediation.

3.1 Inclusion of Safety-Related Requirements Derived from Risk Assessment

Deficiency

The SRS does not document safety-related requirements derived from a risk assessment (hazard analysis).

Evidence

> There is no mention or section dedicated to safety-related requirements in the SRS:
>
> The SRS document outlines specific functional requirements but lacks safety-related requirements derived from risk assessments.
>
> **Reference:** *XXX 001 Software Requirement Specifications Rev B - signed.pdf*

Why This is a Deficiency

According to the audit instructions, the SRS must include safety-related requirements derived from a risk assessment (hazard analysis). This ensures that all potential hazards have been considered, and appropriate requirements are in place to mitigate associated risks.

How to Fix

- Perform a comprehensive risk assessment focusing on software-related hazards, including those associated with algorithms.
- Update the SRS to include explicit safety requirements derived from the risk assessment. For each identified hazard, specify corresponding software requirements that mitigate the risk.
- Establish traceability between the risk management documentation and the SRS by referencing specific hazard IDs and risk control measures in the requirements.

3.2 Insufficient Traceability Between SRS and Risk Management Documentation

Deficiency

There is inadequate traceability between the SRS and other software documentation elements, particularly the risk management files. The SRS does not reference the risk assessment outcomes or link requirements to identified risks.

Evidence

> The SRS lacks references to the risk management documentation, and there is no traceability matrix linking requirements to hazards.
>
> **STATEMENT:**
>
> *"...with sufficient information to understand the traceability of the information with respect to the other software documentation elements (e.g., risk management file, software design specification...)."*

Why This is a Deficiency

Traceability ensures that all requirements are aligned with risk controls and that any changes in one document are reflected in the others. It is essential for demonstrating that safety considerations are fully integrated into the software development process.

How to Fix

- Create a traceability matrix that links each safety-related requirement in the SRS to the corresponding hazard and risk control measure in the risk management files.
- Reference specific sections, hazard IDs, or page numbers in the risk management documentation wherever safety requirements are specified in the SRS.
- Ensure that the SRS, risk management files, and other documentation are kept synchronized through configuration management practices.

3.3 Lack of Comprehensive Error Definition and Handling Requirements

Deficiency

The SRS does not provide detailed specifications for error definitions and handling mechanisms, especially for safety-critical functions.

Evidence

> Error handling is mentioned but not thoroughly detailed in the SRS.
>
> **STATEMENT:**
>
> *"The architecture for the device and each of its software items shall satisfy the requirement specification, which include error handling and safety requirements..."*
>
> **Reference:** *"XXX 001 Software Architecture and Detail Design.pdf"*, Section: 5 Architecture Overview, Pages: 6-7

Why This is a Deficiency

The audit instructions require the SRS to specify error definitions and handling procedures. Proper error handling is crucial to prevent and mitigate hazardous situations.

How to Fix

- Define all possible error conditions for each function in the software, including both expected and unexpected errors.
- Specify the handling procedures for each error, detailing how the software should respond to prevent hazardous outcomes.
- Include requirements for logging errors, notifying users, and safely recovering from error conditions.
- Ensure error handling requirements are aligned with the risk assessment and that they mitigate identified risks.

3.4 Incomplete Performance Requirements with Undefined Acceptance Criteria

Deficiency

Performance requirements in the SRS lack detailed acceptance criteria, ranges, limits, and what actions to take if performance thresholds are not met.

Evidence

> **STATEMENT:**
>
> *"Calculation of an inverse solution must be achieved in under 5 minutes."*
>
> **Reference:** *"XXX 001 Software Requirement Specifications Rev B - signed.pdf"*, Section: 3.6 Performance, Page: 16
>
> However, there are no specified actions if the calculation exceeds 5 minutes, nor are there defined acceptable ranges or tolerance levels.

Why This is a Deficiency

The audit instructions specify the need to include all ranges, limits, defaults, and specific values that the software will accept. Undefined acceptance criteria make it impossible to verify and validate performance requirements effectively.

How to Fix

> - Define acceptable performance ranges and what constitutes acceptable delays or deviations.
> - Specify actions the software should take if performance thresholds are exceeded, such as notifying the user or aborting the operation.
> - Include requirements for handling performance degradation gracefully to maintain usability and safety.

3.5 Missing User Interface Requirements for Error Notifications and Warnings

Deficiency

The SRS does not include requirements for informing users about errors, warnings, or abnormal conditions through the user interface.

Evidence

> User interaction requirements focus on functionality but do not address error messaging.

> There is no mention of how the software communicates issues to the user.

Why This is a Deficiency

Users need to be informed of errors to take appropriate action. Without clear error notifications, users may unknowingly rely on inaccurate data, leading to potential harm.

How to Fix

> - Include requirements specifying how errors and warnings are displayed to the user, including the content, format, and priority of messages.
> - Define user interface behaviors for different error conditions, ensuring that critical issues are prominently communicated.
> - Align these requirements with the error handling procedures to provide a consistent and effective user experience.

3.6 Insufficient Requirements for Software of Unknown Provenance (SOUP)

Deficiency

The SRS does not specify functional and performance requirements for SOUP components used in the software, which are essential for ensuring safety.

Evidence

> **STATEMENT:**
>
> *"Specification of the functional and performance requirements of each SOUP item that is necessary for the Safety Requirements."*
>
> **Reference:** *"XXX 001 Software Architecture and Detail Design.pdf"*, Section: 5 Architecture Overview, Pages: 6-7
>
> The SRS lacks detailed requirements addressing the SOUP components.

Why This is a Deficiency

SOUP components may introduce risks if not properly controlled. Requirements must be established to manage these risks and ensure that SOUP items perform as needed in safety-critical applications.

How to Fix

- Identify all SOUP components within the software.
- Define specific functional and performance requirements for each SOUP item, focusing on their role in safety-critical functions.
- Include requirements for monitoring, updates, and mitigation strategies should a SOUP component fail or be compromised.

3.7 Lack of Requirements for Protection Against Misuse

Deficiency

The SRS does not include requirements to prevent or mitigate hazards resulting from misuse or user errors.

Evidence

The need for misuse protection is mentioned in the architecture document but not reflected in the SRS.

STATEMENT:

"...protection from misuse shall be introduced: e.g., by-passing hardware interlocks, redundancy, diversity, functional programming."

Reference: *"XXX 001 Software Architecture and Detail Design.pdf"*, Section: 5 Architecture Overview, Pages: 7-8

Why This is a Deficiency

Users may unintentionally misuse the software, leading to hazardous situations. Requirements must specify how the software prevents or mitigates the effects of misuse.

How to Fix

> - Define requirements that limit user inputs to acceptable ranges, provide warnings when potentially unsafe actions are attempted, and prevent actions that could lead to hazardous states.
> - Include user training requirements or automated safeguards within the software.
> - Ensure that these misuse prevention measures are linked to the risk assessment and hazard analysis.

3.8 Incomplete Specifications of the Intended Operating Environment

Deficiency

The SRS lacks detailed specifications of the intended operating environment, including network requirements, hardware specifications, and environmental conditions that may affect software performance.

Evidence

> The SRS mentions general hardware requirements but does not specify environmental conditions or detailed network performance criteria.
>
> **STATEMENT:**
>
> *"The operating environment for XXX 001 requires Google Chrome and a specified operating system."*
>
> **Reference:** *"XXX 001 Software Description Rev B.pdf"*, Pages: 2-4

Why This is a Deficiency

Understanding the intended operating environment is crucial for software reliability and performance. Environmental factors can significantly impact software behavior, and requirements must address these factors.

How to Fix

> - Specify environmental conditions such as acceptable temperature ranges, humidity levels, and electrical requirements.

- Detail network performance requirements, including minimum bandwidth, latency tolerances, and reliability expectations.
- Include requirements for operating system versions, hardware specifications, and compatibility considerations.

Conclusion and Recommendations

The SRS for the XXX 001 device requires significant improvements to meet the audit instructions fully. The deficiencies identified pertain to critical areas such as safety, risk management, error handling, cybersecurity, performance, and data integrity.

Actionable Steps

1. **Enhance Safety Requirements:**
   Integrate safety-related requirements derived from comprehensive risk assessments. Establish clear traceability between the SRS and risk management documentation.
2. **Improve Error Handling Specifications:**
   Define detailed error conditions and handling procedures. Include requirements for user notifications and recovery actions.
3. **Refine Performance Criteria:**
   Specify precise performance acceptance criteria, including ranges and limits. Define actions for handling performance deviations.
4. **Specify User Interface for Error Notifications:**
   Include requirements for displaying errors and warnings to users.
5. **Address SOUP Components:**
   Define requirements for all SOUP items to ensure safety and performance.
6. **Incorporate Misuse Protection:**
   Include requirements to prevent and mitigate risks from user errors or misuse.
7. **Detail Operating Environment Requirements:**
   Specify environmental and network conditions that impact software operation.

8. **Update Documentation Accordingly:**
   Revise the SRS and related documents to address all identified deficiencies.
   Maintain synchronization between all documentation through version control and configuration management.

By addressing these deficiencies, the XXX 001 device's SRS will fulfill its role in guiding the development of a safe, effective, and compliant medical device software. Compliance with the audit instructions and regulatory requirements will be achieved, ensuring the device can be successfully brought to market.

References

- XXX 001 Software Requirement Specifications Rev B - signed.pdf
- XXX 001 Software Architecture and Detail Design.pdf
- XXX 001 Cybersecurity Test Report Rev A.pdf
- XXX 001 Software Description Rev B.pdf

Please ensure that all updates are made in accordance with the latest regulatory standards and guidelines. Consultation with a regulatory specialist or compliance officer is recommended to verify that all requirements are fully met.