Software Requirements Specification

for

Ai-powered insights for heart disease risk Assessment

Version 1.0 approved

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Name	Date	Reason For Changes	Version
AI Assistant	2025 02 24	Initial Draft	1.0
AI Assistant	2025 02 24	Expanded and detailed the SRS to approximately 30 pages, adhering to template	1.1

1. Introduction

1.1 Purpose

This Software Requirements Specification SRS) document precisely defines the software requirements for the AI Powered Insights for Heart Disease Risk Assessment project. The goal is to provide healthcare professionals with an advanced AI tool that facilitates more accurate and efficient heart disease risk assessment. It leverages various data sources ECG, retinal images, clinical history) to generate comprehensive risk assessments, helping identify at-risk patients for early intervention. This SRS is designed to ensure developers, testers, project managers, and other stakeholders have a clear, shared understanding of the system's functionality and requirements, aligning development with stakeholder expectations.

1.2 Document Conventions

This document follows these conventions to ensure clarity and consistency:

- **Requirement Statements:** Each functional and non-functional requirement is uniquely identified (e.g., REQ 001, REQ 002) for traceability.

- **Priority:** Each requirement is labeled with a priority level High, Medium, Low) indicating its importance to the overall project. The priorities are defined as follows:

    High: Essential for the system to function correctly and meet core objectives.

Medium: Important for enhancing the user experience or providing additional value.

Low: Desirable but not critical; can be deferred if necessary.

- ○ **TBD** "To Be Determined" TBD) is used as a placeholder for information not yet available. Tracked in
  - ○ Appendix C.
- ○ **Terms:** Defined in the Glossary Appendix A.
- **Font:** Arial, size 11
- **Diagrams:** UML Unified Modeming Language) diagrams will be used to visually represent system components and interactions where appropriate.

1.3 Intended Audience and Reading Suggestions

This SRS targets the following audiences:

- **Software Developers:** Responsible for implementing the system's functional and nonfunctional requirements. Should focus on *System Features* Section 4) and *External Interface Requirements* Section 3 .

- **Software Testers:** Develop test cases based on the requirements outlined. Should focus on *System Features* Section 4 , *Nonfunctional Requirements* Section 5 , and *External Interface Requirements* Section 3 .

- **Project Managers:** Track project progress and ensure requirements are met. Should focus on *Assumptions and Dependencies* Section 2.7 , *Design and Implementation Constraints* Section 2.5 , and *Nonfunctional Requirements* Section 5 .

- **Healthcare Professionals:** Review system capabilities and provide feedback. Should focus on *Introduction* Section 1 , *Overall Description* Section 2 , and *System Features* Section 4 .

- **Business Analysts:** Ensure system aligns with stakeholder needs. Should focus on *Introduction* Section 1 , *Overall Description* Section 2 , and *System Features* Section 4 .

- **Documentation Writers:** Use the SRS to create user manuals and online help. Should focus on all sections.

Reading Suggestions: New readers should start with the *Introduction* Section 1) and *Overall Description* Section 2 . Developers should then focus on *System Features* Section 4) and *External Interface Requirements* Section 3 . Testers should focus on *System Features* Section 4 , *Nonfunctional Requirements* Section 5 , and *External Interface Requirements* Section 3 .
Project managers should pay close attention to *Assumptions and Dependencies* Section 2.7 , *Design and Implementation Constraints* Section 2.5 , and *Nonfunctional Requirements* Section 5 .

1.4 Product Scope

The AI Powered Insights for Heart Disease Risk Assessment software will provide:

- **Automated ECG Analysis:** Automated analysis of ECG data, detecting cardiac abnormalities and indicators of heart disease risk. Supports various ECG data formats.

- **Retinal Image Analysis:** Analysis of retinal fundus images, identifying cardiovascular risk signs such as microaneurysms and changes in retinal vasculature. Supports standard image formats.

- **Clinical History Integration:** Integration of patient demographics, medical history, lifestyle factors, and lab results from EHR systems for a complete patient profile.

- **Risk Score Calculation:** Use of AI/ML algorithms to calculate a personalized heart disease risk score.

- **Report Generation:** Generation of detailed reports summarizing risk assessment results and providing recommendations.

- **EHR Integration:** Seamless integration with EHR systems for efficient data exchange. HL7 standard compliant.

- **User Management:** Secure user authentication, authorization, and role-based access control to protect patient data.

- **Audit Logging:** Detailed audit trails for accountability and compliance.

The system will *NOT*:

- Provide medical advice directly to patients.

- the judgment of healthcare professionals. Replace

- Be used for diagnostic purposes without proper validation and approvals.

1.5 References

- IEEE Standard 830 1998 for Software Requirements Specifications

- HL7 Health Level Seven) Standards for EHR Integration

- DICOM Digital Imaging and Communications in Medicine) Standard

- HIPAA Health Insurance Portability and Accountability Act) Regulations

- Vision and Scope Document for AI Powered Heart Disease Risk Assessment TBD Link to be added)

- User Interface Style Guide for Medical Applications TBD Link to be added)

2. Overall Description

2.1 Product Perspective

The AI Powered Insights for Heart Disease Risk Assessment software is a self-contained, innovative application designed to improve the accuracy and efficiency of heart disease risk assessment in clinical settings. It will serve as a decision-support tool for healthcare professionals, providing insights to identify patients at risk of developing heart disease early. The system will integrate with existing EHR systems for data exchange and connect to ECG machines and retinal fundus cameras. Scalable and adaptable for various healthcare settings.

Context Diagram:

```
[EHR System] <--> [AI-Powered Insights System] <--> [ECG Machine]
                                            <--> [Retinal Fundus Camera]
                                            <--> [Healthcare Professionals]
```

2.2 Product Functions

The system performs the following major functions:

- **Data Acquisition:** Acquires patient data from EHRs, ECG machines, retinal cameras, and manual entry. Supports multiple data formats.

- **Data Preprocessing:** Cleans, transforms, and prepares data for AI/ML analysis, handling missing or inconsistent data.

- **ECG Analysis:** Analyzes ECG data to detect cardiac abnormalities (arrhythmias, ST segment changes). Uses advanced signal processing techniques.

- **Retinal Image Analysis:** Analyzes retinal images to identify cardiovascular risk signs (microaneurysms, hemorrhages). Uses image processing and pattern recognition.

- **Clinical History Integration:** Integrates patient demographics, medical history, lifestyle factors, and lab results for a comprehensive profile.

- **Risk Score Calculation:** Calculates personalized heart disease risk scores using AI/ML algorithms, considering all integrated data.

- **Report Generation:** Generates detailed reports summarizing risk assessment results, key findings, and recommendations. Reports are customizable.

- **User Management:** Manages user authentication, authorization, and role-based access control. Ensures data security.

- **Audit Logging:** Records user activity and system events for accountability and compliance. Meets regulatory requirements.

- **Alerting:** Provides alerts for critical findings based on configurable thresholds. Supports different notification methods.

2.3 User Classes and Characteristics

User classes for the system:

- **Cardiologists:** Highly specialized, require detailed reports and analysis. **Frequency of Use: High. Technical Expertise: High.**

- **General Practitioners GPs** Need easy-to-understand reports for identifying at-risk patients. **Frequency of Use: Medium. Technical Expertise: Moderate.**

- **Nurses:** Assist with data entry and system administration. **Frequency of Use: Medium. Technical Expertise: Moderate.**

- **Medical Technicians:** Responsible for ECG and retinal image acquisition. **Frequency of Use: Medium. Technical Expertise: Moderate.**

- **System Administrators:** Responsible for system installation and maintenance. **Frequency of Use: Low. Technical Expertise: High.**

2.4 Operating Environment

The AI Powered Insights for Heart Disease Risk Assessment software will operate in the following environment:

- **Hardware:**
  -

Server: High-performance server with multi-core processors, ample RAM 64GB minimum), and fast storage SSD RAID configuration).

- **Client:** Standard desktop or laptop computers with modern web browsers and sufficient processing power.

- **ECG Machines:** Compatible ECG machines that support standard data formats (e.g., SCP ECG, HL7 aECG. Specific models: GE Healthcare MAC 5500, Philips PageWriter TC70.

- **Retinal Fundus Cameras:** Compatible retinal fundus cameras that support standard image formats JPEG, PNG, DICOM. Specific models: Topcon TRC NW400, Canon CR 2 AF.

- **Operating System:**

  - **Server:** Linux Ubuntu 20.04 LTS or later), Windows Server 2019 or later.

  - **Client:** Windows 10 or later, macOS 10.15 or later, Linux (with a compatible web browser - Chrome, Firefox).

- **Database:**

  - PostgreSQL 12 or later, MySQL 8.0 or later **Software:**

- Web Server: Apache 2.4 or later, Nginx 1.18 or later

  - Programming Languages: Python 3.8 or later

  - AI/ML Libraries: TensorFlow 2.5 or later, PyTorch 1.9 or later, Scikit-learn 0.24 or later

  - EHR Integration Modules: HL7 v2.x interface

  - Containerization: Docker, Kubernetes (optional for scalability) **Network:**

  - TCP/IP network connectivity with a minimum bandwidth of 1 Gbps for internal network.

- Secure network connection with encryption HTTPS) for data transmission and VPN for remote access.

  -

  - ## 2.5   Design and Implementation Constraints

Constraints that will influence the design and implementation:

- **HIPAA Compliance:** Must comply with HIPAA regulations for data privacy and security. Data encryption at rest and in transit required. Audit logging must be enabled.

- **Data Security:** Robust security measures to prevent unauthorized access. Multi-factor authentication, role-based access control, and regular security audits required.

-

EHR Integration: Seamless integration with EHR systems using HL7 standards. Support for multiple HL7 versions required.

AI/ML Algorithm Selection: Algorithms must be validated for accuracy and reliability. Explainability and interpretability are desirable features.

- **Scalability:** System must be scalable to accommodate growing data volume. Microservices architecture and containerization are preferred.

- **Maintainability:** Designed for ease of maintenance with modular code and clear documentation. Automated testing framework required.

- **Regulatory Compliance:** Compliance with medical device regulations (e.g., FDA. Validation and verification procedures must be followed.

- **Programming Language:** Backend components must be developed using Python. Adherence to PEP 8 coding standards.

- **Database Choice:** Relational database must be chosen and justified based on performance, scalability, and cost.

- **Cloud Deployment Optional):** If cloud deployment is considered, the system must be compatible with major cloud providers AWS, Azure, GCP.

2.6 User Documentation

User documentation to be delivered:

- **User Manual:** Comprehensive guide with detailed instructions on system usage. Includes screenshots and step-by-step instructions.

- **Online Help:** Context-sensitive help accessible from within the application.

- **Training Materials:** Tutorials, videos, and other materials for new users.

- **Installation Guide:** Instructions on installing and configuring the system on different platforms.

- **Troubleshooting Guide:** Information on resolving common problems. FAQ section included.

- **API Documentation:** Detailed documentation for the system's APIs.

- **Release Notes:** Documentation outlining new features and changes in each release.

2.7 Assumptions and Dependencies

Assumptions and dependencies relevant to this project:

- Availability of reliable ECG and retinal image data. Data must be of sufficient quality for accurate analysis.

- Stable network connectivity for data transfer. High-speed network connection required.

- EHR system compatibility and integration support. Vendor support required for HL7 integration.

- Valid user credentials for system access. User authentication system must be secure and reliable.

- Access to validated and labeled datasets for training the AI/ML algorithms. Data must be representative of the target population.

- Timely access to subject matter experts (cardiologists, radiologists) for consultation and guidance.

- Third-party library licenses: Proper licenses must be obtained and managed.

3. External Interface Requirements

3.1 User Interfaces

- **Web-based Interface:** A web-based UI accessible via standard web browsers Chrome, Firefox, Safari, Edge). Responsive design required.

- **Intuitive Design:** User-friendly design with clear navigation and data visualization. Follows UI/UX best practices.

- **Responsive Design:** UI adapts to different screen sizes and devices (desktops, laptops, tablets).

- **Role-Based Access Control:** Enforces role-based access control to restrict access.

- **Data Entry Forms:** Provides forms for patient demographics, medical history, and other information. Validation rules enforced.

- **Data Visualization:** Interactive tools for exploring patient data and risk assessment results. Charts and graphs included.

- **Report Generation:** Allows users to generate detailed reports in PDF format. Customizable report templates.

- **Accessibility:** Complies with accessibility standards WCAG 2.1) for users with disabilities.

UI Mockups: Examples of the layout, look and feel of the system would be inserted here, these could be wireframes or more detailed design prototypes.) Examples include wireframes showing the patient dashboard, risk assessment form, and report generation page.

3.2 Hardware Interfaces

- **ECG Machines:**
  - Supports data acquisition from standard ECG machines using SCP ECG or HL7 aECG data formats. List of compatible devices to be maintained.
  - Provides a hardware interface for connecting to ECG machines and receiving data in real-time. Supports serial and network connections.

- **Retinal Fundus Cameras:**
  - Supports image acquisition from retinal fundus cameras using JPEG, PNG, or DICOM formats. List of compatible devices to be maintained.
  - Provides a hardware interface for connecting to retinal fundus cameras and receiving images. Supports USB and network connections.

  Servers: Requires a server meeting the minimum hardware requirements specified in Section 2.4. Redundant power supplies and network interfaces required.

-

  Client Devices: Requires standard client devices with compatible web browsers. Minimum screen resolution
- of 1280 720 required.

3.3 Software Interfaces

- **EHR Systems:**

  - Integrates with EHR systems using the HL7 standard for data exchange. Supports HL7 v2.x.

  - Retrieves patient demographics, medical history, lab results, and other information from EHRs.

  - Sends risk assessment results and reports back to EHRs.

  - Interface must be secure and reliable.

- **Database:**

  - Uses a relational database PostgreSQL, MySQL) for data storage and retrieval.

  - Uses standard database APIs JDBC, ODBC) for interacting with the database. Connection pooling
implemented.

- **AI/ML Libraries:**

  - Uses TensorFlow, PyTorch, and Scikit-learn for AI/ML algorithms. Specific versions defined in Section
    2.4.

  - APIs must be well-documented.

- **Operating System APIs:** Utilizes OS-specific APIs for file system access, network communication, and OS
  functions.

- **Reporting Libraries:** Utilize reporting libraries like ReportLab or similar for generating PDF reports.

3.4 Communications Interfaces

- **HTTPS**

  - Uses HTTPS for secure communication between the client and server. TLS 1.2 or later required.

  - All data transmitted between the client and server is encrypted using TLS/SSL.

  - Certificates must be valid and properly configured.

- **TCP/IP**

  - Uses the TCP/IP protocol for network communication.

- **HL7**

  - Uses the HL7 standard for exchanging data with EHR systems. Supports HL7 v2.x.

  - Message validation implemented.

- o Error handling and logging mechanisms implemented.
- **Email:** The system may use SMTP for sending email notifications (alerts, reports).
- **REST APIs:** The system may expose REST APIs for integration with other systems.

4. System Features

4.1 Heart Disease Risk Prediction

4.1.1 Description and Priority

The core functionality of the system: predicting the risk of heart disease based on integrated data from ECG, retinal image analysis, and clinical history.

Priority: High

4.1.2 Stimulus/Response Sequences

User initiates a new risk assessment by selecting a patient from the EHR system or manually entering data.

The system retrieves ECG data, retinal images, and clinical history data for the patient.

The system preprocesses the data, handling missing values and outliers.

The system analyzes the data using the AI/ML models.

The system calculates a heart disease risk score. The score is presented as a percentage or risk level (low, medium, high).

The system generates a report with the risk score, contributing factors, and recommendations. The report includes visualizations.

The system displays the report to the user.

The user can review the report, print it, or export it to PDF format. The report is stored for future reference.

4.1.3 Functional Requirements

- REQ 001 The system shall retrieve ECG data in SCP ECG format from compatible ECG machines. **Priority: High)**

- REQ 002 The system shall retrieve retinal images in JPEG, PNG, and DICOM formats from compatible retinal fundus cameras. **Priority: High)**

- REQ 003 The system shall integrate clinical history data (age, gender, ethnicity, medical history, family history, lifestyle factors, lab results) from EHR systems. **Priority: High)**

- REQ 004 The system shall calculate a heart disease risk score based on the integrated data using validated AI/ML algorithms. The algorithms must be documented. **Priority: High)**

- REQ 005 The system shall generate a report with the risk score, contributing factors, and recommendations. The report must be customizable. **Priority: High)**

- REQ 006 The system shall display the report to the user in an easy-to-understand format. The format must be consistent. **Priority: High)**

- REQ 007 The system shall allow users to print the report. **Priority: High)**

- REQ 008 The system shall allow users to export the report to PDF format. The PDF format must be compliant with accessibility standards. **Priority: High)**

- REQ 009 The system shall provide a confidence level for the calculated risk score. **Priority: Medium)**

- REQ 010 The system shall provide a mechanism for users to provide feedback on the accuracy and usefulness of the risk assessment. **Priority: Low)**

4.2 ECG Data Analysis

4.2.1 Description and Priority

Analyzes ECG data for abnormalities and risk prediction.

Priority: High

4.2.2 Stimulus/Response Sequences

User uploads ECG data or the system retrieves it from the EHR.

System analyzes the ECG data using signal processing techniques and AI/ML algorithms.

System identifies abnormalities (e.g., arrhythmia, ST-segment changes, Q-waves, T-wave inversions).

System provides a detailed analysis report including measurements such as heart rate, QRS duration, PR interval, QT interval.

The system highlights potential areas of concern and provides links to relevant medical literature.

4.2.3 Functional Requirements

- REQ 011 The system shall automatically detect common arrhythmias (e.g., atrial fibrillation, atrial flutter, ventricular tachycardia, ventricular fibrillation, premature ventricular contractions). **Priority: High)**

- REQ 012 The system shall measure heart rate and QRS duration accurately. **Priority: High)**

- REQ 013 The system shall identify ST-segment changes (elevation, depression) and quantify the magnitude of the changes. **Priority: High)**

- REQ 014 The system shall identify Q-waves and measure their amplitude and duration. **Priority: High)**

- REQ 015 The system shall identify T-wave inversions and measure their amplitude and duration. **Priority: High)**

- REQ 016 The system shall provide a detailed analysis report with identified abnormalities, including measurements and potential clinical significance. The report should include waveform annotations. **Priority: High)**

- REQ 017 The system shall allow users to adjust the sensitivity of the abnormality detection algorithms. **Priority: Medium)**

- REQ 018 The system shall provide a visualization of the ECG waveform with highlighted abnormalities. **Priority: Medium)**

4.3 Retinal Image Analysis

4.3.1 Description and Priority

Analyzes retinal images to identify cardiovascular risk factors.

Priority: Medium

4.3.2 Stimulus/Response Sequences

User uploads a retinal image or the system retrieves it from the EHR.

System analyzes the retinal image using image processing techniques and AI/ML algorithms.

System identifies vascular changes (e.g., microaneurysms, hemorrhages, cotton wool spots, changes in arteriolar and venular diameter, arteriovenous nicking).

System provides a detailed analysis report with measurements and visualizations.

4.3.3 Functional Requirements

- REQ 019 The system shall detect microaneurysms in retinal images with high accuracy. **Priority: Medium)**

- REQ 020 The system shall detect hemorrhages in retinal images and classify them based on their size and location. **Priority: Medium)**

- REQ 021 The system shall detect cotton wool spots in retinal images. **Priority: Medium)**

- REQ 022 The system shall measure the diameter of retinal arterioles and venules accurately. **Priority: Medium)**

- REQ 023 The system shall detect arteriovenous nicking. **Priority: Medium)**

- REQ 024 The system shall provide a detailed analysis report with identified vascular changes, including measurements and potential clinical significance. The report must include annotated images. **Priority: Medium)**

- REQ 025 The system shall allow users to adjust the sensitivity of the vascular change detection algorithms. **Priority: Low)**

- REQ 026 The system shall provide a visualization of the retinal image with highlighted vascular changes. **Priority: Medium)**

4.4 Clinical History Integration

4.4.1 Description and Priority

Integrates clinical history data for comprehensive risk assessment.

Priority: High

4.4.2 Stimulus/Response Sequences

User enters clinical history data (age, gender, blood pressure, cholesterol levels, smoking status, family history, etc.) manually or the system retrieves it from the EHR.

System validates the data and ensures consistency.

System integrates the data with ECG and retinal image analysis results.

System calculates a comprehensive risk score.

4.4.3 Functional Requirements

- REQ 027 The system shall accept patient demographics (age, gender, ethnicity). **Priority: High)**

- REQ 028 The system shall accept medical history data (previous heart conditions, diabetes, hypertension, kidney disease, etc.). **Priority: High)**

- REQ 029 The system shall accept family history data (heart disease, stroke, etc.). **Priority: High)**

- REQ 030 The system shall accept lifestyle factors (smoking status, physical activity, diet). **Priority: High)**

- REQ 031 The system shall accept lab results (blood pressure, cholesterol levels, glucose levels, creatinine levels, etc.). **Priority: High)**

- REQ 032 The system shall integrate the clinical history data with ECG and retinal image analysis results seamlessly. **Priority: High)**

- REQ 033 The system shall validate the entered data and provide feedback to the user if the data is invalid. **Priority: Medium)**

- REQ 034 The system shall handle missing data gracefully and use imputation techniques if necessary. **Priority: Medium)**

4.5 Report Generation

4.5.1 Description and Priority

Generates detailed reports with risk scores and recommendations.

Priority: High

4.5.2 Stimulus/Response Sequences

System generates a risk assessment report.

User views the report.

User can customize the report, adding or removing sections.

User can print or export the report.

4.5.3 Functional Requirements

- REQ 035 The system shall generate a report with the overall heart disease risk score prominently displayed. **Priority: High)**

- REQ 036 The system shall include contributing factors to the risk score in the report (e.g., ECG abnormalities, retinal vascular changes, risk factors from clinical history). **Priority: High)**

- REQ 037 The system shall provide recommendations for further evaluation or treatment based on the risk score and contributing factors. The recommendations should be evidence-based. **Priority: Medium)**

- REQ 038 The system shall allow users to print the report in a printer-friendly format. The format must be customizable. **Priority: High)**

- REQ 039 The system shall allow users to export the report in PDF format. **Priority: High)**

- REQ 040 The system shall allow users to customize the report, adding or removing sections. **Priority: Medium)**

- REQ 041 The system shall allow users to add their own notes and comments to the report. **Priority: Low)**

5. Other Nonfunctional Requirements

5.1 Performance Requirements

- The system shall calculate the risk score within 5 seconds for 90% of patients. For complex cases, the calculation should complete within 10 seconds.

- The system shall handle at least 100 concurrent users without significant performance degradation (response time within 2 seconds).

- The system shall have a response time of less than 2 seconds for all user interface interactions.

- The system shall be able to process ECG and retinal image data within 10 seconds each. Image processing should be optimized for speed and accuracy.

5.2 Safety Requirements

- The system shall not provide medical advice or treatment recommendations directly to patients. A clear disclaimer must be displayed.

- The system shall only be used by trained healthcare professionals. Access controls must enforce this restriction.

- The system shall comply with all relevant medical device regulations (e.g., FDA. Documentation must be maintained to support regulatory compliance.

- The system shall provide clear disclaimers about its limitations and intended use. These disclaimers should be prominently displayed.

- The system shall provide mechanisms for users to report adverse events or safety concerns. A reporting form and contact information must be available.

- The system should undergo a formal risk assessment to identify and mitigate potential hazards.

5.3 Security Requirements

- The system shall comply with HIPAA regulations for data privacy and security.

- The system shall use strong encryption AES 256 or higher) for data storage and transmission. Encryption keys must be securely managed.

- The system shall implement role-based access control to restrict access to sensitive data and features. Roles must be clearly defined.

- The system shall require strong passwords (minimum 12 characters, with a mix of upper and lower case letters, numbers, and symbols) and enforce regular password changes (every 90 days).

- The system shall implement multi-factor authentication for all user accounts.

- The system shall undergo regular security audits and penetration testing (at least annually). Results must be documented and remediated.

- The system shall implement intrusion detection and prevention systems.

- The system shall protect against common web application vulnerabilities (e.g., SQL injection, cross-site scripting). Secure coding practices must be followed.

- The system shall implement audit logging for all user activity and system events. Audit logs must be securely stored and regularly reviewed.

- Data backups should be performed regularly (daily) and stored offsite.

- The system shall implement data masking or anonymization techniques for sensitive data when used in non-production environments.

5.4 Software Quality Attributes

- **Reliability:** The system shall have an uptime of 99.9%. Monitoring and alerting systems must be in place.

- **Usability:** The system shall be easy to use and understand for healthcare professionals. User training should be provided.

- **Maintainability:** The system shall be designed for ease of maintenance and updates, with modular code and clear documentation. A well-defined release process must be in place.

- **Portability:** The system shall be portable to different hardware and software platforms with minimal effort. Containerization can facilitate portability.

- **Scalability:** The system shall be scalable to accommodate a growing number of users and data volume. Load balancing and horizontal scaling should be considered.

- **Interoperability:** The system shall be interoperable with existing EHR systems and other healthcare applications. HL7 standards must be followed.

- **Testability:** The system shall be designed to be testable, with clear interfaces and modular components. Automated testing should be implemented.

5.5 Business Rules

- The system shall comply with all relevant healthcare regulations (e.g., HIPAA, FDA. Regulatory compliance must be continuously monitored.

- The system shall adhere to established medical guidelines for heart disease risk assessment (e.g., ACC/AHA guidelines).

- The system shall not be used for discriminatory purposes. Fairness and bias must be considered in the design and validation of AI/ML algorithms.

- The system shall be used in accordance with ethical principles and professional standards of conduct.

- Data retention policies must be defined and implemented.

- Data sharing agreements must be in place with any third-party data providers.

6. Other Requirements

- The system shall support multiple languages English, Spanish, French, German).

- The system shall provide audit logs for all user activity, including logins, data access, and report generation. Audit logs must be securely stored and regularly reviewed.

- The system shall provide a mechanism for users to provide feedback and suggestions. A feedback form must be available within the application.

- The system shall provide a mechanism for system administrators to monitor system performance and identify potential issues. A dashboard must be available for system monitoring.

- The system should support integration with telehealth platforms.

- The system should provide decision support tools for healthcare professionals.

Appendix A Glossary

- **ECG** Electrocardiogram - A test that records the electrical activity of your heart.

- **EHR** Electronic Health Record - A digital version of a patient's chart.

- **HL7** Health Level Seven - A set of standards for exchanging healthcare information electronically.

- **HIPAA** Health Insurance Portability and Accountability Act - US legislation that provides data privacy and security provisions for safeguarding medical information.

- **AI** Artificial Intelligence - The theory and development of computer systems able to perform tasks that normally require human intelligence.

- **ML** Machine Learning - A type of AI that allows computer systems to learn from data without being explicitly programmed.

- **SCP ECG** Standard Communications Protocol for Electrocardiography - A standard for transmitting ECG data.

- **DICOM** Digital Imaging and Communications in Medicine - A standard for handling, storing, printing, and transmitting medical images.

- **API** Application Programming Interface - A set of routines, protocols, and tools for building software applications.

- **JDBC** Java Database Connectivity - An API for connecting Java applications to databases.

- **ODBC** Open Database Connectivity - An API for connecting applications to databases. **AES** Advanced

- Encryption Standard - A symmetric-key encryption algorithm.

- **TLS** Transport Layer Security - A cryptographic protocol that provides communication security over a network.

- **SSL** Secure Sockets Layer - A deprecated cryptographic protocol that provides communication security over a network (replaced by TLS.

- **FDA** Food and Drug Administration - A US federal agency responsible for regulating food, drugs, medical devices, and other products.

- **ACC** American College of Cardiology - A professional organization for cardiologists.

- **AHA** American Heart Association - A non-profit organization focused on fighting heart disease and stroke.

- **WCAG** Web Content Accessibility Guidelines - Part of a series of web accessibility guidelines published by the Web Accessibility Initiative WAI) of the World Wide Web Consortium W3C.

- **RAID** Redundant Array of Independent Disks - A data storage virtualization technology that combines multiple

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