**Diagnosis of Cardiovascular Diseases in patients using CNN**

**(As a part of ACTS Management System)**

**Functional Requirement Specification Document**

**23-07-2021**

**Functional Requirements Document**

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**Abbreviations**

|  |  |
| --- | --- |
| CNN | Convolutional Neural Network |
| CVD | Cardiovascular Disease |
| FRS | Functional Requirement Specifications |
| HIS | Hospital Information System |
| EHR | Electronic Health Record |
| HIPAA | Health Insurance Portability and Accountability Act |
| GDPR | General Data Protection Regulation |
| UI | User Interface |
| API | Application Programming Interface |
| DICOM | Digital Imaging and Communication in Medicine |
| ML | Machine Learning |
| ROI | Region of Interest |
| QA | Quality Assurance |
| SDLC | Software Development Life Cycle |
| FDA | Food and Drug Administration |
| ECG | Electrocardiogram |

**CONTENTS**

[1](#_gjdgxs) **INTRODUCTION** 1

[1.1 Purpose 1](#_30j0zll)

[1.2 Background 1](#_1fob9te)

[1.3 Scope 2](#_3znysh7)

[1.4 References 2](#_2et92p0)

[1.5 Document Overview 2](#_qsh70q)

**2 UAN Allotment System 3**

**3 FUNCTIONAL REQUIREMENTS 3**

3.1 Registration of Departments 4

3.1.1 Registration of Departments 4

3.1.2 Description 4

3.1.3 Functionalities identified 5

3.1.4 Field validations and business rules 5

3.2 API for Generation of UAN 5

3.2.1 UAN Allotment for a single worker 6

3.2.1.1 Description 7

3.2.1.2 Cross Functional Diagram 7

3.2.1.3 Functionalities identified 5

3.2.1.4 Pre-requisites, Assumptions and Dependencies 7

3.2.1.5 Field validations and business rules 7

3.2.2 UAN Allotment for bulk 10

3.2.2.1 Description 10

3.2.2.2 Cross Functional Diagram 10

3.2.1.3 Functionalities identified 5

3.2.2.4 Pre-requisites, Assumptions and Dependencies 11

3.2.2.5 Field validations and business rules 12

[3.3 Updation in UAN Data 13](#_2u6wntf)

3.3.1 Description 13

3.3.2 Cross Functional Diagram 14

3.3.3 Functionalities identified 5

3.3.4 Pre-requisites, Assumptions and Dependencies 14

3.3.5 Field validations and business rules 15

[3.4 Family Member Details 17](#_37m2jsg)

3.4.1 Description 17

3.4.2 Cross Functional Diagram 17

3.4.3 Functionalities identified 5

3.4.4 Pre-requisites, Assumptions and Dependencies 18

3.4.5 Field validations and business rules 18

3.5 Other API Integration with different departments 20

3.5.1 Description 20

3.5.2 Cross Functional Diagram 20

3.5.3 Functionalities identified 5

3.5.4 Pre-requisites, Assumptions and Dependencies 21

3.5.5 Field validations and business rules 21

3.6 Implementation of Aadhaar Data Vault 21

3.7 Download UAN 21

3.8 Print UAN 21

3.9 Report Generation 21

3.10 Data Migration 21

**4.External Interfaces 22**

**5.Audit and Provenance 22**

**6**.**Current UAN Schema (Shared by the Departments) 22**

**7.Data Migration of UANs from EPFO to UAN Engine 22**

# INTRODUCTION

## This document details the Functional Requirement Specification (FRS) for a system designed for the diagnosis of cardiovascular disease in patients using Convolutional Neural Networks (CNN). This advanced diagnostic tool leverages deep learning algorithms to analyse medical imaging data, providing accurate and timely diagnoses to assist healthcare professionals in clinical decision-making.

## 1.1 Purpose

## This document provides a comprehensive description of requirements for the "Diagnosis of Cardiovascular Disease in Patients Using CNN" project. It aims to capture and communicate specific functional, technical, and operational needs that are crucial for the system's development and ultimate success. It serves multiple purposes, including outlining the project's overall purpose, defining its intended functionalities, specifying expected outcomes, and detailing the necessary steps to achieve these goals. Additionally, the document addresses various constraints under which the system must operate, such as technical limitations, regulatory compliance (e.g., HIPAA, GDPR), and operational requirements like usability and scalability. It also outlines interfaces with external applications, including user interfaces (UI) for medical professionals to interact with the system, data interfaces for seamless integration with hospital information systems (HIS) and electronic health records (EHR), and specifications for APIs enabling connectivity with other diagnostic tools. The document is intended for stakeholders including healthcare providers, hospital administrators, the development team, and regulatory bodies to ensure alignment with clinical needs, operational objectives, legal standards, and technical specifications throughout the Software Development Life Cycle (SDLC).

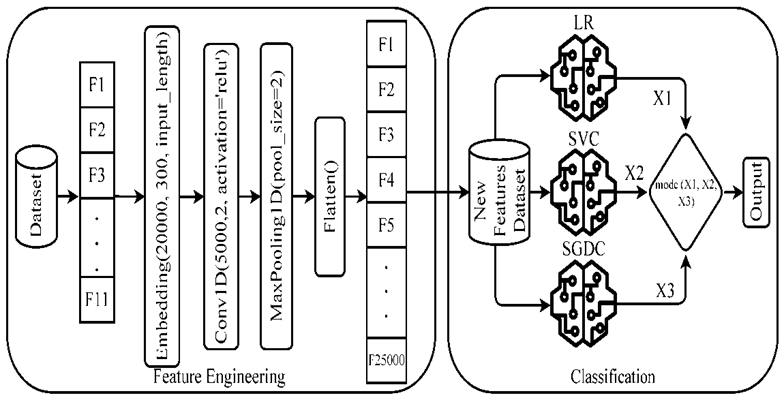
## 1.2 Background

## The "Diagnosis of Cardiovascular Disease in Patients Using CNN" project is driven by several key factors. Firstly, cardiovascular diseases (CVDs) pose a significant global health challenge, necessitating early detection and intervention to improve patient outcomes and reduce mortality rates. Traditional diagnostic methods can be subjective and error-prone, highlighting the urgent need for more accurate and objective diagnostic tools. Furthermore, advancements in artificial intelligence (AI) and machine learning, particularly Convolutional Neural Networks (CNNs), have revolutionized medical imaging by offering exceptional capabilities in analysing complex conditions like CVDs. These AI-driven systems can process large volumes of medical data swiftly, providing faster diagnoses and scalable solutions that can be seamlessly integrated into existing healthcare systems. The project aims to enhance diagnostic capabilities by leveraging CNNs to analyse medical images accurately, ensuring healthcare providers can make informed clinical decisions. It prioritizes integration with hospital information systems (HIS) and electronic health records (EHR), ensuring data accessibility and adherence to healthcare regulations such as HIPAA and GDPR for patient privacy and security. Designed for scalability and flexibility, the system is poised to evolve with future technological advancements, maintaining its relevance in improving cardiovascular healthcare delivery.

## 1.3 Scope

The project employs Convolutional Neural Networks (CNNs) for automated cardiovascular disease diagnosis through medical image analysis. It produces detailed diagnostic reports featuring detected conditions, probability assessments, and visual indicators via an intuitive interface. Integration with hospital information systems (HIS) and electronic health records (EHR) ensures data privacy and compliance with healthcare regulations such as HIPAA and GDPR. This approach enhances diagnostic precision, accelerates processing times, optimizes healthcare resources, maintains result consistency across users, and supports accessibility in various healthcare settings and remote environments. The system architecture encompasses layers for data input, pre-processing, CNN-based analysis, result interpretation, user interaction, seamless integration with other systems, and robust security and regulatory adherence.

***Figure 1: System Architecture***



## 1.4 References

## The development of this system references the following documents and standards:

## IEEE Standard for Software Requirements Specifications (IEEE 830-1998).

## ISO/IEC/IEEE 29148:2011 - Systems and software engineering — Life cycle processes — Requirements engineering.

## HIPAA Privacy Rule for the protection of patient data.

## Relevant clinical guidelines for the diagnosis and management of cardiovascular diseases.

## 1.5 Document Overview

# Project Goals

# Automated Diagnosis: Use CNNs to analyse medical images for detecting cardiovascular diseases.

# Diagnostic Reports: Generate detailed reports with findings and visual markers.

# User Interface: Offer a user-friendly interface for data upload and result viewing.

# System Integration: Integrate with hospital information systems (HIS) and electronic health records (EHR).

# Key Elements

# Constraints: Compliance with healthcare regulations (HIPAA, GDPR).

# Assumptions: Availability of high-quality images and computational resources.

# Dependencies: Integration with existing HIS and EHR systems.

# Requirements: High diagnostic accuracy, data security, and intuitive user interface.

# FUNCTIONAL REQUIREMENTS

* Data Collection and Pre-processing
* CNN Model Development
* Prediction Algorithms
* User Interface (UI)
* Reporting and Visualization
* System Integration
* Performance Optimization
* Security and Compliance
* Maintenance and Support
* Training and Documentation

### 2.1 Functionality 1

### 2.1.1 Description

This functionality is meant for collecting and pre-processing patient data, which includes various types of medical data such as ECG, MRI, and echocardiogram images. The goal is to ensure that the data is clean, properly formatted, and ready for input into the CNN model.

### 2.1.2 Functional Requirements Identified

| **SN** | **Functionality** | **Process** | **Remarks/Additional Info** |
| --- | --- | --- | --- |
| FR 1.1 | Data Acquisition | Collect data from various medical devices and sources. | Includes ECG, MRI, and echocardiogram data. |
| FR 1.2 | Data Cleaning | Remove noise and handle missing values. | Ensure data quality for accurate model training. |
| FR 1.3 | Data Normalization | Normalize data for uniform scale. | Important for consistent input into the CNN. |
| FR 1.4 | Data Augmentation | Augment images to increase dataset size. | Techniques like rotation, flipping, etc. |
| FR 1.5 | Data Storage | Store pre-processed data securely. | Use SQL/NoSQL databases or cloud storage. |

### 2.1.3 Fields Validations

| **SN** | **Field Name** | **Field Description** | **Validations** | **Remarks** |
| --- | --- | --- | --- | --- |
| 1 | Patient ID | Unique identifier for each patient. | Must be unique and not null. | Mandatory |
| 2 | Patient Name | Name of the patient. | Cannot be empty; should be a string. | Mandatory |
| 3 | Date of Birth | Patient's date of birth. | Must be a valid date. | Mandatory |
| 4 | ECG Data | Raw ECG data. | Must be in correct format (e.g., CSV). | Mandatory |
| 5 | MRI Images | MRI scan images. | Must be in correct format (e.g., JPEG). | Mandatory |
| 6 | Echocardiogram | Echocardiogram images. | Must be in correct format (e.g., PNG). | Mandatory |
| 7 | Data Collection Date | Date when data was collected. | Must be a valid date. | Mandatory |

This table lists the various fields that will be there in the form for the requirement

### 3.2.1.4 Pre-requisites, Assumptions and Dependencies

### The system for diagnosing cardiovascular disease using CNNs has specific prerequisites, assumptions, and dependencies crucial for its functionality. Prerequisites include access to comprehensive medical imaging data, such as X-rays and MRIs, alongside patient demographic and clinical information necessary for accurate analysis. It assumes reliable internet connectivity for data transmission, ensuring seamless operation, particularly in environments requiring remote access or cloud-based processing.

### Assumptions encompass the expectation of high-quality medical imaging data suitable for CNN analysis and the availability of the system when healthcare professionals need to access it for patient diagnosis. Additionally, it assumes users possess sufficient proficiency to interact with the system effectively, understanding its outputs and diagnostic recommendations.

### Dependencies involve the integration with Hospital Information Systems (HIS) and Electronic Health Records (EHR) for seamless data exchange and synchronization. This integration is essential for maintaining up-to-date patient records and supporting clinical decision-making. The system also relies on APIs to incorporate additional data inputs or specialized diagnostic functionalities beyond standard medical imaging, enhancing its diagnostic capabilities.

### Furthermore, compliance with healthcare regulations such as HIPAA and GDPR is critical to safeguard patient data privacy and security. Adherence to these regulatory frameworks influences the system's design, operational protocols, and data handling practices, ensuring confidentiality and trust among healthcare providers and patients alike.

### (Example user data should be uploaded or PRN should be generated)

# External Interfaces

To elaborate on external interfaces for the system designed to diagnose cardiovascular disease using CNNs:

The system may include external interfaces for seamless integration with other healthcare portals or systems. This could involve functionalities such as:

1. Integration with Hospital Information Systems (HIS):

- Facilitating the exchange of patient data, medical histories, and diagnostic results between the CNN-based diagnostic system and existing HIS platforms used within healthcare facilities.

2. Electronic Health Records (EHR) Integration:

- Ensuring compatibility with EHR systems to retrieve patient information and update medical records based on diagnostic outcomes generated by the CNN system.

3. API Integration with Diagnostic Tools:

- Implementing Application Programming Interfaces (APIs) to connect with external diagnostic tools or medical devices for additional data input or specialized analysis beyond standard medical imaging.

4. Redirection to Referral Systems:

- Providing functionality to redirect healthcare providers to specialized referral systems or telemedicine platforms based on diagnostic findings, facilitating further consultation or treatment planning.

These external interfaces are crucial for enhancing the system's functionality, supporting interoperability across different healthcare platforms, and ensuring comprehensive patient care through seamless data exchange and collaborative healthcare practices.