Software Requirements Specification for Software Engineering: AI for Chest X-Ray Read

Team 17, Team RAdiAIdance
Allison Cook
Ibrahim Issa
Mohaansh Pranjal
Nathaniel Hu
Tushar Aggarwal

November 3, 2023

Contents

Revision History

Date	Developer(s)	Notes
October 1st, 2023	Allison Cook, Ibrahim, Mohaansh, Nathaniel, Tushar	Initial Draft of SRS document
October 6th, 2023	Allison, Ibrahim, Mohaansh, Nathaniel, Tushar	Edits to SRS document (NFRs)
October 6th, 2023	Ibrahim	added functional requirements
October 6th, 2023	Mohaansh	improved Functional Requirements
October 20th, 2023	Mohaansh, Tushar	Further improvements

This document describes the requirements for the AI for Chest X-Ray Read. The template for the Software Requirements Specification (SRS) is a subset of the Volere template (**?**). Sections 1-5 (with all their subsections) in the original template were combined into the new **Project Drivers** section.

Sections 6-9 (with all their subsections) in the original template were combined into the new **Functional requirements** section, with a new **Traceability Matrix** subsubsection and a new **Formal Specification for the ML Algorithm** subsection added in. Sections 10-17 (with all their subsections) in the original template were combined into the new **Non-functional requirements** section. Sections 18-26 (with all their subsections) in the original template were combined into the new **Project Issues** section. A new section, **Appendix**, was added.

1 Project Drivers

This section covers the various drivers of this project, including the purpose of the project, the various stakeholders, the various mandated constraints, naming conventions and terminology, and relevant facts and assumptions.

1.1 Purpose of the Project

This project aims to provide a system that will reduce the amount of time radiologists and medical professionals will need to spend reviewing chest X-rays of patients. Users of the completed solution proposed in this project will be able to upload a chest x-ray and receive a generated diagnostic radiology report outlining any abnormalities in the given image.

1.1.1 User Business

The user businesses are medical institutions (e.g. hospitals) and other medical imaging businesses (e.g. diagnostic centres). These businesses aim to review and analyze patient chest X-rays, perform diagnostics, report their findings and present the results to their patients and/or relevant third parties as soon as possible.

1.1.2 Goals of the Project

The primary goal of the project is to provide accurate detection of abnormality given an x-ray image and generate a diagnostic radiology report outlining any abnormalities. The project's other goals are to provide secure and remote access to the system while having an intuitive user interface. A further stretch goal of the project is to be able to generate structured or free-formed radiology diagnostic reports using natural language processing (NLP).

1.2 Stakeholders

This subsection outlines the various stakeholders of this project's proposed solution and describes each in detail with regard to their relevance to this project's success. These include the clients, customers, other stakeholders and hands-on users. Their personas, assigned priorities, user participation and the maintenance users and service technicians are also described in detail.

1.2.1 Client

The following are the clients of the project's proposed solution:

- **Doctors**: want the tedious work of analyzing chest x-rays, performing diagnostics and writing radiology reports to be semi-/fully-automated
- **Patients**: wants chest x-ray results faster with the same accuracy
- **Diagnostics Teams**: wants to maximize the number of chest X-rays performed and processed for patients

These are the people expected to be the primary users of the project's proposed solution. They are expected to use this proposed solution primarily in their daily work as medical professionals, or benefit from it (i.e. the patients).

1.2.2 Customer

The customers of the project's proposed solution are described as follows:

- **Medical Institutions**: want to process chest x-rays faster to get results for patients in time-critical situations (e.g. detect time-sensitive diseases)

- **Diagnostic Centres**: want to process chest x-rays faster to maximize the number of chest x-rays processed for patients, but not necessarily as time-sensitive (e.g. routine checkups)

1.2.3 Other Stakeholders

The following are the other stakeholders of the project's proposed solution:

- Medical institutions' IT departments
- Developers

These are the other stakeholders who do not directly use the project's proposed solution but are involved in supporting it in carrying out its intended functions successfully.

1.2.4 Hands-On Users of the Project

The following are the hands-on users of the project's proposed solution:

- **Medical professionals** using this software to perform an initial analysis of chest x-rays and diagnose diseases and other health conditions

As was mentioned earlier, these users are expected to use the project's proposed solution in their daily work lives to support their work.

1.2.5 Personas

The following are descriptions outlining the personas modelling the respective stakeholders and users of the project's proposed solution:

- **Doctors/Medical Professionals**
  - Stressed, under pressure to analyze chest x-rays, perform diagnoses and present results to patients and all other relevant stakeholders as soon as possible.
  - Want the information presented to them such that they can glance over it quickly and grab the relevant information to present
  - May be looking to verify the position of lines and tubes in patients in the ICU or during/after interventions

- **Patients**
  - May be stressed, or worried about chest x-ray results for a variety of reasons
  - Maybe waiting on results for the diagnosis of possible cardiac or lung conditions
  - For ruling out diseases for regulatory reasons such as immigration or occupational health assessments
- **Medical Institution IT Department**
  - Want to ensure the security of systems to ensure patient privacy of their medical records

1.2.6 Priorities Assigned to Users

The following are the assigned priorities of the users of this project's proposed solution:

- **Doctor/Medical Professional**: key user, the expected primary user of the proposed solution to assist them in their work
- **Patient**: secondary user, benefits from having radiology analyses and diagnostic reports generated from their chest x-rays with faster results
- **Medical Institution IT Department**: tertiary user, supports the function of the proposed solution

1.2.7 User Participation

The user participation of the main users of the project's proposed solution is described in further detail below:

- **Doctors/Medical Professionals**
  - User feeds chest x-ray images into the software for analysis and diagnosis
  - User reviews output diagnostic report produced by the software
- **Patients**

- User is presented with the results of the diagnostic report by the doctor/medical professional

- **Medical Institution IT Department**
  - User authorizes the chest X-ray images to be taken from the medical institution's medical information systems by authorized users

1.2.8 Maintenance Users and Service Technicians

The maintenance users and service technicians of the project's proposed solution are described below:

- **Developers/Testers**, those responsible for the development of the project's proposed solution, as well as maintaining it (fixing bugs, adding updates implementing new features/improving existing ones)

1.3 Mandated Constraints

This subsection describes the various constraints placed on this project's proposed solution in more detail. These include the solution constraints, the implementation environment of the current system, supporting partner or collaborative applications and existing off-the-shelf software. The anticipated workplace environment and schedule, budget, and enterprise constraints are also described in more detail here.

1.3.1 Solution Constraints

The following are constraints placed on the project's proposed solution. Each is described in more detail, including its rationale and fit criteria, as shown below:

MC1. The product shall operate as a web application

Rationale: This will permit the users at different hospitals to use the system without any change to their institutional system

Fit Criterion: The product will contain the necessary back-end, front-end code, and database to run as a web application

1.3.2 Implementation Environment of the Current System

The following are constraints resulting from the implementation environment of the current system:

- **N/A**: no constraints on the implementation environment of the current system have been identified

1.3.3 Partner or Collaborative Applications

The following are partner or collaborative applications that the project's proposed solution is expected to work with:

- Medical institution's internal IT systems and databases where the patients' chest X-rays and other relevant medical records are stored

1.3.4 Off-the-Shelf Software

There are very few off-the-shelf software with functionality comparable to the project's proposed solution as most software has been developed in research studies to verify that AI can be used to accurately diagnose and identify abnormalities in chest X-rays.

1.3.5 Anticipated Workplace Environment

The anticipated workplace environment for the project's proposed solution is described as follows:

- **Medical Institutions**: chest x-rays taken to diagnose diseases or conditions, verify positions of lines and tubes in ICU patients before/after interventions; more time-critical
- **Diagnostics Offices**: chest x-rays taken to diagnose diseases or conditions, for routine checkups or regulatory reasons (e.g. immigration, occupational health assessments); less time-critical

1.3.6 Schedule Constraints

The schedule constraints (i.e. project deadlines) for the project's proposed solution are described as follows:

MC2. The viability of key parts of the project's proposed solution are demonstrated at the **Proof of Concept Demonstration**

Rationale: This ensures that the key parts of the project's proposed solution (i.e. chest x-ray analysis performed by ML model, web application server front- and back-end, generation of radiology report components) can be accomplished within a reasonable time.

Fit Criterion: The key components of the project's proposed solution are demonstrated to be viable (i.e. workable with sample training data chest x-rays) at the proof-of-concept demonstration taking place between November 13 - 24, 2023.

MC3. The functionality of the initial version of the project's proposed solution is demonstrated at the **Revision 0 Demonstration**

Rationale: This ensures that the functionality of the initial version of the proposed solution is accomplished within a timeline that allows for further testing and revision after this demonstration

Fit Criterion: The functionality of the initial version of the proposed solution is accomplished, with it working (with sample training data chest x-rays) at the revision 0 demonstrations taking place between February 5, 1- 16, 2024.

MC4. The functionality of the first revision of the project's proposed solution is demonstrated at the **Final/Revision 1 Demonstration**

Rationale: This ensures that the functionality of the first revision of the proposed solution includes revisions made from further testing and the (earlier) demonstration of the initial version of this solution

Fit Criterion: The functionality of the first revision of the proposed solution is accomplished, with revisions made, with it working at the final/revision 1 demonstration taking place between March 18 - 24, 2024.

1.3.7 Budget Constraints

The following are budget constraints for the project's proposed solution:

MC5. There is a budget constraint of **$750** for this project's proposed solution

Rationale: To ensure the project's proposed solution is not bought or a 'ready-made' solution, and ensure all incurred costs are minimized to ensure cost-efficiency.

Fit Criterion: The total cost of all hardware/software that needs to be purchased to complete the project's proposed solution is less than or equal to $750.00

1.3.8 Enterprise Constraints

Given that the project's proposed solution is expected to interface with a medical institution's IT systems, the following enterprise constraints apply:

- **N/A**: no enterprise constraints on the project's proposed solution have been identified

1.4 Naming Conventions and Terminology

This subsection describes all of the naming conventions and terminology relevant to documenting this project's proposed solution. This mainly includes the glossary of all terms (including acronyms) that are used by stakeholders involved in the project.

1.4.1 Glossary of All Terms, Including Acronyms, Used by Stakeholders involved in the Project

The naming conventions and terminology relevant to documenting this project's proposed solution that is used by stakeholders involved in this project are detailed in Table 1, shown below:

Table 1: Glossary of All Terms, Including Acronyms, Used By Stakeholders

Term/Acronym	Description
AI/ML	Artificial Intelligence/Machine Learning: what powers the core functionality of this project's proposed solution
DICOM	Digital Imaging and Communications in Medicine
MC	Mandated Constraints: the various constraints put on this project's proposed solution
BUC	Business Use Case: a scenario describing a possible business use case of this project's proposed solution
PUC	Product Use Case: a scenario describing a possible individual product use case of this project's proposed solution
FR	Functional Requirement: a requirement stating a functionality that the project's proposed solution must provide
NFR	Nonfunctional Requirement: a requirement stating a property that the project's proposed solution must have

1.5 Relevant Facts And Assumptions

This subsection includes all of the relevant facts, business rules and assumptions relevant to this project's proposed solution, described in further detail below.

1.5.1 Relevant Facts

The following are facts relevant to the project's proposed solution:

- Chest X-rays are the most common medical imaging modality
- Chest X-rays constitute 40% of the 3.6 billion medical imaging procedures performed worldwide each year

1.5.2 Business Rules

The business rules relevant to the project's proposed solution are described in detail below:

- proper security protocols are followed when retrieving and storing patients' medical records and data (i.e. chest x-rays)
- proper patient privacy policies are followed when processing and sharing patients' medical information with other parties (i.e. only shared with authorized parties)
- proper patient data protection policies are followed when processing and storing patients' medical information

1.5.3 Assumptions

The following are assumptions made about the project's proposed solution:

- The system has access to a DICOM server with the required chest X-ray images
- The accuracy of the system will not be 100%
- The model will be trained with a smaller section of the chest X-ray library due to limited computational power

2 Functional Requirements

This section describes the various points of the scope of the work and the functional requirements of this project's proposed solution.

2.1 The Scope of the Work

This subsection describes the scope of the work to be done for the project's proposed solution. This includes the current situation, the context of the work, work partitioning and a business use case scenario.

2.1.1 The Current Situation

The following points describe the current situation that the project's proposed solution was conceptualized in:

- Chest x-rays, constituting 40% of the 3.6 billion annual medical imaging procedures globally, serve as a primary diagnostic tool for various lung and heart conditions.

- Radiologists and healthcare professionals face significant time constraints in analyzing chest X-rays, potentially leading to:
  - time-critical delays with life-threatening implications for patients (in ICU, during or after interventions, etc.)
  - less time-critical delays for patients undergoing checks for regulatory reasons (e.g. immigration or occupational health assessments)

2.1.2 The Context of the Work

The following context diagram shown in Figure 1 shows the context that the project's proposed solution is expected to work and be used in.

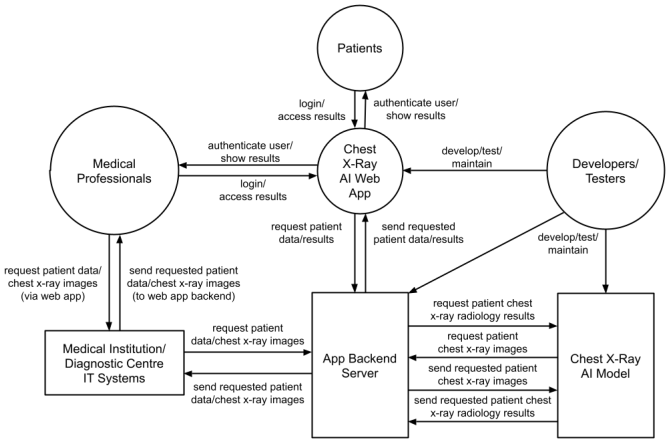

Figure 1: Context Diagram describing The Context of the Work

2.1.3 Work Partitioning

The following Tables 2 and 3 detail how the work will be partitioned for this project's proposed solution:

Table 2: Work Partitioning Table

Event Number	**Event Name**	**Input(s)**	**Output(s)**
1	Login User	user's login credentials	user's login credentials authenticated
2	Request Patient Data	request for patient data/chest x-ray images	requested patient data/ chest x-ray images
3	Request Radiology Analysis	request for radiology analysis of patient chest x-ray images	radiology report (elements) of the radiology analysis of the patient's chest x-ray images
4	Access/View Radiology Analysis	request to access/ view the radiology results report (elements)	radiology results report (elements) are shown to the user
5	Save Radiology Analysis	request to save the radiology results report (elements)	radiology results report (elements) are saved (to the medical institution's/diagnostic centre's IT systems)

Table 3: Work Partitioning Summaries

Event Number	**Summary**
1	user enters in login credentials into web app, and web app authenticates the login credentials
2	user requests patient data/chest x-ray images (from medical institution/diagnostic centre IT systems)
3	user requests radiology analysis of patient chest x-ray images
4	user accesses/views resulting radiology report (elements) of the radiology analysis of the patient's chest x-ray images
5	user saves resulting radiology report (elements) of the radiology analysis of the patient's chest x-ray images

2.1.4 Specifying a Business Use Case (BUC)

The following is a Business Use Case Scenario specified for the project's proposed solution:

1. **Patient arrival:** A patient arrives at the emergency room with severe respiratory symptoms, the attending doctor orders a chest X-ray for assessment of the patient's lungs.

2. **AI chest X-ray:** An X-ray of the patient's chest is taken and input into the system. The system identifies key abnormalities in the patient.

3. **Diagnostic report:** The system generates a list of the identified findings and their severity levels. The user interface presents this information clearly and concisely.

4. **Treatment:** The doctor quickly reviews the AI-generated report without examining the X-ray and begins treatment.

2.2 Business Data Model and Data Dictionary

2.2.1 Business Data Model

The following points detail the business data model of the project's proposed solution:

- **N/A**: this subsection was not filled out, as the details of the business data model will be decided on later in the design and implementation process of the project's proposed solution.

2.2.2 Data Dictionary

The following points detail the data dictionary of the project's proposed solution:

- **N/A**: this subsection was not filled out, as the details of the data dictionary items will be decided on later in the design and implementation process of the project's proposed solution.

2.3 The Scope of the Product

This subsection describes the scope of the product, including the product boundary, the product use case table and individual product use cases.

2.3.1 Product Boundary

The application encompasses the entire life cycle of the Automated Chest X-ray Diagnosis System, from the initial input of a chest X-ray image to the generation of a structured radiology report. It includes all components such as the Computer Vision and Neural Network modules, User Interface, and Security.

2.3.2 Product Use Case Table

The following table, Table 4, summarizes the product use cases for the project's proposed solution:

Table 4: Product Use Case Table

Use Case ID	Use Case Summary
PUC1	Process chest X-ray image using computer vision module
PUC2	Generate a list of identified findings
PUC3	Convert results into a structured set of findings on the x-ray.
PUC4	Display diagnostic findings on the user interface

2.3.3 Individual Product Use Cases (PUCs)

The following are the individual product use cases (PUCs), with a description, lists of actors, preconditions and postconditions provided for each.

PUC1. **Description:** the system takes a chest X-ray image as input and processes it to identify abnormalities

Actors: computer vision module, chest x-ray image

Precondition(s): valid chest x-ray image input is provided

Postcondition(s): processed image with identified abnormalities

PUC2. **Description:** the system generates a comprehensive list of identified findings based on the processed chest X-ray image

Actors: computer vision module, neural network module

Precondition(s): processed image with abnormalities is provided

Postcondition(s): A list of identified findings is generated

PUC3. **Description:** The system converts the list of identified findings into a structured radiology report

Actors: list of findings

Precondition(s): A list of identified findings is provided

Postcondition(s): diagnostic report is generated

PUC4. **Description:** The user interface module displays the diagnostic report for the user

Actors: user interface module, user

Precondition(s): diagnostic report is provided

Postcondition(s): diagnostic report is displayed on the user interface

2.3.4 Traceability Matrix

The following Table 5 shows the traceability of each functional requirement to their specific product use cases and vice versa.

Table 5: Traceability Matrix

FR \ PUC	PUC1	PUC2	PUC3	PUC4
FR1	X			
FR2		X		
FR3			X	X
FR4				X
FR5	X	X		
FR6				X
FR7	X			
FR8	X			

2.4 Functional Requirements

This subsection describes the functional requirements of the project's proposed solution in detail. It also includes the formal specification description of the machine learning (ML) algorithm to be used in the solution.

2.4.1 Functional Requirements

The following are the functional requirements defined for this project's proposed solution. They are described in detail below, with a rationale and fit criterion detailed for each. The individual product use cases associated with each functional requirement are also shown.

FR1. **Description:** The system shall accept and read DICOM images as input.

Rationale: The model shall use DICOM as the format is easy to process.

Fit Criterion: The model can successfully process DICOM files.

Use Case(s): PUC1

FR2. **Description:** The system shall reject images given in a non-DICOM format.

Rationale: The system will process images in a DICOM format and will have no image conversion functionality.

Fit Criterion: The system successfully rejects non-DICOM images.

Use Case(s): PUC1

FR3. **Description:** The system shall display JPEG images in the findings.

Rationale: Since the system uses JPEG as input for the model, it is also used to display results.

Fit Criterion: The interface is able to map the findings on a JPEG image of the x-ray.

Use Case(s): PUC2

FR4. **Description:** The system shall generate and display a structured set of findings and demographic information about the patient.

Rationale: Displaying a report would help understand the findings of the chest x-ray.

Fit Criterion: The system can successfully label the x-rays with the correct diseases normalcy 90% of the time.

Use Case(s): PUC3, PUC4

FR5. **Description:** The system shall be able to fetch patients' records on retrieval request by the user.

Rationale: Generated reports and findings need to be accessed in the future when required.

Fit Criterion: The system can display the past findings stored in the database.

Use Case(s): PUC4

FR6. **Description:** The system shall detect and classify the following diseases/infections to a certain accuracy: Pneumonia, Atelectasis, Cardiomegaly, Pleural Effusion

Rationale: Users need information on whether a chest x-ray image depicts any diseases or not.

Fit Criterion: The area under the ROC curve for each disease after testing the model is greater than the recommended threshold for accurate results (Refer to Table 6).

Use Case(s): PUC1, PUC2

FR7. **Description:** The system shall be accessible remotely via a web interface.

Rationale: The database would most likely be on a cloud service, and the system would need to be used remotely from anywhere by the medical professional.

Fit Criterion: The interface can retrieve required information from the remote server.

Use Case(s): PUC4

FR8. **Description:** The system shall convert images from a DICOM file to a jpeg, jpg or other suitable image format to be processed by the ML algorithm.

Rationale: Chest x-ray data is stored in DICOM format, and the model uses jpeg images to identify diseases as it is more feasible.

Fit Criterion: The system can successfully convert a DICOM x-ray image to a jpeg.

Use Case(s): PUC1

FR9. **Description:** The system shall have a backend database that stores the patient records linked to their diagnostic findings.

Rationale: The information should be stored for future access by users.

Fit Criterion: User data is stored in a backend database, and can be updated and accessed.

Use Case(s): PUC4

FR10. **Description:** The system shall allow users to create an account and login.

Rationale: Sensitive data needs authorization to be accessed.

Fit Criterion: User is able to login through their credentials and access the functions of the system.

Use Case(s): PUC2

FR11. **Description:** The system shall have a search function to search for diagnoses specific to a patient's details (name, ID, etc)

Rationale: Allows fast retrieval of information.

Fit Criterion: User is able to search for a patient using their personal information or identifier.

Use Case(s): PUC4

Table 6: ROC Threshold Table

Disease/Infection	Expected Area Under ROC Curve
Pneumonia	0.8
Atelectasis	0.8
Cardiomegaly	0.85
Pleural Effusion	0.9

2.5 Formal Specification for the ML Algorithm

This subsection details the formal specification for the machine learning algorithm. The machine learning algorithm can be considered a function (f). The primary output would be to detect n different types of diseases.

$$f : Image \to \mathbb{R}^n$$
$$f(I) = \{x_i | x_i \in \mathbb{R}; i, n \in \mathbb{N} | 0 \leq x_i \leq 1, 1 \leq i \leq n\}$$

Where the input domain is an x-ray image and the output codomain of the function is a vector with n dimensions. Each real number in the vector represents the probability of having a certain disease. The report created needs to have a definite prediction (1 or 0) for each disease. The prediction vector is based on whether the probability is above a threshold. Suppose each disease has a threshold (t_i) for deciding whether the disease is present:

$$t_i : \mathbb{R}, 0 \leq t_i \leq 1, 1 \leq i \leq n$$

Then the vector constituting the predictions is:

$$predictions : \{0, 1\}^n$$
$$predictions = \left\{ p_i \middle| p_i \in \{0, 1\}; i, n, \in \mathbb{N}; x_i \in f(I) \middle| 1 \leq i \leq n, p_i = \begin{Bmatrix} 0 & x_i < t_i \\ 1 & x_i \geq t_i \end{Bmatrix} \right\}$$

3 Non-functional Requirements

This section covers the various subgroups of non-functional requirements. This includes look and feel requirements, usability and humanity requirements, performance requirements, operational and environmental requirements, maintainability and support requirements, security requirements, cultural requirements and compliance requirements.

3.1 Look and Feel Requirements

This subsection details the look and feel requirements of the project's proposed solution. This encompasses the appearance and style requirements of the solution's user interface.

3.1.1 Appearance Requirements

NF-AR0 Visual elements shall be consistent, using a clean and intuitive design.

Rationale: A simple appearance will allow ease of use and minimize complexities from any unintentionally non-intuitive design.

Fit Criterion: After one use 80% of users shall find the design intuitive and visually satisfying.

3.1.2 Style Requirements

NF-SR0 The overall style of the user interface shall align with healthcare industry standards and best practices.

Rationale: Since the system will be used in medical offices it shall comply with the industry standards to get approval for use.

Fit Criterion: The industry standards are met.

3.2 Usability and Humanity Requirements

This subsection details the usability and humanity requirements of the project's proposed solution's user interface:

3.2.1 Ease of Use Requirements

NF-EUR0 The application interface shall only include the minimum necessary elements for the system to function effectively.

Rationale: The simplicity of the system is important to ensure that the system is easy for all users to interact with.

Fit Criterion: Testers should not be able to identify any element of the user interface that does not serve any immediate and apparent use.

Traceability: Traces to functional requirements involving the user interface.

3.2.2 Personalization and Internationalization Requirements

NF-PIR0 The interface shall have both official languages of Canada, English and French.

Rationale: In Canada, people should be able to work in their preferred official language, as per the Official Languages Act(**?**).

Fit Criterion: The core services shall be available in English and French

3.2.3 Learning Requirements

NF-LR0 The interface should be straightforward and easy for all trained hospital or office staff to use.

Rationale: The system shall require no training for the use of the interface to allow for smooth integration into the daily activities of the staff.

Fit Criterion: During a user's first use of the system, they shall spend no more than 30 seconds reviewing the user interface.

3.2.4 Understandability and Politeness Requirements

NF-UPR0 The chest x-ray reports should be coherent and understandable by a radiologist or relevant medical professional.

Rationale: The report must be able to outline the findings and any abnormalities determined by the AI model in medical terms with an explanation to be of use to the doctors

Fit Criterion: A radiologist or radiologist resident shall be able to comprehend the report findings and justification after reading it once

3.2.5 Accessibility Requirements

NA

3.3 Performance Requirements

This subsection details the performance requirements of the project's proposed solution:

3.3.1 Speed and Latency Requirements

NF-SLR0 The system shall return a report generated from an input within a reasonable amount of time.

Rationale: The system should be comparable to the time radiologists and residents need to examine a chest X-ray.

Fit Criterion: A report is generated within 5 minutes.

3.3.2 Safety-Critical Requirements

NF-SCR0 The system will not collect identifying data not necessary for diagnosis.

Rationale: Managing all relevant health data for patients requires extra safety measures and puts their data at risk, to minimize the risk all nonessential data will not be collected by the system

Fit Criterion: Only data pertaining to diagnosis are collected (X-ray images, age, previous conditions.)

3.3.3 Precision or Accuracy Requirements

NF-PAR0 See FR#5.

3.3.4 Robustness or Fault-Tolerance Requirements

NF-RFTR0 The system shall be available 99.7% of the time, with 30 minutes a week of allowable downtime.

Rationale: Since the system is aiding in hospital settings, which can run 24/7, offline time should be minimized to allow for the best use of the system.

Fit Criterion: The system functions with only 30 minutes of downtime per week of operation.

3.3.5 Capacity Requirements

NF-CR0 The system shall be able to receive and process multiple images at a time.

Rationale: Multiple patients may require reviews on their chest X-ray at the same point in time and the system should be able to accommodate a small increase in demand.

Fit Criterion: The system shall be able to process 3 or more images at a given time.

3.3.6 Scalability or Extensibility Requirements

NF-SER The system architecture should grow to accommodate an increasing number of chest X-ray images and users as the hospital's workload grows. This is not a concern for this project's current timeline.

3.3.7 Longevity Requirements

NA

3.4 Operational and Environmental Requirements

This subsection details the operational and environmental requirements for this project's proposed solution:

3.4.1 Expected Physical Environment

NF-EPE0 The system will be used in hospitals and diagnostic offices.

Rationale: This follows from our determined stakeholders for this project and from what the system is built to achieve.

Fit Criterion: *NA*

3.4.2 Wider Environment Requirements

NA

3.4.3 Requirements for Interfacing with Adjacent Systems

NF-RIAS0 The system will require access to the host computer's files for image upload.

Rationale: The system requires chest X-ray images to identify any abnormalities in the X-ray, so the system must interface with their computer to facilitate this upload.

Fit Criterion: The user will be able to upload an image from their computer to the system

3.4.4 Production Requirements

NF-PR0 The system will be accessible through a web application which requires access to the Internet.

Rationale: This allows the system to not be dependent on the type of system currently in-place at hospitals and other medical offices where it could be used.

Fit Criterion: The system can be accessed through a while connected to the Internet.

3.4.5 Release Requirements

NA

3.5 Maintainability and Support Requirements

This subsection details the maintainability and support requirements for this project's proposed solution:

3.5.1 Maintenance Requirements

NF-MR0 Maintenance of the system will be done by the developers alongside the local IT team.

Rationale: The developers will work on ensuring the system is working and updated as needed, the local IT team will ensure it's working with the offices existing system.

Fit Criterion: *NA*

3.5.2 Supportability Requirements

NF-SR0 The system is self-supporting and will be accompanied by information on the model.

Rationale: This allows for less issues with security and dependencies as the system will have all the functionality it needs to operate within it's self.

Fit Criterion: The system supports all functionality needed to operate independently.

3.5.3 Adaptability Requirements

NA

3.6 Security Requirements

This subsection details the security requirements for this project's proposed solution:

3.6.1 Access Requirements

NF-AR0 The x-ray images should only be accessible to authorized users. Authorized users include doctors and IT staff responsible for storing medical data for the medical institution.

Rationale: This is to keep health records confidential and accessible to only those that have permission to view, such as a doctor or nurse.

Fit Criterion: Users with authorized username and password will be able to access the X-ray image.

NF-AR1 The system should allow access to generated reports only by medical professionals and the patient to whom the report belongs.

Rationale: Similarly to NF-AR0 this is to keep health records confidential and accessible to only those that have permission to view, such as a doctor or nurse.

Fit Criterion: Users with authorized username and password will be able to access the generated report.

3.6.2 Integrity Requirements

NF-IR0 The system will encrypt all stored data

Rationale: This is to help ensure that if the system is attacked any data is not easily collected.

Fit Criterion: All data is not stored in plain language.

3.6.3 Privacy Requirements

NF-PR0 Only authorized users, doctors, will have access to patients information.

Rationale: Similarly to Access requirements this is to keep records confidential and accessible to only those that have permission to view.

Fit Criterion:

NF-PR1 The system should maintain the privacy of the patient's personal and medical information.

Rationale: This is to follow the medical practices of keeping patient privacy.

Fit Criterion: Patient information is not openly accessible.

3.6.4 Audit Requirements

NF-AR0 Regular security audits and vulnerability assessments shall be conducted to maintain a secure environment.

Rationale: This is to ensure that all data is keep private and protected while ensuring that the system is able to provide accurate results for diagnoses.

Fit Criterion: The system maintains a 90% accuracy rate and authorization safe guards are functioning during an audit.

3.6.5 Immunity Requirements

NA

3.7 Cultural Requirements

This subsection details the cultural requirements for this project's proposed solution:

3.7.1 Cultural Requirements

NF-CR0 The system can be used by anyone.

Rationale: There are many different people living and working in Canada, they should all be able to use the system.

Fit Criterion: All users find the system intuitive and can understand the system after the first use.

3.8 Compliance Requirements

This subsection details the compliance requirements for this project's proposed solution.

3.8.1 Legal Requirements

NF-LR0 Patients must consent to the collection of their data and retention of health information must comply with the Person Health Information Protection Act in Canada (**?**).

Rationale: This allows for the system to be able to collect relevant data for diagnosis while operating in Canada.

Fit Criterion: The Person Health Information Protection Act regulations are followed.

3.8.2 Standards Compliance Requirements

NF-SCR0 The system shall comply with the Canadian healthcare standards.

Rationale: Since the system will be used within medical centres for diagnostics it is considered a software medical technology and to be used in hospitals it must meet the standards.

Fit Criterion: The standards are met.

4 Project Issues

This section covers the various project issues, namely open issues, off-the-shelf solutions, new problems, tasks, migration to the new product, costs, waiting room and ideas for solutions.

4.1 Open Issues

- **Algorithm Optimization:** The optimization of algorithms for the computer vision and neural network modules require further exploration to enhance the efficiency and accuracy of chest X-ray analysis.
- **Web Application Dependency:** The dependency on a web application for system functionality may pose challenges in environments with restricted internet access.
- **Data Security Measures:** The implementation of robust security measures to protect patient information requires careful consideration and potential enhancements.

4.2 Off-the-Shelf Solutions

4.2.1 Ready-Made Products

- **Deep Learning Frameworks:** Leveraging existing deep learning such as PyTorch or TensorFlow to accelerate the development and optimization of the computer vision and neural network modules.
- **User Interface Libraries:** Utilizing established user interface libraries like React or Angular to expedite the development of the user interface component.

4.2.2 Reusable Components

N/A

4.2.3 Products That Can Be Copied

- **Web Application Frameworks:** Identifying web application frameworks (i.e. Django, Ruby, ExpressJS) that align with the project's requirements to serve as a foundation for the system.

4.3 New Problems

4.3.1 Effects on the Current Environment

- Introduction of this technology may lead to an over-reliance, potentially diminishing the role of traditional diagnostic methods.
- In the event of software malfunction, there is a risk of significant delays, surpassing current delay times.

4.3.2 Effects on the Installed Systems

N/A

4.3.3 Potential User Problems

- Some radiologists and healthcare professionals may exhibit skepticism toward adopting this technology.
- There is a risk of user error, such as unintentional submission of non-X-ray images.

4.3.4 Limitations in the Anticipated Implementation Environment That May Inhibit the New Product

- The system is designed to process only one image at a time, potentially hindering workflow efficiency in scenarios where batch processing is desired.
- A functional web application is needed to run the software.

4.3.5 Follow-Up Problems

N/A

4.4 Tasks

4.4.1 Project Planning

Deliverable	Deadline
Problem Statement and Goals, Development Plan	September 25th, 2023
Requirements Document, Revision 0	October 6th, 2023
Hazard Analysis, Revision 0	October 20th, 2023
V&V Plan, Revision 0	November 3rd, 2023
Proof of Concept Demonstration	November 13th - 24th, 2023
Design Document, Revision 0	January 17th, 2023
Revision 0 Demonstration	February 5th - February 16th, 2024
V&V Report, Revision 0	March 6th, 2024
Final Demonstration, Revision 1	March 18th - March 29th, 2024
EXPO Demonstration	April TBD
Final Documentation, Revision 1	April 4th, 2024

4.4.2 Planning of the Development Phases

1. **Initiation Phase** (September 5th, 2023 - September 25th, 2023)
    - Team building and project selection.
    - Identify the project supervisor.
    - Create a *GitHub* project repository.
2. **Planning Phase** (September 26th, 2023 - October 11th, 2023)
    - Create a Development Plan.
    - Define the problem and scope of the project.
    - Identify stakeholders and investigate their needs.
    - Create SRS Documentation.
3. **First Implementation Phase** (October 12th, 2023 - November 24th, 2023)
    - Address the implementation challenges of the project.
    - Perform Hazard Analysis.
    - Create the Verification and Validation Plan.

- Present Proof of Concept Demonstration.

4. **Second Implementation Phase** (November 25th, 2023 - January 17th, 2024)
    - Implement the main features of the project.
    - Perform testing.
    - Optimize the implementation details of the project.
    - Create the Design Document (Version 0).
5. **Evaluation Phase** (January 18th, 2024 - March 6th, 2024)
    - Evaluate the achievement of project goals.
    - Perform risk and security assessments.
    - Conduct user-end testing assessments.
    - Demonstrate Revision 0.
    - Prepare the Verification and Validation Report.
6. **Closure Phase** (March 7th, 2024 - April 4th, 2024)
    - Conduct the final demonstration.
    - Get ready for the Expo Demonstration.
    - Complete all documentation.

4.5 Migration to the New Product

4.5.1 Requirements for Migration to the New Product

N/A

4.5.2 Data That Has to be Modified or Translated for the New System

N/A

4.6 Costs

There are no costs anticipated with this project, however, should any purchases be necessary the total will not exceed $750.

4.7 User Documentation and Training

This subsection contains the details of all needed user documentation and training for this project's proposed solution.

4.7.1 User Documentation Requirements

The system will have the following documentation provided to the users:

User Interface: The system will have a guide outlining the use of each section of the UI and accepted forms on data that can be uploaded to the system.

Model: The model is more complex and will come with details pertaining to the accuracy of detection, which diseases the system can identify, the policy of storing and keeping information, and maintenance and updates.

4.7.2 Training Requirements

There will be no training requirements.

4.8 Waiting Room

N/A

4.9 Ideas for Solution

N/A

References

Official Languages Act.

Personal Health Information Protection Act, 2004. S.O. 2004, CHAPTER 3.

James Robertson and Suzanne Robertson. *Volere Requirements Specification Template*. Atlantic Systems Guild Limited, 16 edition, 2012.

5 Appendix

5.1 Reflection

The information in this section will be used to evaluate the team members on the graduate attribute of Lifelong Learning. Please answer the following questions:

1. What knowledge and skills will the team collectively need to acquire to complete this capstone project? Examples of possible knowledge to acquire include domain-specific knowledge from the domain of your application, software engineering knowledge, mechatronics knowledge or computer science knowledge. Skills may be related to technology, writing, presentation, team management, etc. You should look to identify at least one item for each team member.

2. For each of the knowledge areas and skills identified in the previous question, what are at least two approaches to acquiring the knowledge or mastering the skill? Of the identified approaches, which will each team member pursue, and why did they make this choice?

The main skills that the team shall collectively aim to learn through this project are documentation, version control and management of group work using GitHub, and project specific knowledge such as computer vision/machine learning. The team aims to learn about machine learning by reading various research papers about chest x-ray disease detection. There are also skills that different team members aim to learn individually through this project.

For documentation, version control, and GitHub management, the team plans to adopt a hands-on approach by actively engaging in a collaborative projects, leveraging GitHub for version control, and documenting their progress consistently. To delve into computer vision and machine learning, the team aims to combine theoretical understanding with practical implementation. They will explore online courses, tutorials, and community forums to grasp foundational concepts, while simultaneously working on the chest X-ray disease detection project to apply this knowledge in a real-world context. Each team member will choose the approach that aligns with their preferred learning style, some might favor structured courses while others opt for self-directed exploration. This diversity in learning approaches ensures a comprehensive understanding of the subjects.