CHESTLENS AI

System Requirements Document

Group 18

Supervisor	
Name: **Email:** **Organization:**	Dr. Mehdi Moradi moradm4@mcmaster.ca McMaster University, CAS
Team Member 1	
Name: **Email:** **Student Number:**	Abhishek Sharma shara109@mcmaster.ca 400322503
Team Member 2	
Name: **Email:** **Student Number:**	Anthony Vu vua11@mcmaster.ca 400306059
Team Member 3	
Name: **Email:** **Student Number:**	Hussein Saad saadh@mcmaster.ca 400307995
Team Member 4	
Name: **Email:** **Student Number:**	Nathan Starr starrn@mcmaster.ca 400323095
Team Member 5	
Name: **Email:** **Student Number:**	Yuvraj Jain jainy3@mcmaster.ca 400259484

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Team Member Contributions

Sections Worked On	Team Member
• 1.0, 2.0, 3.0, 3.1, 3.2, 3.3, 3.4, 3.7, 3.7.1, 3.7.2, 4.0, 4.1, 4.2, 4.3, 6.0, 6.1, 6.2	Abhishek Sharma
• 1.0, 2.0, 4.2, 5.0, 5.1, 5.3	Anthony Vu
• 1.0, 2.0, 4.2, 5.0, 5.8, 5.8.1, 5.8.2, 5.8.3, 5.9, 5.9.1, 5.9.2, 5.9.3, 5.9.4, 5.9.5	Hussein Saad
• 1.0, 2.0, 3.0, 3.4, 3.5, 3.6, 4.2, 5.0, 5.2, 5.5, 5.6, 5.7, 5.7.1, 5.7.2	Nathan Starr
• 1.0, 2.0, 4.0, 4.2, 5.0, 5.4, 5.4.1, 5.4.2, 6.1	Yuvraj Jain

1.0 Revision History

Version Number	Authors	Description	Date
0	• Abhishek Sharma • Anthony Vu • Hussein Saad • Nathan Starr • Yuvraj Jain	Started Initial Draft	October 10th, 2023
1	• Abhishek Sharma • Anthony Vu • Hussein Saad • Nathan Starr • Yuvraj Jain	Updated SRS for final submission	March 26th, 2024

2.0 Glossary

Term	Definition
AI Model	An Artificial Intelligence (AI) model is a program that analyzes datasets to find patterns and make predictions. Source: Link
CNN	Convolutional Neural Networks is a deep learning algorithm that takes in an image and assigns weights and biases in order to make sense of it. Source: Link
DICOM	DICOM® — Digital Imaging and Communications in Medicine — is the international standard for medical images and related

	information. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. Source: Link
IVDDs	In Vitro Diagnostic Devices (IVDDs) is any medical device that is covered by section 3 of Medical Device Regulations. This covers devices used for detecting diseases. Source: Link
MIT License	Is an open-source permissive software license created by Massachusetts Institute of Technology. Source: Link
ML	Machine Learning (ML) is a branch of Artificial Intelligence (AI) and computer science which focuses on the use of data and algorithms to imitate the way that humans learn, gradually improving its accuracy. Source: Link
PACS	A picture archiving and communication system (PACS) is a computerized means of replacing the roles of conventional radiological film: images are acquired, stored, transmitted, and displayed digitally. When such a system is installed throughout the hospital, a filmless clinical environment results. Source: Link
Radiographers	Radiographers are also known as radiologic technologists and they are healthcare professionals who operate special scanning machines that make images for medical purposes. They use tools and procedures such as: ● CT scanners ● Fluoroscopies ● MRIs ● PET scanners ● Radiotherapy ● Ultrasounds ● X-rays Radiographers' tasks include: ● Helping oncologists with radiation treatment for cancer patients. ● Preparing patients for radiologic procedures. ● Maintaining imaging equipment.

	• Ensuring that safety protocols are being followed. • Helping surgeons, such as with imaging during complicated procedures. Source: Link
Radiologist	Radiologists are medical doctors that specialize in diagnosing and treating injuries and diseases using medical imaging (radiology) procedures (exams/tests) such as X-rays, computed tomography (CT), magnetic resonance imaging (MRI), nuclear medicine, positron emission tomography (PET) and ultrasound. Source: Link, Radiology Workflow Diagram: Link
ROC Curve	An ROC curve (receiver operating characteristic curve) is a graph showing the performance of a classification model at all classification thresholds. This curve plots two parameters: True Positive Rate and False Positive Rate. Source: Link
SaMD	Software as a Medical Device (SaMD) is a legal classification of software that is classified as a Medical Device under the Food and Drugs Act. Source: Link
X-ray	An X-ray is a form of high energy electromagnetic radiation that can pass through most objects, including the body. X-rays travel through the body and strike an x-ray detector (such as radiographic film, or a digital x-ray detector) on the other side of the patient, forming an image that represents the “shadows” of objects inside the body. Source: Link

3.0 Purpose of The Project

3.1 Context & Overall Objectives

For our project we will be implementing an AI model for chest x-rays to identify common diseases. The main objective of using an AI model on chest x-rays is to identify negative results or identify what diseases are present and the location of these diseases with the use of visual mapping.

3.2 Current Situation

Currently radiographers facilitate the imaging process for x-rays and radiologists manually analyze the produced medical images to find any abnormalities, injuries or diseases.

3.3 Expected Benefits

We believe that creating an AI for chest x-rays is beneficial since it can be used by radiologists to help confirm or identify any abnormalities, injuries and diseases present in x-ray images. Having the assistance of an AI model will save radiologists time and save hospitals money since the analysis process will be sped up and a diagnosis can be given to patients faster.

3.4 Functionality Overview

In terms of functionality, our project will consist of two main parts, a front-end website, and a back-end for image processing through AI. Specifically, the front-end website will allow for uploads of DICOM images as it is standard in hospitals and it will return the image with tags for what disease(s) it found, as well as the image itself with highlighted locations of where it has found any disease(s). For the back-end we will be training our model in Python, which has a number of tools and libraries for ML. In terms of datasets for training we have identified a number of sources for chest x-rays such as Kaggle, CheXpert from Stanford, MIMIC, and open libraries on GitHub like TorchXRayVision that combine datasets.

3.5 High-Level Usage

Once X-rays are taken and uploaded to the front end website Radiologists will be able to run them though our model. From there they will be able to view the x-ray that has visual mapping with areas of interest as well as tags with disease and location. They will also have access to the patient's information accessible through the front end website. They will also be able to view x-rays from previous visits.

3.6 Limitations & Exclusions

One limitation of our project is not having direct access to a PACS (Picture Archiving and Communication System) server. For the purposes of this project we will not include a simulated PACS server because it is not necessary given the scope of the project. In the future we may use Amazon Web Services (AWS) to simulate a PACS server if needed, so we left these requirements in the document at a lower priority.

3.7 Stakeholders & Requirement Sources

3.7.1 Direct Stakeholders

The direct stakeholders for this project will be radiologists who will be examining the x-rays and medical imaging technologists (radiographers) who will be taking the x-rays.

3.7.2 Indirect Stakeholders

The indirect stakeholders will be the hospital administrative staff who will be sourcing the x-rays in DICOM format from PACS (Picture Archiving and Communication System) and helping with other administrative details. Another indirect stakeholder will be the patient themself since their recovery journey will be influenced by the findings found by the chest x-ray AI model.

4.0 Constraints & Functional Requirements

4.1 Constraints

- Due to security concerns in real hospitals we will not have access to the actual PACS servers used in hospitals. In the future to overcome this constraint we plan to simulate the experience of interacting with a PACS server by creating a PACS server on Amazon Web Services (AWS).
    - Given the nature of the information being stored and accessed from the PACS server security is a constraint. AWS meets these security constraints since all information between AWS data centers is encrypted thus allowing us to securely push and pull information from the server. Also due to the many security features offered by AWS we can securely keep information within the server.
- Since most hospitals use computers to analyze x-rays we will be implementing the front end of our project through a website. We chose to use a website over a mobile app since information can be better viewed on computer websites when compared to mobile applications.
- It is the industry standard to have all x-ray images in DICOM format. For this reason, we will be using data sources that contain DICOM images to ensure that our model can accept x-rays in DICOM format to meet industry standards.
- There is a time constraint to complete this project. As per the requirements of this project, we are required to have a prototype by the end of November 2023 and a functioning version by the end of March 2024.
- Since the project will be dealing with sensitive patient data we will be required to follow legal privacy requirements. The legal requirements can be found in section 5.6 below.
- Many of the team members will be working on their personal laptops which have limited power and storage. This limited power and storage will make it difficult to train the model with large datasets. To overcome this constraint we may look into getting additional GPU power and storage from the faculty or external sources such as AWS.

4.2 Functional Requirements

The following functional requirements are priority ranked using the following priorities:

P0 (Minimum Viable Product)

- The AI model should be able to identify the following 5 diseases (Atelectasis, Cardiomegaly, Consolidation, Edema, and Pleural Effusion) and No Finding.
- The application must be compatible with DICOM x-ray images.
    - This means that the application will allow uploads of DICOM images in the front end and that the AI model in the backend must be able to process/work with DICOM x-ray images.
- The AI model for the application will use a pre-trained ML model. More details can be seen in section 5.8 below.
- The AI model testing requirements/methods are specified in section 5.9 below.
- The expected area under the ROC curve for each disease is the following:
    - Expected area under ROC curve for Atelectasis: 0.8
    - Expected area under ROC curve for Cardiomegaly: 0.85

    - Expected area under ROC curve for Consolidation: 0.85
    - Expected area under ROC curve for Edema: 0.85
    - Expected area under ROC curve for No Finding: 0.85
    - Expected area under ROC curve for Pleural Effusion: 0.92
- The application should provide necessary information regarding the patient, including the patient's id, name, sex, birth date, patient age at acquisition date, x-ray information such as view position and acquisition date, and previously uploaded x-rays.
- The application should output a clear analysis of the x-ray by providing tags of diseases identified by the AI model.
- The front end of our application should be implemented as a website.
- The application should provide the opportunity for radiologists to provide feedback or specific comments regarding the impressions and findings.

With the requirements specified above our project will have enough components to complete its main goal of aiding radiologists by identifying what diseases are present and the location of these diseases. This minimum viable product will allow radiologists to access the front end of our website online where they can see an analysis of x-ray images taken in the hospital and be aided in making diagnoses of Atelectasis, Cardiomegaly, Consolidation, Edema, Pleural Effusion and No Findings with the use of disease tags identified by our AI model and provide any comments.

P1: The requirements given a priority of P1 are the next set of features that can be added to the minimal viable product to give the direct stakeholders an improved experience.

- The application should highlight/shade each region of the x-ray affected by identified disease(s).
    - This feature should effectively provide a visual mapping of areas of interest on the x-ray to better assist the radiologists.
- The AI model used in the application will be trained from scratch by us.

P2: The requirements given a priority of P2 are features that may be added at a later time, these requirements are not critical to the functioning of the base application.

- The disease tags provided by the application will have a probability associated with them.
- The application should implement a simulated PACS server on Amazon Web Services.
- The application should provide additional information for identified disease(s). This additional information includes descriptions of abnormalities, disease specification, and relevant measurements.

P3: The requirements given a priority of P3 are nice to have, but not required.

- The application should display previous x-rays of patients along with the corresponding findings, notes, radiologists who provided analytical findings, and the radiographer who took the x-ray.
    - Having this past information should allow radiologists to compare current results to previous results and determine if the conditions are improving or further treatment is needed. (Temporal Analysis)

- Based on the level of severity, the system should give probabilistic feedback on areas of the scan through color gradience; red indicates immediate attention needed, yellow indicates moderate concern while blue represents a less urgent state
- The application will be expected to be up and running at all times since most hospitals work 24/7/365. This means that our application can only be down for maintenance for a very limited amount of time only when absolutely required.
- The application takes into account the legal requirements regarding patient personal data.
- The application can be reformatted to meet all legal and industry standards so that it can be incorporated into a hospital's existing radiology workflow.

4.3 Data Requirements

- In the future a PACS server may be simulated on Amazon Web Services (AWS). This means that all data will be stored on AWS.
    - All x-rays, patient data, and notes must be securely loaded and stored into the simulated PACS server on AWS.
    - All X-rays, patient data, and notes must be securely accessed from the simulated PACS server on AWS.
    - Hospital administrative staff must be able to access and maintain information on the simulated PACS server on AWS through a secure connection.
    - All images must be stored on the simulated PACS server on AWS in DICOM format to meet industry standards. If the images are not in DICOM format the simulated PACS server should not allow the upload.
    - (This ensures that there are no invalid/garbage x-ray images stored in the server).
- Radiologists must only be able to view and modify patient data for patients assigned to them. In other words, radiologists should not be able to see data or modify patient data for patients under the care of another radiologist, they should only be able to see and modify the data for their own patients.
    - Radiologists should only be able to see and edit other radiologists' patient data if it has been shared with them for collaboration purposes to get a better diagnosis.
- The radiographers must be able to securely upload x-ray images and notes for a specific patient to the front end website.
- The AI model must create a new copy of a patient x-ray and run on the new copy. This will ensure that all visual mappings, areas of interest, as well as disease tags will be on the new copy and preserve the original copy for reference purposes. After the AI model has finished running, this new copy with the findings should then be returned to the front end website. This will ensure that all outputs from the model will link to the correct patients in the future when a radiologist accesses a specific patient's file.
- When a radiologist accesses a specific patient's file on the application, the application must correctly provide information for the specified patient. The data that should be displayed by the application when accessing a patient file can be seen below:
    - Comprehensive information about the patient’s name, sex, birth date, patient age at acquisition date, x-ray information such as view position and acquisition date, and past scans.

- Patient diagnoses and supporting X-rays. There should be the original x-ray for reference and the x-ray image produced by the AI model with visual mapping, areas of interest, tags with disease and location and accompanying highlighting based on the disease location.
- Previous x-rays of patients along with the previous comments.
- (Having this information will allow radiologists to compare current results to previous results and determine if the conditions are improving or further treatment is needed).

5.0 Non-Functional Requirements

5.1 Performance & Speed Requirements

- Our AI model is expected to complete scanning and reporting a single x-ray DICOM image in less than 10 seconds.
- Since it is vital to minimize false negatives in a healthcare environment, our ROC curve will have a relatively high false positive rate.
- The expected area under ROC for specific diseases are further specified under section 4.2 (P0).

5.2 Operational & Environmental Requirements

- Devices using our software are connected to the internet.
- Devices accessing the front end of our project are using a Chromium-based browser.

5.3 Security & Privacy Requirements

- If we plan to create a simulated PACS server, having a secure channel for communication between the PACS server and our system is critical to ensuring patient safety and compliance with local authorities.
- Any external software we may use (open-source, AWS, etc.) must be well-tested for security and privacy.
- At least one developer will always be on-call to patch any zero-day vulnerabilities that are detected/reported.

5.4 Look & Feel Requirements

5.4.1 Appearance Requirements

- Interfaces should be intuitive and provide easy navigation for both radiologists and hospital administrators.

5.4.2 Style Requirements

- Our interface should include:

    1. **Patient Information:** name, sex, patient id, birth date and patient age at x-ray date.
    2. **Disease Specification and Visualization:** display information regarding diagnoses with visual mapping to the areas affected.

3. **X-ray information:** x-ray position, x-ray acquisition date and past scans.

5.5 Usability and Humanity Requirements

- Our software will be easy to use. The users targeted to use our product are Radiologists who are very busy and do not have time to spend learning un-intuitive elements of our product.
- The design of our interactive elements should be of such that it is clear to identify that they are interactable.
- It must be made clear when data is being processed by the server. If the analysis of an x-ray is being computed then the user must be made aware of this so they know the information will be available soon, and is not missing.
- Acronyms should be avoided where possible to make readability easier and to avoid misunderstandings with other acronyms that use the same letters.

5.6 Legal Requirements

- Our software will use the open source MIT License.

Legal requirements would need to be satisfied before going into use in Hospitals but will not be required for this project in its scope as a capstone project.

- Before using software doctors must agree they are responsible for any diagnoses and not the software.
- Health Canada would classify this software as a class 3 SaMD (Software as a Medical Device) non-IVDD (non-vitro diagnostic device) because it provides a diagnostic output and analyzes medical images.
- As a medical Device the software will follow the FOOD AND DRUGS ACT Medical Devices Regulations SOR/98-282.
  Link
- Our software will also go through the following application process for a new Class 3 non-in vitro diagnostic device in Canada.
  Link

5.7 Assumptions & Invariants

5.7.1 Assumptions

- Our model is being used by trained radiologists.
- Radiologists make the final diagnosis.
- X-rays and patient data is available.

5.7.2 Invariants

- Introduction of our software should not affect how x-rays are taken.
- The PACS server used by the Hospital should continue to be maintained by the Hospital and remain unchanged.
- How images are uploaded to the Hospital PACS server should not be impacted by our product.
- Use of our software does not affect hospital procedures for diagnosis.

5.8 Training Requirements

5.8.1 Training Environment

Hardware Limitations
Given the training will be done on our personal computers (see section 4.1) we might face extended training times depending on the size of the dataset and the complexity of the model.

Hardware
- **Faculty Server:** s3090a
- **GPU:** 2 x RTX 3090
- **CPU:** Xeon w5-2455X @ 3.2 GHz
- **RAM:** 128GB

Software
- **Operating Systems:** Windows, MacOS, Linux.
- **AI Packages:** PyTorch and TorchXrayVision.
- **Other Libraries:** OpenCV, Scikit-learn, Tabulate, Scikit-image, Flask, Grad-CAM Pandas

5.8.2 Dataset

Like mentioned in section 3.4, we have identified multiple datasets from various trusted sources. We will use the MIMIC dataset to train our model since it is a great source due to the scale, high image resolution, accurate annotations and pathological diversity. This dataset is also commonly used in research which makes it optimal for benchmark analysis. Furthermore, the TorchXRayVision library provides pre trained models on this dataset as well as other extensively used ones, which makes it an excellent choice for benchmarking.

Data Preprocessing
- Implement a 70% training, 10% validation, and 20% testing split.
- Convert DICOM images to Tensors for model training.

5.8.3 Training Procedure

Model training will be done on 70% of the dataset while never training on the remaining 30%. The 10% validation set will be used to evaluate the accuracy of our model during the training. The remaining 20% will be used to determine the final accuracy of our model and will only be tested once with no further training taking place.

Evaluation Metrics: ROC curve, precision, recall, F1 score.

Given our hardware constraints, we aim to frequently backup data and model checkpoints. Regular evaluations and constant resource monitoring will be practiced to ensure smooth training.

5.9 Testing

5.9.1 Testing Environment

Our hardware and software infrastructure is that of training (section 5.8.1).

5.9.2 Testing Methodology

As mentioned in the previous section, 20% of the dataset will be used to determine the final accuracy of our model and will only be tested once with no further training taking place. Evaluation Metrics include ROC curve, precision, recall, F1 score.

5.9.3 Testing Data

Testing will be completed on the 20% testing set and will be evaluated on ROC curve, precision, recall, F1 score.

5.9.4 Performance Metrics

We expect our model to perform at a certain base accuracy. To be specific, the following metrics are the minimum for each of their respective tasks:

- **Scanning & Reporting:** Analyze & report a DICOM image in <10 seconds.
- **Area Under ROC:** >80-92% depending on disease (see 4.2 P0) for disease detection.

5.9.5 Evaluation Methods

We will use a multitude of evaluation methods, and make iterative changes to our model to ensure our accuracy requirements are met. We will make use of the following methods and metrics for evaluation:

- **Metrics:** Precision, recall, F1-score, and AUC.
- **Visualization:** ROC curves for comprehensive understanding.
- **Error Analysis:** Prioritize understanding false negatives reducing them.
- **Baseline Comparison:** Evaluate the model's performance against baseline or previous models to understand its relative efficiency.

Integrating these testing methods and frameworks will ensure the accuracy and efficiency of our model to facilitate smooth operation in a hospital setting.

6.0 Risks & Predicted Issues

6.1 Risks

- When working with AI models there is a risk that the model produces false negatives or false positives due to the fact that it is hard to get 100% accuracy when working with an AI model.

- There is a potential security risk if we decide to use AWS to simulate a PACS server since security cannot always be guaranteed when using an external source.
- The training data used to develop the AI model might be biased, resulting in disparities in disease detection among different demographic groups.
- Image quality is another constraint we may face while working on this project. Even when images are in DICOM format it is possible to have “bad X-ray images” and they need to be ruled out.

6.2 Predicted Issues

- It is known that it is difficult to create an AI model that can detect changes in X-rays over time with high accuracy. With this known fact we predict that it may be difficult to create a highly accurate AI model that can detect changes in X-rays.
- We predict that It is going to be difficult to simulate a PACS server on AWS in the future since we don’t know all of the internal details of implementing a PACS server.