FDA Submission

Your Name: Sascha Metzger

Name of your Device: Chest X-Rays Pneumonia Detector

Algorithm Description

1. General Information

Intended Use Statement: Help Radiologists in detecting Pneumonia in Chest X-Rays

Indications for Use:

- Applicable for men and women from 1 to 90 years old
- Chest X-Ray image must be taken in the AP or PA position
- Chest X-Ray image must be in DICOM format

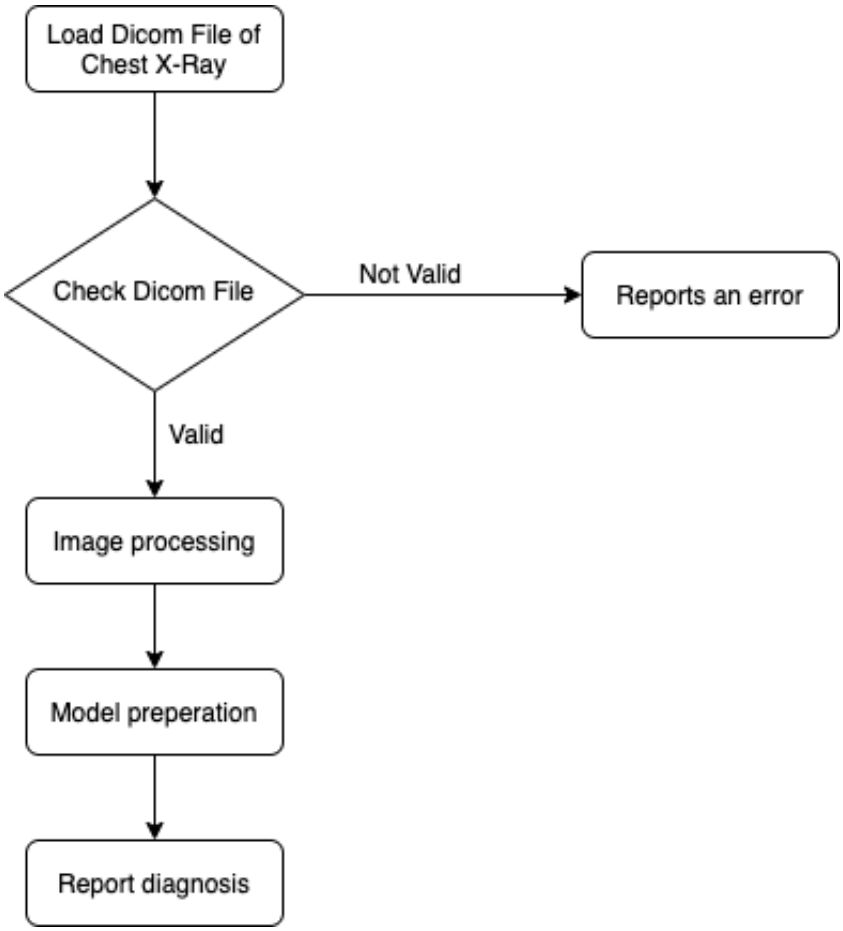
Device Limitations:

- Diagnosis can be made on a computer with a standard CPU, although a GPU is preferred

Clinical Impact of Performance:

- The model has a lower precision and higher recall
- This means the model is most confident when the test result is negative
- Therefore it is best used for worklist prioritization and not as a diagnosis tool

2. Algorithm Design and Function



DICOM Checking Steps:

- Modality is "DX"
- Body part examined is "CHEST"
- Patient Position is "PA" or "AP"

Preprocessing Steps:

- Image is normalized
- Image is reshaped
- Image is repeated across 3 channels

CNN Architecture:

```
Model: "sequential_4"
_________________________________________________________________
Layer (type)                 Output Shape              Param #
=================================================================
model_4 (Model)              (None, 7, 7, 512)         14714688
_________________________________________________________________
flatten_4 (Flatten)          (None, 25088)             0
_________________________________________________________________
dropout_11 (Dropout)         (None, 25088)             0
_________________________________________________________________
dense_11 (Dense)             (None, 1024)              25691136
_________________________________________________________________
dropout_12 (Dropout)         (None, 1024)              0
_________________________________________________________________
dense_12 (Dense)             (None, 512)               524800
_________________________________________________________________
dropout_13 (Dropout)         (None, 512)               0
_________________________________________________________________
dense_13 (Dense)             (None, 256)               131328
_________________________________________________________________
dropout_14 (Dropout)         (None, 256)               0
_________________________________________________________________
dense_14 (Dense)             (None, 1)                 257
=================================================================
Total params: 41,062,209
Trainable params: 28,707,329
Non-trainable params: 12,354,880
```

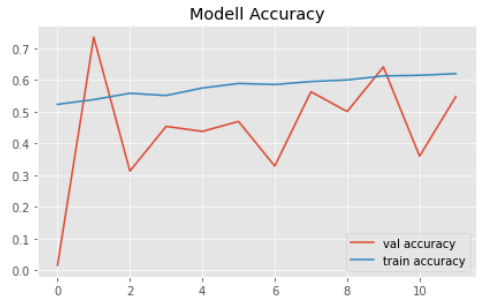
- The model is based on the VGG16 model
- The model uses the first 17 layers of the VGG16 model
- The VGG16 model output is flattened and passed through several additional dense and dropout layers

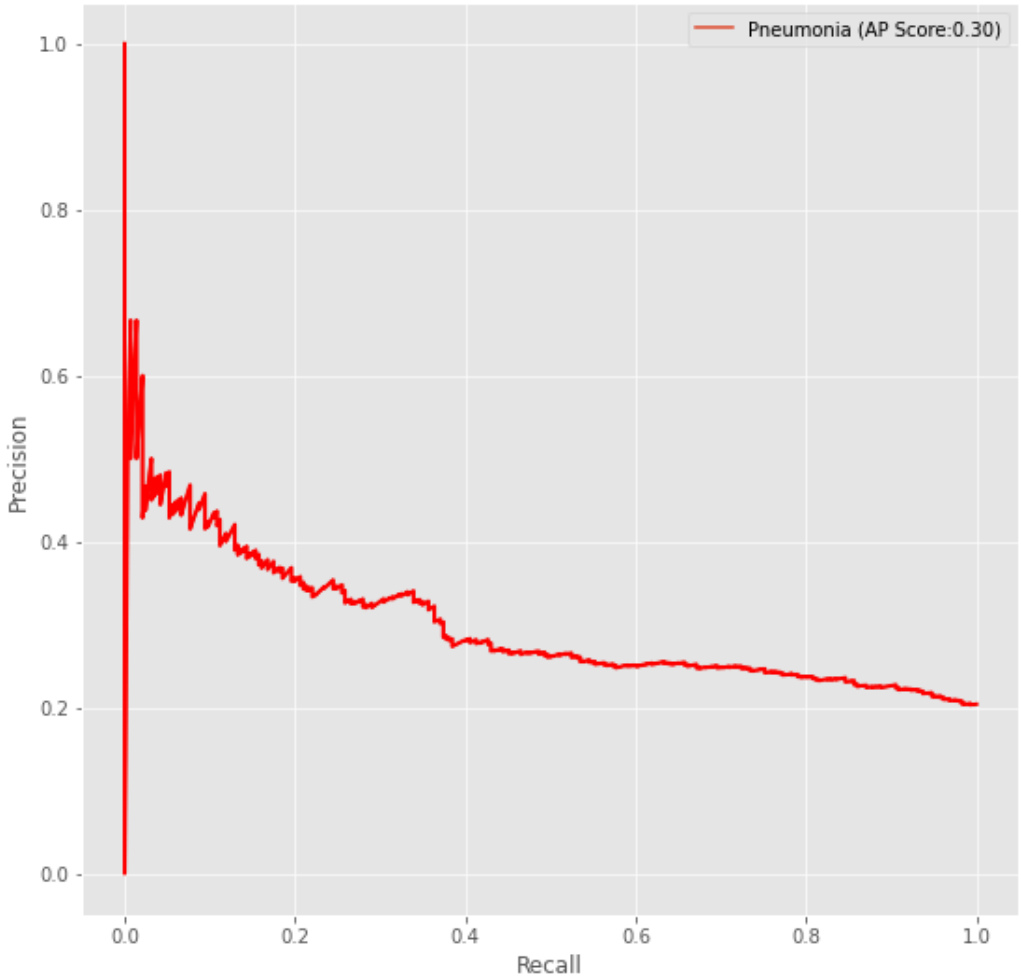
3. Algorithm Training

Parameters:

- Types of augmentation used during training
  - Horizontal flips
  - No Vertical flip s
  - Height shift range of 0.1,
  - Width shift range of 0.1,
  - Rotation range of 25,
  - Shear range of 0.1,
  - Zoom range of 0.15
- Batch size: 64
- Optimizer learning rate: 1e-4
- Layers of pre-existing architecture that were frozen: First 17 layers of VGG model

- Layers of pre-existing architecture that were fine-tuned: None
- Layers added to pre-existing architecture: Flatten, Dense and Dropout layers





Final Threshold and Explanation:

- Threshold: 0.5111328
- F1 Score: 0.3713298791018998

The final threshold of 0.51 was based on the highest F1 Score of 0.37. Based on this paper the average radiologist has a F1 Score of 0.387. This means this model achieved nearly the same performance as the average radiologist.

4. Databases

- The Dataset can be found here: NIH Chest X-ray Dataset
- It contains 112,120 chest x-ray images
- Each image has the following meta data:
  - Image Index
  - Finding Labels
  - Follow-up #
  - Patient ID
  - Patient Age
  - Patient Gender
  - View Position
  - Original Image Size
  - Original Image Pixel Spacing

Description of Training Dataset:

- The training data is split equally between Pneumonia and non Pneumonia patients
- It contains 2290 images

Description of Validation Dataset:

- The training data has 20% Pneumonia and 80% non Pneumonia patients
- It contains 1430 images

5. Ground Truth

- 112,120 X-ray images with disease labels from 30,805 unique patients
- The disease labels were created using Natural Language Processing (NLP) to mine the associated radiological reports
- The labels are expected to be >90% accurate and suitable for weakly-supervised learning
- The data includes 14 common thoracic pathologies:
  - Atelectasis
  - Consolidation
  - Infiltration
  - Pneumothorax

- Edema
- Emphysema
- Fibrosis
- Effusion
- Pneumonia
- Pleural thickening
- Cardiomegaly
- Nodule
- Mass
- Hernia

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

- Applicable for men and women from 1 to 90 years old
- Chest X-Ray image must be taken in the AP or PA position
- Chest X-Ray image must be in DICOM format

Ground Truth Acquisition Methodology:

- Silver Standard: Validation by 3 different radiologists

Algorithm Performance Standard:

- The algorithm's F1 score should be more than that of average radiologist (0.387)