# FDA Submission

**Your Name:** Fatma El Zahraa Samir

**Name of your Device:** Pneumonia Detector from Chest X-ray

## Algorithm Description

### 1. General Information

**Intended Use Statement:**

Assisting the rediological diagnosis of presence or absence of pneumonia from chest X-rays with the view positions  of AP and PA

**Indications for Use:**

Reduce the time of radiological diagnosis in chest X-ray:

- Both men and women
- Age: 1 to 90

X-Ray image properties:

- Body part: Chest
- Position: AP (Anterior/Posterior) or PA (Posterior/Anterior)
- Modality: DX (Digital Radiography)

**Device Limitations:**

The model is recommended for use without following comorbid thoracic pathologies:

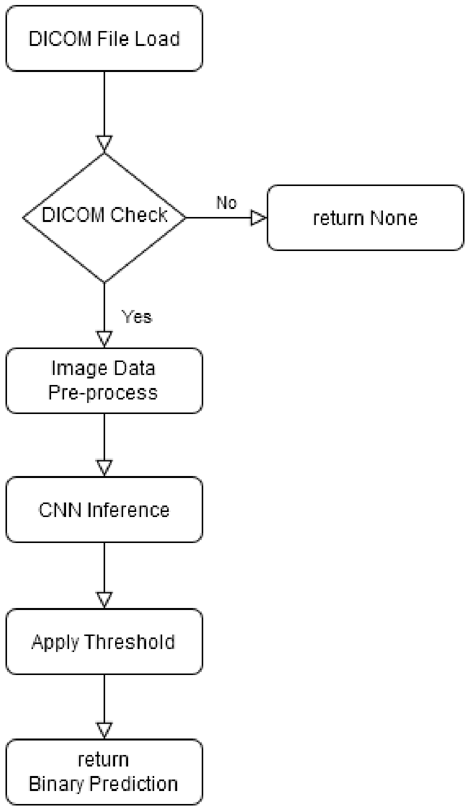
- Consolidation
- Edema
- Effusion
- Hernia

- because that can decrease the performance of the model as the pixel intensity distribution is quite similar to the pneumonia one and the algorithm will not be able to identify pneumonia correctly.
- The system required high computing power computer or cloud-based service, and a digital scan of chest X-ray.

**Clinical Impact of Performance:**

- False Negatives mean the patient who has Pneumonia is diagnosed as healthy and may lead to missing treatment.
- False Positives mean the patient who is healthy is diagnosed with Pneumonia and may lead to unnecessary check of the radiologist
- In this situation, False Negative is worst than False Positive.

## 2. Algorithm Design and Function




**DICOM Checking Steps**

pydicom library is used to obtain the data from DICOM image. The algorithms first:

- Check Patient Age is between 1 and 90 (inclusive)
- Check Examined Body Part is 'CHEST'
- Check Patient Position is either 'PA' (Posterior/Anterior) or 'AP' (Anterior/Posterior)
- Check Modality is 'DX' (Digital Radiography)

If the DICOM does not meet all these criterias, the X-ray will not be assessed.

### Preprocessing Steps

The algorithm performs the following preprocessing steps on an image data:

- Converts RGB to Grayscale (if needed)
- Re-sizes the image to 244 x 244 (as required by the CNN)
- Normalizes the intensity to be between 0 and 1 (from original range of 0 to 255)

### CNN Architecture

The CNN architecture is taken from VGG16 with transfer learning

Below is the CNN architecture graph:

```
Model: "model_1"
_________________________________________________________________
Layer (type)                 Output Shape              Param #
=================================================================
input_1 (InputLayer)         (None, 224, 224, 3)       0
_________________________________________________________________
block1_conv1 (Conv2D)        (None, 224, 224, 64)      1792
_________________________________________________________________
block1_conv2 (Conv2D)        (None, 224, 224, 64)      36928
_________________________________________________________________
block1_pool (MaxPooling2D)   (None, 112, 112, 64)      0
_________________________________________________________________
block2_conv1 (Conv2D)        (None, 112, 112, 128)     73856
_________________________________________________________________
block2_conv2 (Conv2D)        (None, 112, 112, 128)     147584
_________________________________________________________________
block2_pool (MaxPooling2D)   (None, 56, 56, 128)       0
_________________________________________________________________
block3_conv1 (Conv2D)        (None, 56, 56, 256)       295168
_________________________________________________________________
block3_conv2 (Conv2D)        (None, 56, 56, 256)       590080
_________________________________________________________________
block3_conv3 (Conv2D)        (None, 56, 56, 256)       590080
_________________________________________________________________
block3_pool (MaxPooling2D)   (None, 28, 28, 256)       0
_________________________________________________________________
block4_conv1 (Conv2D)        (None, 28, 28, 512)       1180160
_________________________________________________________________
block4_conv2 (Conv2D)        (None, 28, 28, 512)       2359808
_________________________________________________________________
block4_conv3 (Conv2D)        (None, 28, 28, 512)       2359808
_________________________________________________________________
block4_pool (MaxPooling2D)   (None, 14, 14, 512)       0
_________________________________________________________________
block5_conv1 (Conv2D)        (None, 14, 14, 512)       2359808
_________________________________________________________________
block5_conv2 (Conv2D)        (None, 14, 14, 512)       2359808
_________________________________________________________________
block5_conv3 (Conv2D)        (None, 14, 14, 512)       2359808
_________________________________________________________________
block5_pool (MaxPooling2D)   (None, 7, 7, 512)         0
=================================================================
Total params: 14,714,688
Trainable params: 2,359,808
Non-trainable params: 12,354,880
_________________________________________________________________
```

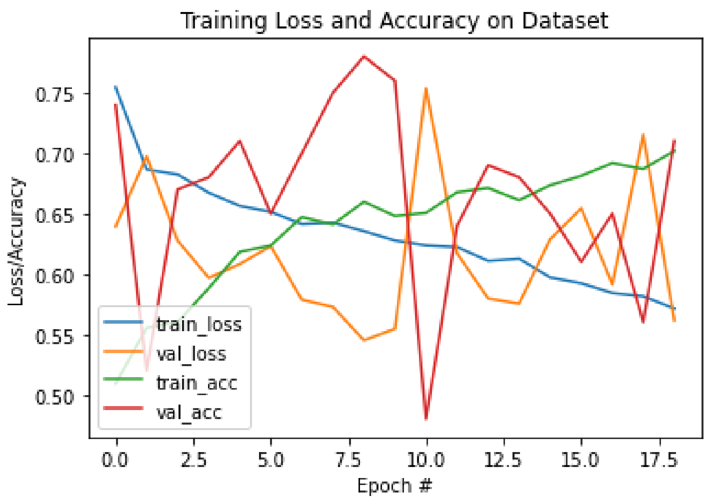
```
Model: "sequential_1"
_________________________________________________________________
Layer (type)                 Output Shape              Param #
=================================================================
model_1 (Model)              (None, 7, 7, 512)         14714688
_________________________________________________________________
flatten_1 (Flatten)          (None, 25088)             0
_________________________________________________________________
dense_1 (Dense)              (None, 512)               12845568
_________________________________________________________________
dropout_1 (Dropout)          (None, 512)               0
_________________________________________________________________
dense_2 (Dense)              (None, 128)               65664
_________________________________________________________________
dropout_2 (Dropout)          (None, 128)               0
_________________________________________________________________
dense_3 (Dense)              (None, 1)                 129
=================================================================
Total params: 27,626,049
Trainable params: 15,271,169
Non-trainable params: 12,354,880
_________________________________________________________________
```

## 3. Algorithm Training

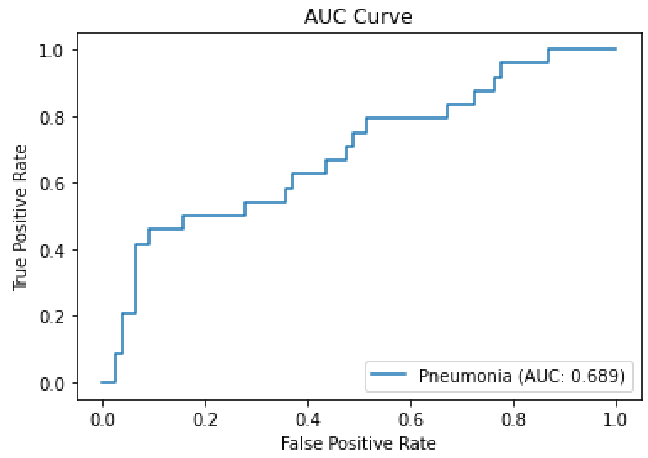
**Parameters:**

- Types of augmentation used during training:
  - horizontal flip: True
  - height shift: 0.1
  - width shift: 0.1
  - rotation angle range: 0 to 20 degrees
  - shear: 0.1
  - zoom: 0.1
- Batch size: 30
- Optimizer learning rate: 1e-4
- Layers of pre-existing architecture that were frozen: block5_pool
- Layers of pre-existing architecture that were fine-tuned: output layer
- Layers added to pre-existing architecture: flatten, dense, dropout

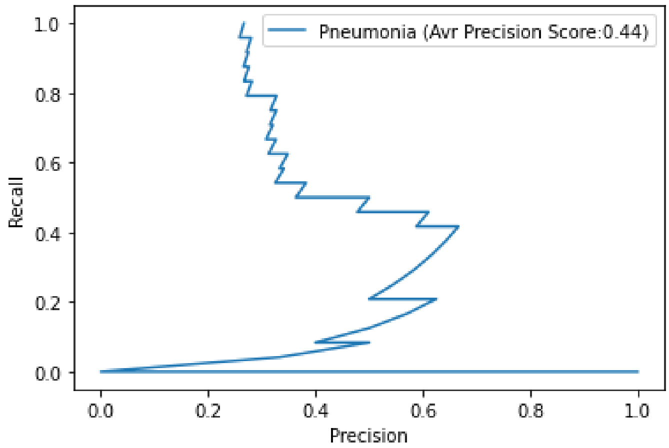
**Algorithm training performance visualization**



AUC (Area Under the Curve) ROC (Receiver Operating Characteristics) curve

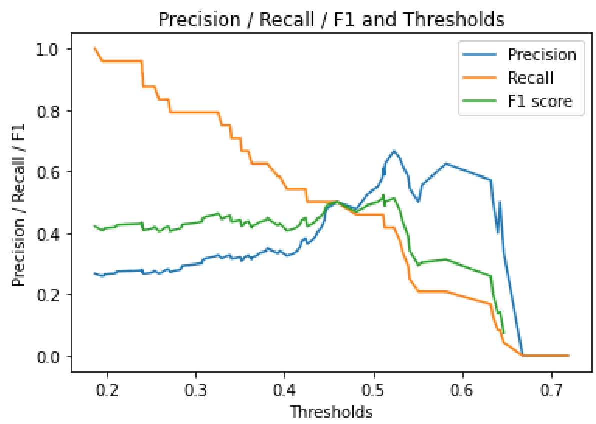



Precision-Recall curve




**Final Threshold and Explanation:**

To have balance between precision and recall, I choose to threshold 0.511 to have maximum F1: 0.5238



## 4. Databases

Datasets are part of the NIH chest X-rays database

**Description of Training Dataset:**

Training dataset consisted of 2290 chest xray images, with a 50/50 split between positive and negative cases.

Example images:

**Description of Validation Dataset:**

Validation dataset consisted of 1430 chest xray images, with 20/80 split between positive and negative cases, which more reflects the occurence of pneumonia in the real world.

## 5. Ground Truth

The groundtruth is NLP-derived labeling with the estimation of accuracy around 90%

## 6. FDA Validation Plan

**Patient Population Description for FDA Validation Dataset:**

The following population subset is to be used for the FDA Validation Dataset:

- Both men and women
- Age 2 to 90
- Without known comorbid thoracic pathologies listed above

The patient may exihibit the following comorbid with Pneumonia: Atelectasis, Cardiomegaly, Consolidation, Edema, Effusion, Emphysema, Fibrosis, Hernia, Infiltration, Mass, Nodule, Pleural_Thickening, Pneumonia, Pneumothorax.

The X-Ray Dicom file should has the following properties: Patient Postition: AP or PA; Image Type: DX; Body Part Examined: CHEST

**Ground Truth Acquisition Methodology:**

The silver standard of radiologist reading

**Algorithm Performance Standard:**

CheXNet on the same dataset obtained a F1 score of 0.435. The metric is used was the binary cross entropy loss to train the model. The algorithm obtained a F1 score of 0.0.52 which is better than the performance score of the radiologists with an average.

| | F1 Score (95% CI) |
|---|---|
| Radiologist 1 | 0.383 (0.309, 0.453) |
| Radiologist 2 | 0.356 (0.282, 0.428) |
| Radiologist 3 | 0.365 (0.291, 0.435) |
| Radiologist 4 | 0.442 (0.390, 0.492) |
| Radiologist Avg. | 0.387 (0.330, 0.442) |
| CheXNet | 0.435 (0.387, 0.481) |