FDA Submission

Your Name: Le Ngoc Anh

Name of your Device: X-Ray Pneumonia Analyzer

Algorithm Description

1. General Information

Intended Use Statement: Support radiologist to detect the presence or absence of pneumonia from Chest X-ray image

Indications for Use: This algorithm is intended for use both man and woman from the ages of 1-95 who have taken X-Rays image of Chest on PA (Posteroanterior) or AP (Anteroposterior) position.

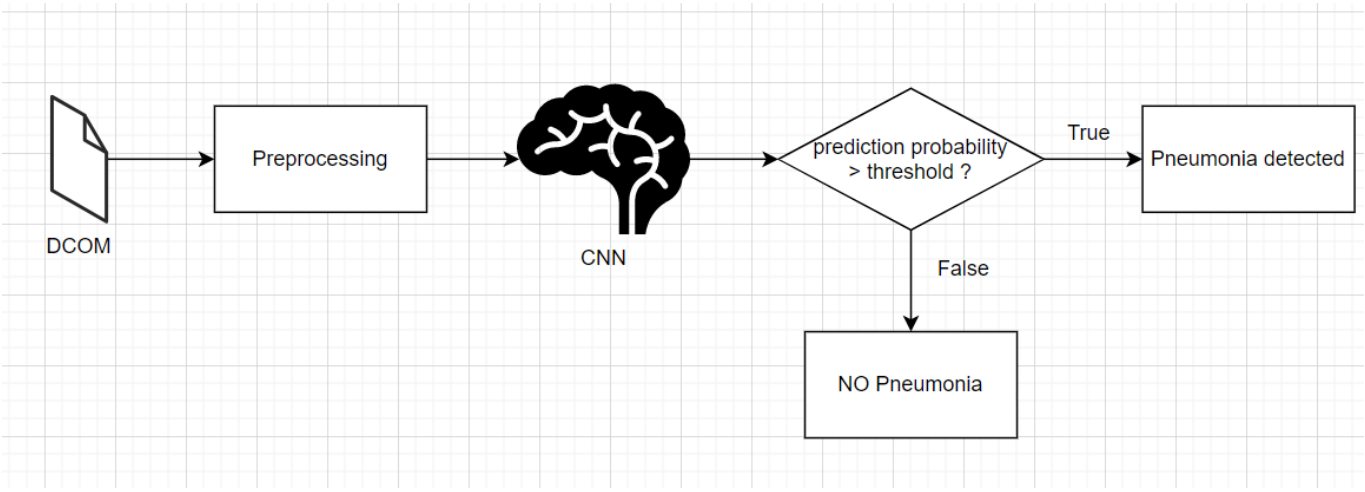
Device Limitations:

- This device is intended only for the analysis of chest X-ray images PA (Posteroanterior) or AP (Anteroposterior) position
- Image resolution is 224x224 pixels
- The model is designed specifically to detect pneumonia only and may not reliably detect other diseases on the chest X-Rays image

Clinical Impact of Performance:

- This model support radiologist to reduce the diagnostic time to detect pneumonia on chest x-rays image

2. Algorithm Design and Function



DICOM Checking Steps:

- The file extention is .dcm
- Can read the file using pydicom.dcmread
- the image is at pixel_array

Preprocessing Steps:

- Use ImageDataGenerator for Preprocessing

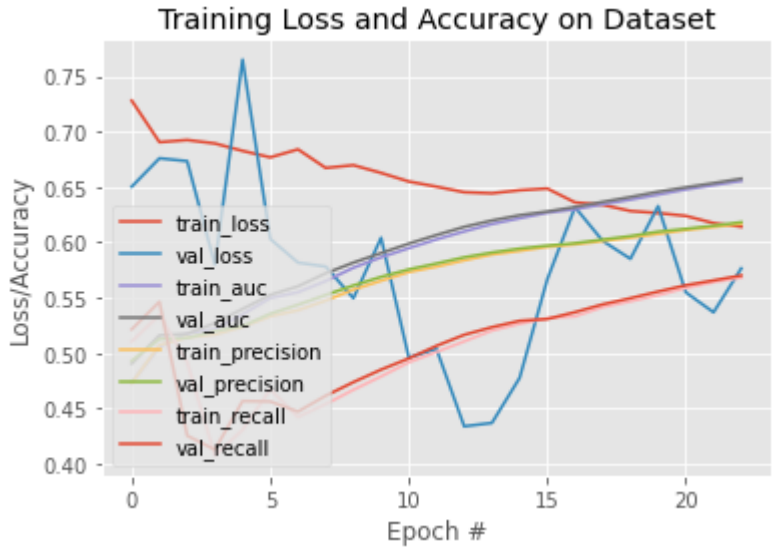
CNN Architecture:

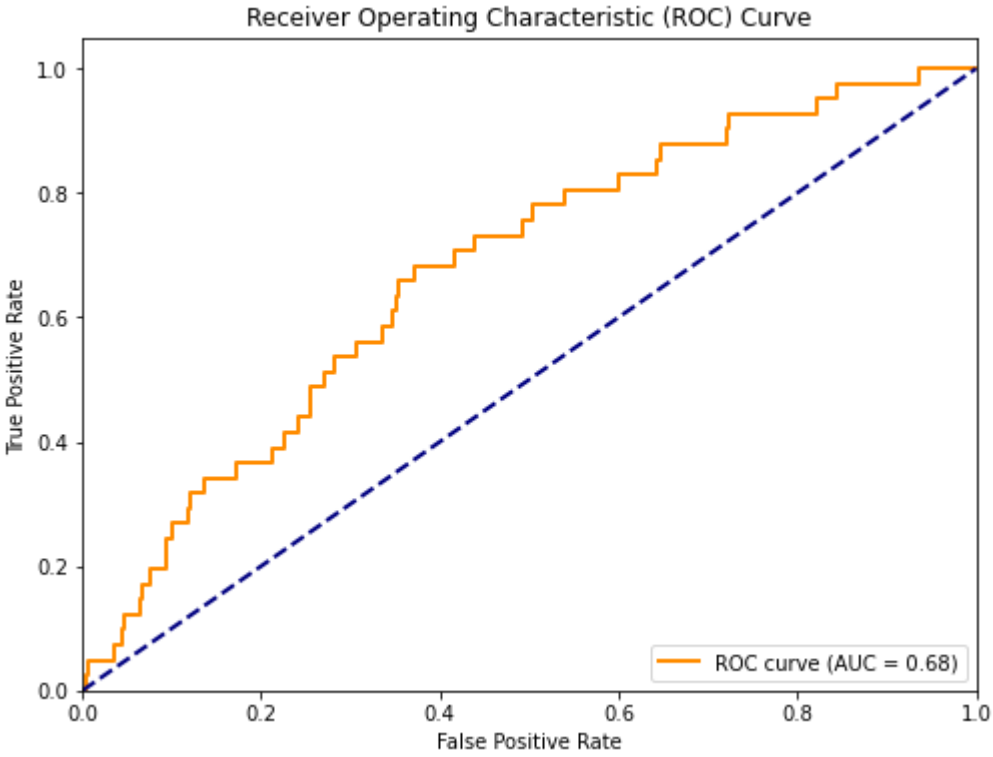
- refer to "my_model.json"

3. Algorithm Training

Parameters:

- Types of augmentation used during training:
  ImageDataGenerator with
  horizontal_flip = True,
  vertical_flip = False,
  height_shift_range= 0.1,
  width_shift_range=0.1,
  rotation_range=20,
  shear_range = 0.1,
  zoom_range=0.1
- Batch size : 16
- Optimizer learning rate: Adam(lr=1e-4)
- Layers of pre-existing architecture that were frozen: vgg_model.layers[0:15]
- Layers of pre-existing architecture that were fine-tuned: vgg_model.layers[15:]
- Layers added to pre-existing architecture new_model.add(Flatten())
  new_model.add(Dropout(0.5))
  new_model.add(Dense(1024, activation='relu'))
  new_model.add(Dropout(0.5))
  new_model.add(Dense(512, activation='relu'))
  new_model.add(Dropout(0.5))
  new_model.add(Dense(256, activation='relu'))
  new_model.add(Dense(1, activation='sigmoid'))





Final Threshold and Explanation: The Threshold is caculated to have the best F1 score

4. Databases

(For the below, include visualizations as they are useful and relevant)

Description of Training Dataset:

- Trainging dataset has 2290 records
- 50% records in training dataset is labeled pneumonia

Description of Validation Dataset:

- Validation dataset has 22424 records
- 286 record is labeled pneumonia

5. Ground Truth

The authors used Natural Language Processing to text-mine disease classifications from the associated radiological reports. The labels are expected to be >90% accurate

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

- Patient age is 1-95 years
- Balance distribution between male and female
- Balance PA and AP view position

Ground Truth Acquisition Methodology: The ground truth for pneumonia use Natural Language Processing to text-mine disease classifications from the associated radiological reports. The labels are expected to be >90% accurate

Algorithm Performance Standard: The best threshold is 0.7964839 has precision 5% and recall 7%