FDA Submission

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Name of your Device: Pneudet 100

Algorithm Description

1. General Information

Intended Use Statement:

This algorithm is intended for use on men and women from age of 1 to 95 who have know lung diseases or have existing diseases one or combination of atelectasis, cardiomegaly, consolidation, edema, effusion, emphysema, fibrosis, hernia, infiltration, mass, nodule, pleural_thickening, pneumonia and pneumothorax.

Indications for Use:

Screening for pneumonia to assist radiologists in non-emergency scenario.

Device Limitations:

Minimum computer specification for the software is 2-core CPU, 16 GB RAM and 32GB disk.

Clinical Impact of Performance:

The algorithm was designed to have higher recall which means there may be more false positive. This means it is more likely for the algorithm to classify a non-pneumonia xray image as containing pneumonia. The algorithm can also produce false negative result where xray image with pneumonia may be classified as not having pneumonia.

2. Algorithm Design and Function

The algorithm uses deep neural network called CNN (Convolutional Neural Network) to classify the present of pneumonia from X-ray scans. The algorithm flow is:

- Image pre-processing
- Feed image into CNN to get output
- If the CNN output exceeds confidence threshold, the image is classified as positive with pneumonia.

DICOM Checking Steps:

DICOM is checked to contain ensure only Xray images of chest are used.

Preprocessing Steps:

Grayscale image is resized to dimension of 224 rows, 224 columns, and converted to 3 color channels. The image pixel values are normalized from [0, 255] to between range of [0,1]

CNN Architecture:

The base network is Resnet50 pre-trained on Imagenet data, followed by:

- Batchnormalization
- Convolutional layer, 1x1 kernel, 1024 filters, stride=1, relu activation

- Dropout
- Batchnormalization
- Convolutional layer, 1x1 kernel, 256 filters, stride=1, relu activation
- Dropout
- Average pooling of 7x7
- Batchnormalization
- Convolutional layer, 1x1 kernel, 1 filters, stride=1, sigmoid activation
- Reshape to [batch_size, 1]

3. Algorithm Training

Parameters:

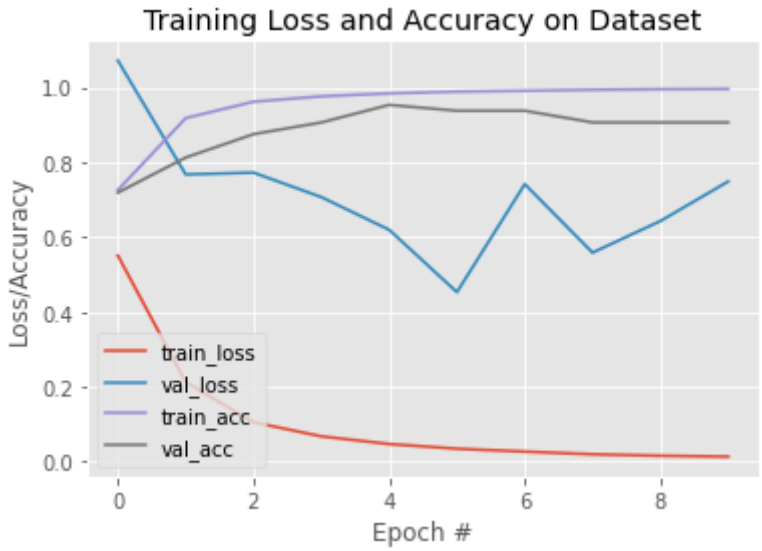
- Types of augmentation used during training, applied only to training dataset
    - random height shift of up to +-15% of images height
    - random width shift of up to +-15% of images height
    - random rotation of +-25 degrees
    - random sheer transformation of up to +-10%
    - random zoom of up to +-10%
- Batch size = 64
- Optimizer learning rate = 0.0001 with decrease of 10% in every epoch after second epoch
- Layers of pre-existing architecture that were frozen.

  None
- Layers of pre-existing architecture that were fine-tuned

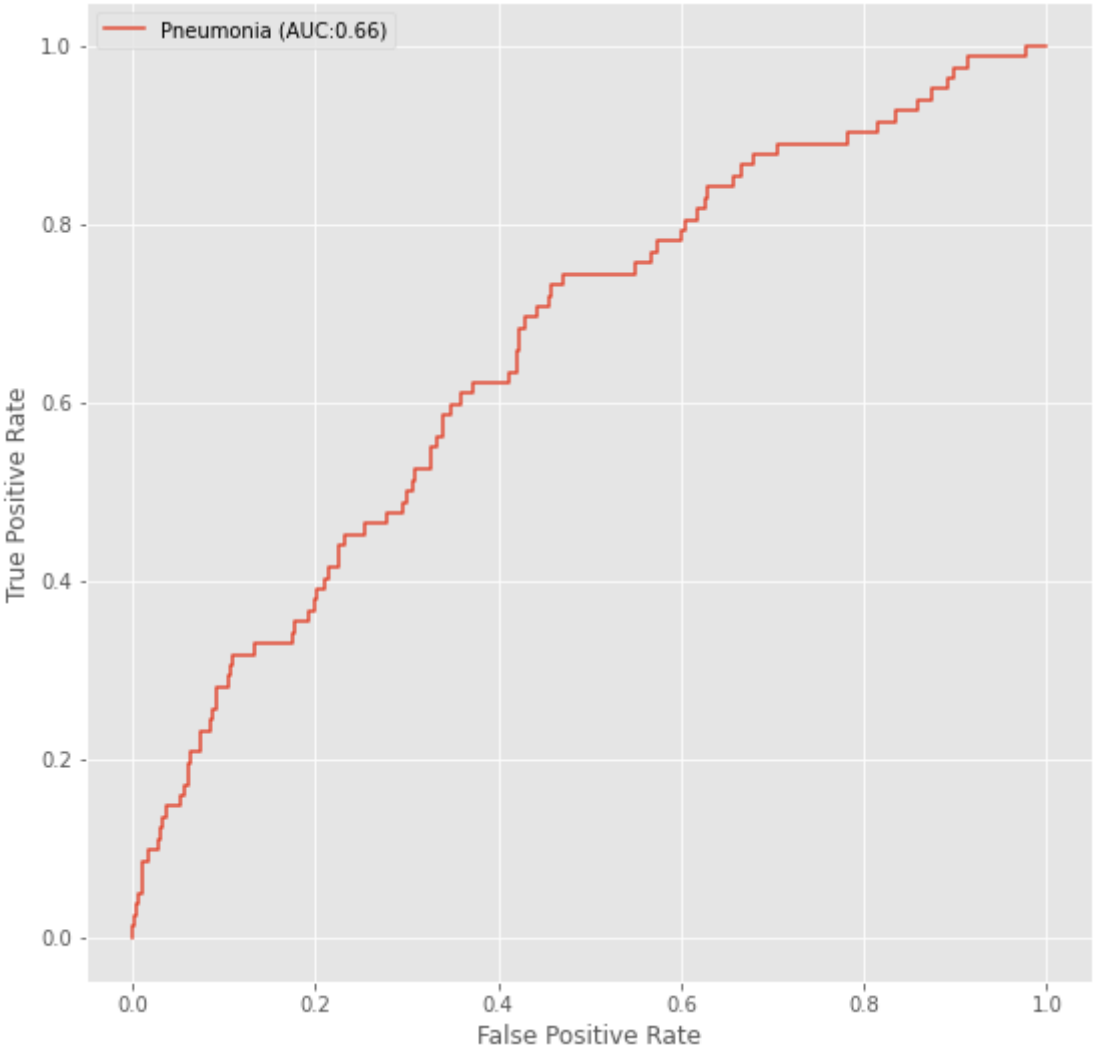
  All layers.
- Layers added to pre-existing architecture

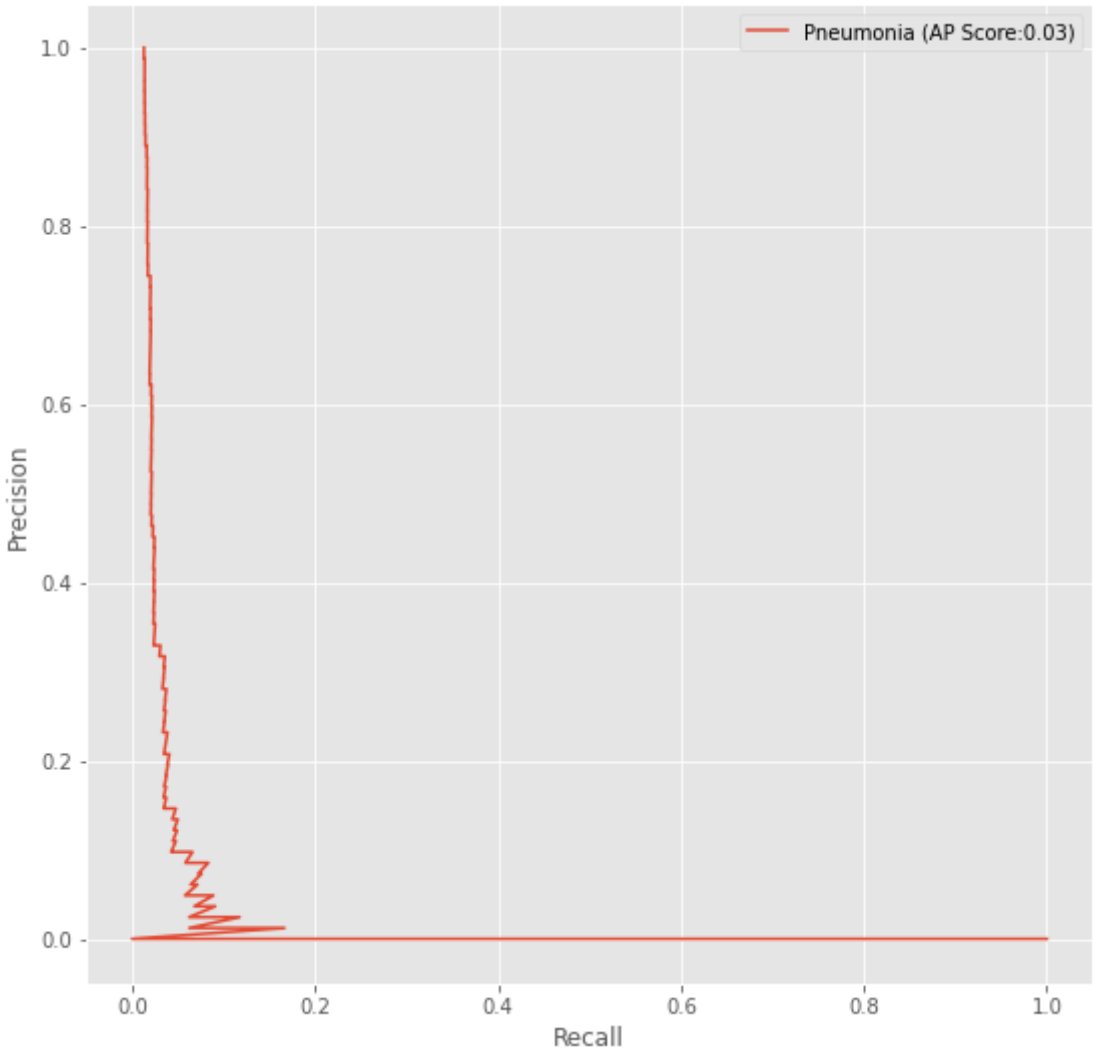
  As described in above.

<< Insert algorithm training performance visualization >>



<< Insert P-R curve >>


Pneumonia (AUC:0.66)
True Positive Rate
False Positive Rate
0.0
0.2
0.4
0.6
0.8
1.0



Final Threshold and Explanation:

The threshold of 0.1 is selected to have higher recall.

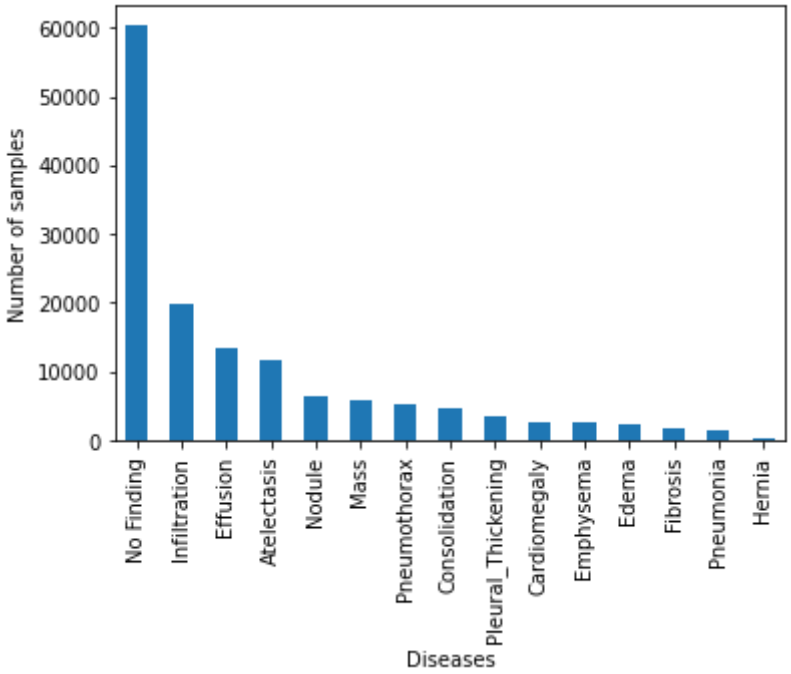
4. Databases

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

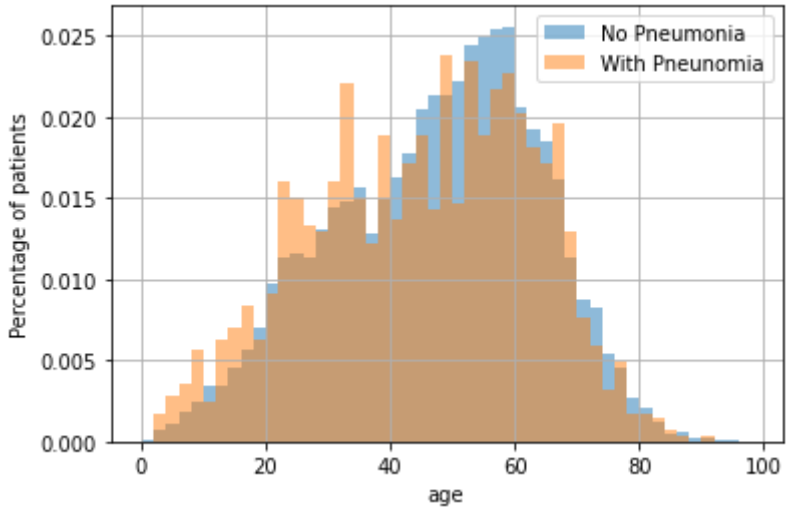
The dataset is obtained from kaggle website that contains 112,120 frontal-view chest X-ray PNG images in 1024*1024 resolution and include 14 common thoracic pathologies:

- Atelectasis
- Consolidation
- Infiltration
- Pneumothorax
- Edema
- Emphysema
- Fibrosis
- Effusion
- Pneumonia
- Pleural thickening
- Cardiomegaly
- Nodule
- Mass
- Hernia

Below is the distribution of diseases in the dataset. Please note that they are not mutually exclusive, meaning one patient can have multiple diseases labelled for a x-ray image.



Age distribution for people with and without pneumonia



There are total of 1431 samples with pneumonia and 110689 samples without pneumonia in the dataset. Age distribution of dataset is 56.5% male and 43.5% female.

Description of Training Dataset:

Validation is a 89696 samples contain 50% positive cases of pneumonia and 50% cases with no pneumonia but may or not may not include other diseases. This is sampled with replacement from dataset excluding validation dataset.

Description of Validation Dataset:

Validation is a 22424 samples which contain 1.27% of true positive.

5. Ground Truth

To create these labels, the authors used Natural Language Processing to text-mine disease classifications from the associated radiological reports. The labels are expected to be >90% accurate and suitable for weakly-supervised learning.

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

The sample population should be taken from men and women distributed between the age of 1 and 100 . Image modality shall be Xray image showing chest in both front and back views. The sample can include people with or without prio diagnosis of pneumonia and other lung diseases.

Ground Truth Acquisition Methodology:

X-ray images validated by at least 3 different radiologists.

Algorithm Performance Standard:

Recall score.