FDA_Submission_Template.md

FDA Submission

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Name of your Device: PneumoniaNet

Algorithm Description

1. General Information

Intended Use Statement:
This model is intended for use on men and women from 1 to 85 years old who have no previous illnesses or who have one or a combination of the following diseases: atelectasis, heart enlargement, standardization, edema, effusion, emphysema, fibrosis, hernia, infiltration, mass, Creed, pleura thickening and pneumothorax

Indications for Use:
Screening for pneumonia to assist radiologists in non-emergency situations.

Device Limitations:
Requires at least a computer with 2-cores CPU and 8 GB RAM.

Clinical Impact of Performance:
The algorithm is designed for high recall predictions. This means that when the algorithm predicts positive, the patient is likely to have pneumonia. The algorithm tends to classify many positive cases, which many of them are considered false positive, as patients who have no pneumonia may be classified as having pneumonia. The algorithm will produce few false negatives cases as x-rays with pneumonia will probably be correctly classified.

2. Algorithm Design and Function

The algorithms uses a deep neural network, specifically ResNet50 architecture to classify the presence of pneumonia from x-ray images. The flow starts with image preprocessing where all images are normalized, then the image is fed to the neural network and the network outputs a probability of having pneumonia. If the output probability is higher than a predefined threshold, it is classified as positive.

DICOM Checking Steps:
It is guaranteed that DICOM only contains the following:

- Body Part Examined = CHEST
- Modality = DX
- Patient Position = AP or PA

Preprocessing Steps:
Images are resized to 224x224, converted to RGB color channels and normalized to the range of [0,1]

CNN Architecture: The base network is ResNet50 pre-trained on ImageNet dataset, followed by:

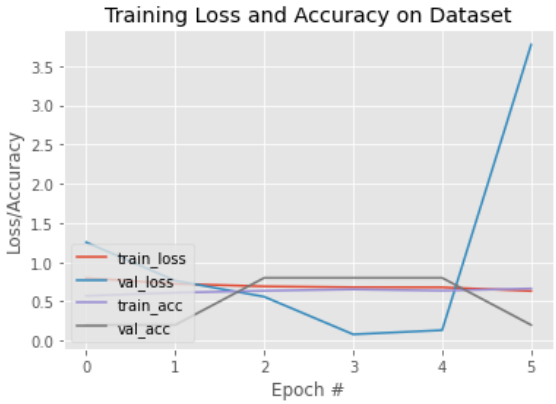
- Batch Normalization
- Conv2d layer with 1x1 kernal, 1024 filters, stride of 1, and relu activation function.
- Dropout of 0.5
- Batch Normalization
- Conv2d layer with 1x1 kernal, 256 filters, stride of 1, and relu activation function.
- Dropout of 0.5

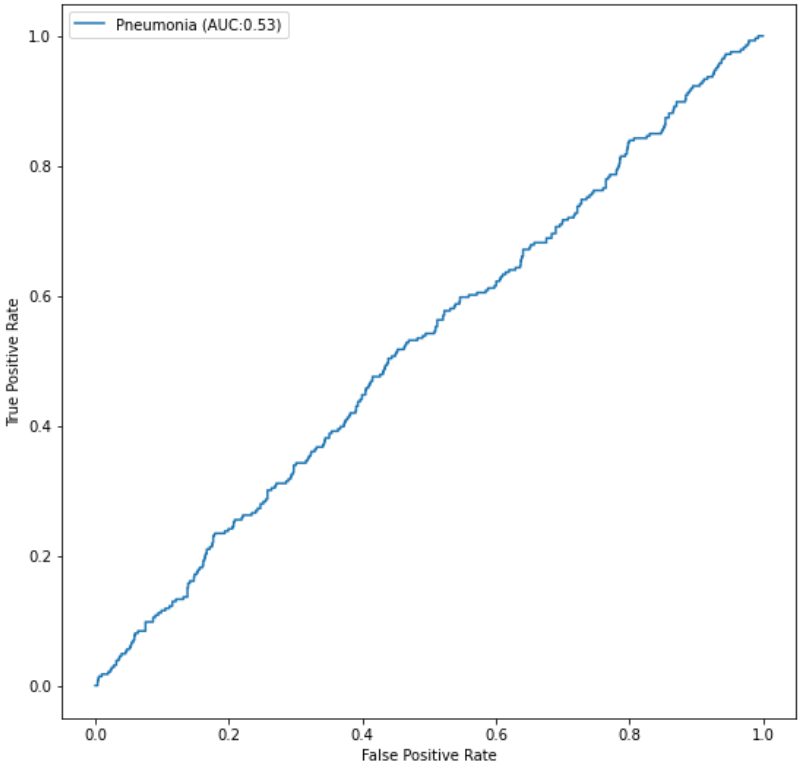
- 7x7 AveragePooling2D layer
- Batch Normalization
- Conv2d layer with 1x1 kernal, 1 filter, stride of 1, and sigmoid activation function.
- Reshape to [batch_size, 1]

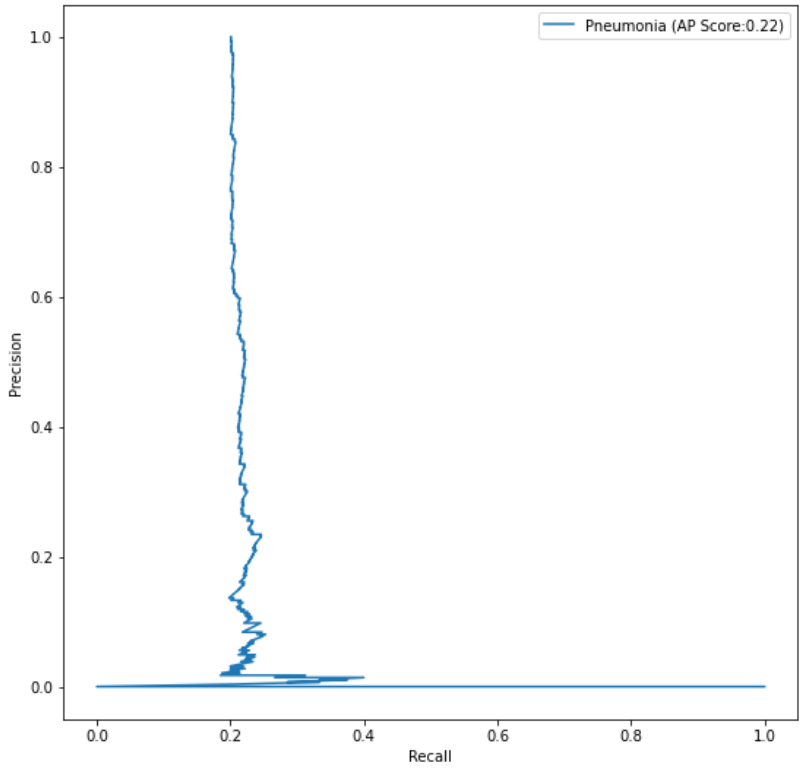
3. Algorithm Training

Parameters:

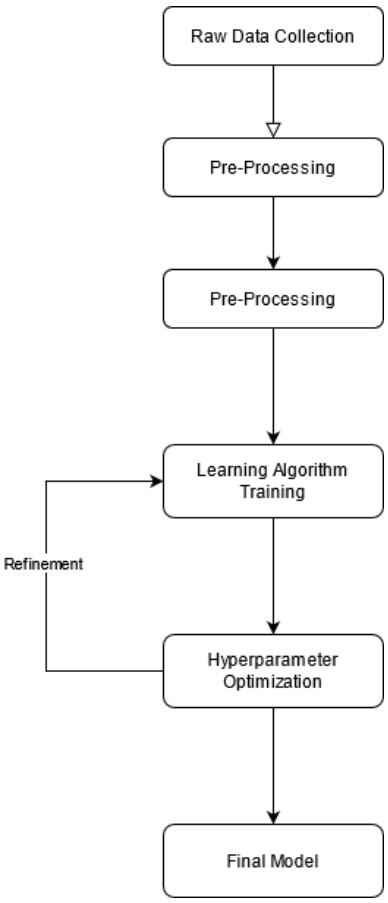
- Types of augmentation used during training
  - Horizontal flip
  - Random height shift of (+/-)10% of the image max.
  - Random width shift of (+/-)10% of the image max.
  - Random rotation shift of (+/-)20 degrees max.
  - Random shear shift of (+/-)10% max.
  - Random zoom of (+/-)10% max.
- Batch size = 64
- Optimizer learning rate = 1e-4
- 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: described above.







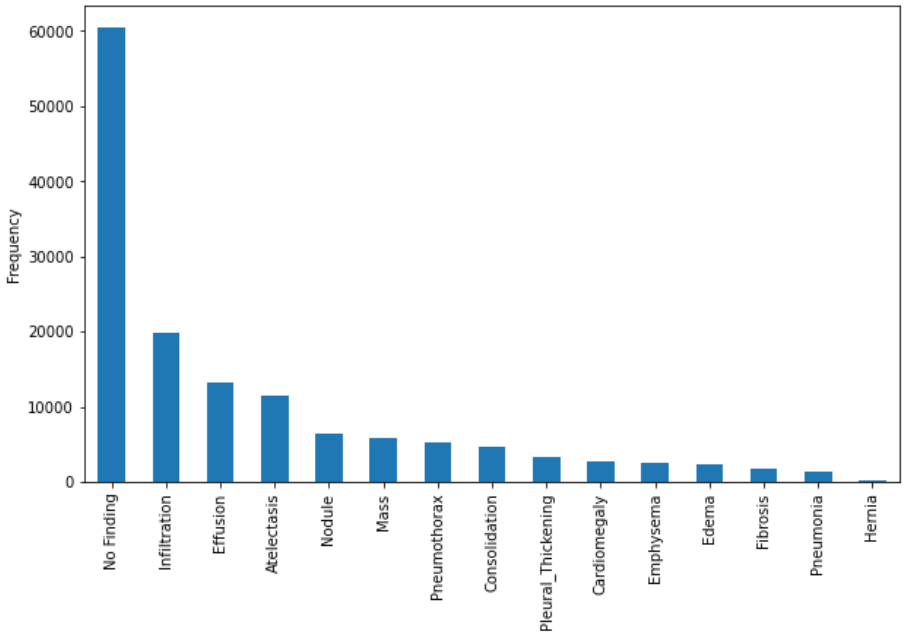
The flowchart of the training process is shown below



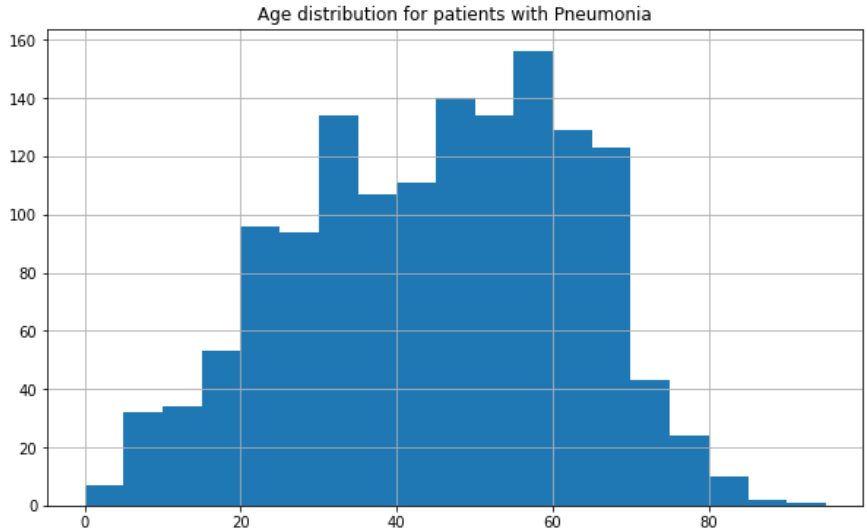
Final Threshold and Explanation:
The final threshold is 0.415 because it gives the highest f1-score

4. Databases

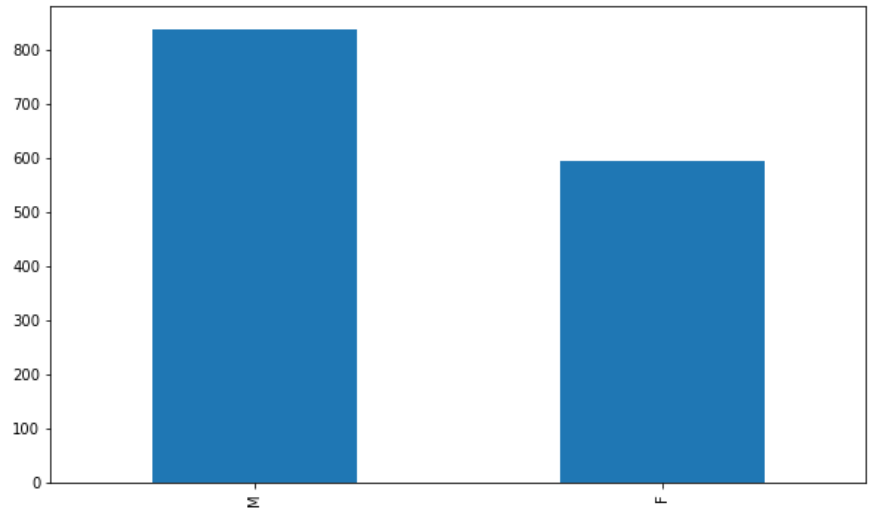
The dataset is obtained from Kaggle. The dataset contains 112,120 chest x-ray images with 1024x1024 resolution. It contains 14 diseases: atelectasis, heart enlargement, standardization, edema, effusion, emphysema, fibrosis, hernia, infiltration, mass, Creed, pleura thickening, pneumothorax, and pneumonia. The figure below shows their distribution. It is to be noted that an image may contain multiple diseases.



The age distribution for people with pneumonia is presented below.



There are 1431 samples with pneumonia and 110689 samples without pneumonia in the dataset. The gender distribution is shown below with 56.5% male and 43.5% female.



Description of Training Dataset: The training dataset is resampled with replacement to have 50% positive cases of pneumonia and 50% with no pneumonia. The total number of images in the training set becomes 2290 images.

Description of Validation Dataset: The validation set has 20% positive cases of pneumonia and 80% with no pneumonia. The total number of images in the validation set is 1430 images.

5. Ground Truth

The labels are obtained using an NLP approach from the radiologist reports. They are expected to be accurate enough.

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:
The sample should be taken from men and women aged 1 to 85 years. The sample can include people with previous lung diseases. X-rays should be for chest only with DX modality.

Ground Truth Acquisition Methodology:
X-ray images are validated by 3 different radiologists.

Algorithm Performance Standard:
Precision: 0.20471281296023564
Recall: 0.972027972027972
Threshold: 0.41545114
F1 Score: 0.3381995133819951