FDA Submission

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Name of Device: Pneumonia Detector 1,000,000

Algorithm Description

1. General Information

Intended Use Statement:
This device is is used to assist a Radiologist in diagnosing pneumonia from x rays of a patient's chest.

Indications for Use:
The device is to be used for prioritizing x rays for evaluation when diagnosing pneumonia.

Device Limitations:
The device is not to be used as a diagnosis tool, as it lacks the accuracy necessary to perform a diagnosis.

Clinical Impact of Performance:
Given a collection of xrays, the tool is used to determine which xrays have highest probability of a positive diagnosis of pneumonia. These xrays can be prioritized for final evaluation by a radiologist, bringing down the average time for pneumonia-positive patients to receive a diagnosis and increases the average time for pneumonia-negative to receive a diagnosis. This allows pneumonia-positive patients to receive treatment faster than they would without the use of the tool.

2. Algorithm Design and Function

Preprocessing Steps:
Before being processed by the tool, xray images must:
- Be resized to 224 x 244 pixels.
- Have the values shifted so they have a mean of 0
- Have an overall standard deviation of 1.

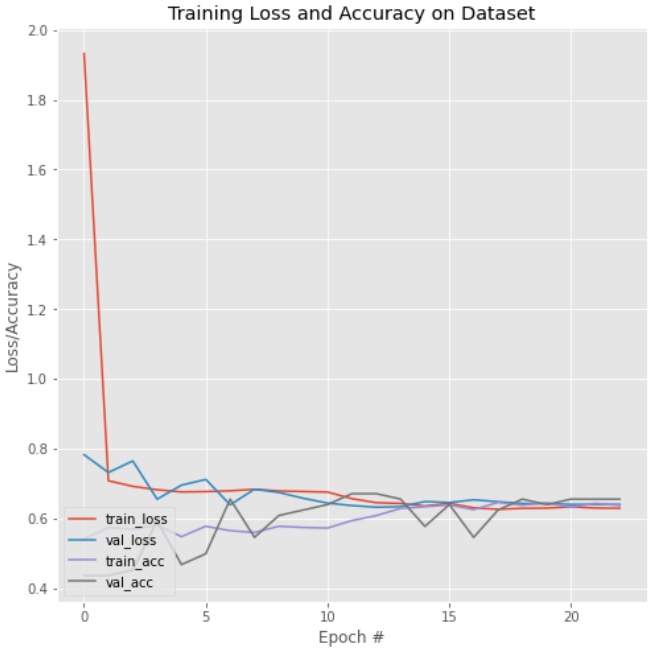
CNN Architecture:
The device uses a variation of the VGG16 image classification model. Transfer learning is applied by removing the last three fully connected layers and replaced they with two fully untrained connected layers. The existing layers from the pre-trained VGG16 model are frozen and the added layers are left unfrozen for training. The output of the tool is a single value between 0 and 1 representing the probability that the given xray is pneumonia positive.

3. Algorithm Training

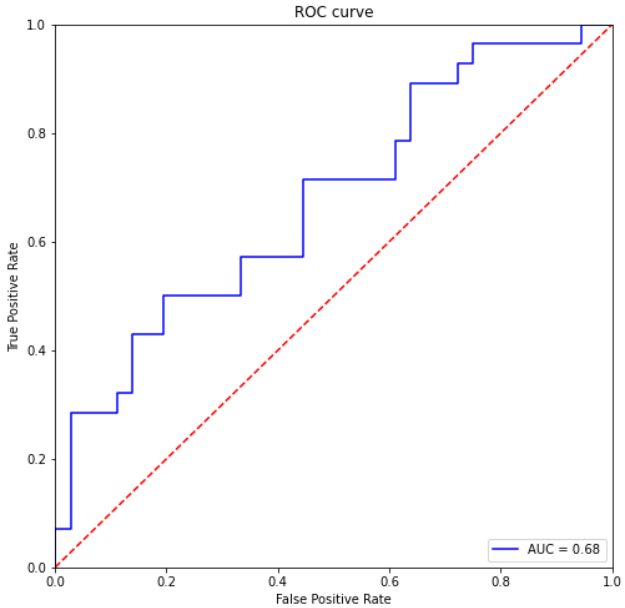
Parameters:
The AI model of the tool was trained using the following parameters.

- A Batch size of 16

- An Optimizer learning rate starting at 0.0001 and decreasing by a factor of 10 until the model effectively stops improving during training.
- The layers from the pre-trained VGG16 model were left frozen that remained unchanged during training.
- No Layers of the pre-existing architecture were fine-tuned
- Layers that were added to the model for classification were not frozen and were trained.
- The following diagram shows the training loss for each training epoch.



- The ROC curve is as follows



Final Threshold and Explanation:

4. Databases

Training Dataset:
The dataset used consists of 112,120 chest x-rays with disease labels acquired from 30,805 patients. The Ground truth was obtained by mining the text from each xray's radiological report. The labels are believed to be over 90% accurate. The final dataset used for training and validation consisted of all 50-50 mix of pneumonia-positive x-rays and pneumonia-negative x-rays.

Validation Dataset:
20% of the dataset was randomly separated for validation.

5. Ground Truth

The Ground truth was obtained by mining the text from each xray's radiological report. The labels are believed to be over 90% accurate.

6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

The patient dataset consists of 30,805 patients who had chest xrays diagnosed for one of the following conditions:

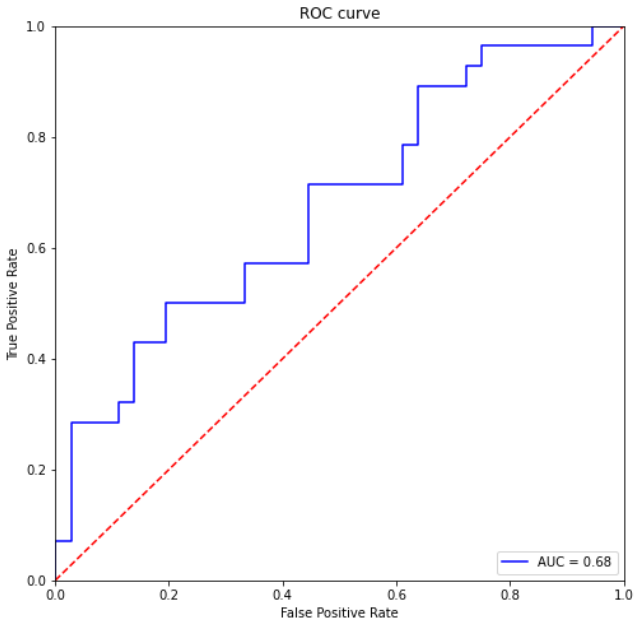
- Emphysema
- Fibrosis
- Hernia Infiltration
- Mass
- No Finding
- Nodule Pleural_Thickening
- Pneumonia
- Pneumothorax

Ground Truth Acquisition Methodology:

The Ground truth was obtained by was obtained by mining the text from each xray's radiological report.

Algorithm Performance Standard:

The algorithm's performance can be viewed by the following ROC curve:



The algorithim's threshold for making a positive diagnosis was determined to be 0.40. At this level, the algorithm was able to achieve a high accuracy while limiting the number of false negatives.