FDA Submission

Your Name: Anil Chokshi

Name of your Device: Pneumonia detection algorithm

Algorithm Description

1. Demonstrationn

Intended use Statement: This algorithm is intended for use in assisting the clinician in cases case setting with a speedy detection of Pneumonia in Chest X-ray. The available dataset for this algorithm is a little diverse.

Indications for Use: This algorithm is used as a Pneumonia classifier in a chest x-ray taken in ancient medical or surgical administration units, accident and emergency and acute care centers. It is intended for use in people aged 18-70 years with no acute history of pneumonia or other lung diseases, who have had a chest x-ray taken.

Device Limitations: The device study was based on images from people's age 20-70 and was significantly less accurate in the presence of concurrent diseases and therefore not recommended for use in the diagnosis of people's cases that have a prior presence of diseases in the lungs or those who have had a thoracic surgery in the past. The algorithm uses non-being Guidelines over 65 years old.

Clinical Impact of Performance:

- Performance Statistics
  - Accuracy: 81%
  - Sensitivity: 0.9444444444444444
  - Specificity: 0
  - Specificity: 0

For this algorithm, relaxing a detection of Pneumonia is not acceptable as human fatigue depends on it. False negatives may slow down the process of treatment and lead to disorders due to unused examination. Therefore false negatives needs more weightage than false positive. Accordingly, the threshold for the algorithm has been weighed in favour of recall/sensitivity.

More concern with high recall which is negative result are not to be pretty, contrast that the model is only negative. Recall does not take false positive though, so we have to be careful dealing with all negative cases as positive. So recall are good for contacting tests.

2. Algorithm Design and Function

Algorithm Flow chart: The chosen pitorch function model is a .dem file, checks the important fields for our device, and returns a prediction with a probability score.

The function, once ported, is required to check the image's possibilities 512 deep that basically of black, and image position (W x H) for each DICOM image and check if the input to the algorithm is valid to be predicted by our algorithm or not.

DICOM Processing Steps: There are three steps

1. Extract the desired attributes: Metadata, CX The image type (CR is a digital radiography "Digital Plain Examination" Rows and Cols "Pixelspacing" Image Dimensions, Image Position (Patient) and Image Orientation (Patient) Pixel Data, Pixel Spacing, Pixel Data.
2. Read the binary data of common dicoms and compare the input to the algorithm is valid to be predicted upon by our device.
3. Finally, valid images are included as input and a numpy array of the image data is returned.

Preprocessing Steps: The preprocess, image function used here based on the image size, when received from dicom, shown, and the image shape. Image shape is 512 x 512 x 1 and the image is converted to a numpy array of shape (512, 512, 1) and dtype uint8 (0-255). These inputs are used to standardize and resize the image which is returned as a processed image.

Image augmentation techniques were also applied prior to training the model impartially by training data.

DICOM Extraction: The pretrained model was created and the 'Kim-Y' digest name reclaimed a binary file in the pretrained model

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Model: "model_2"
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 Layer (type)                   Output Shape         Param #     Connected to
==================================================================================================
 input_1 (InputLayer)           [(None, 224, 224, 1)]  0         []
 conv1_1/Conv2D(conv)           (None, 224, 224, 1)  9          [input_1]
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==================================================================================================
Total params: 225
Trainable params: 0
Non-trainable params: 225
__________________________________________________________________________________________________
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Seven fully connected layers were added to the pretrained model as classifiers. (2 like 7 layers, there were Dropout layers to prevent overfitting)

```
model_2.layers
block0_pool.MaxPool
block1_pool.MaxPool
block2_pool.MaxPool
block3_pool.MaxPool
block4_pool.MaxPool
block5_pool.MaxPool
block6_pool.MaxPool
block7_pool.MaxPool
block8_pool.MaxPool
block9_pool.MaxPool
block10_pool.MaxPool
block11_pool.MaxPool
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block217_pool.MaxPool
block218_pool.MaxPool
block219_pool.MaxPool
block220_pool.MaxPool
block221_pool.MaxPool
block222_pool.MaxPool
block223_pool.MaxPool
block224_pool.MaxPool
block225_pool.MaxPool
```

Layers of pre-existing architecture that were frozen (7 Layers of pretrained model were frozen and therefore not trainable

```
 block0_conv1.Conv2D
 block0_conv2.Conv2D
 block1_conv3.Conv2D
 block1_conv4.Conv2D
 block2_conv5.Conv2D
 block2_conv6.Conv2D
 block3_conv7.Conv2D
 block3_conv8.Conv2D
 block4_conv9.Conv2D
 block4_conv10.Conv2D
 block5_conv11.Conv2D
 block5_conv12.Conv2D
 block6_conv13.Conv2D
 block6_conv14.Conv2D
 block7_conv15.Conv2D
 block7_conv16.Conv2D
 block8_conv17.Conv2D
 block8_conv18.Conv2D
 block9_conv19.Conv2D
 block9_conv20.Conv2D
 block10_conv21.Conv2D
 block10_conv22.Conv2D
 block11_conv23.Conv2D
 block11_conv24.Conv2D
 block12_conv25.Conv2D
 block12_conv26.Conv2D
 block13_conv27.Conv2D
 block13_conv28.Conv2D
 block14_conv29.Conv2D
 block14_conv30.Conv2D
 block15_conv31.Conv2D
 block15_conv32.Conv2D
 block16_conv33.Conv2D
 block16_conv34.Conv2D
 block17_conv35.Conv2D
 block17_conv36.Conv2D
 block18_conv37.Conv2D
 block18_conv38.Conv2D
 block19_conv39.Conv2D
 block19_conv40.Conv2D
 block20_conv41.Conv2D
 block20_conv42.Conv2D
 block21_conv43.Conv2D
 block21_conv44.Conv2D
 block22_conv45.Conv2D
 block22_conv46.Conv2D
 block23_conv47.Conv2D
 block23_conv48.Conv2D
 block24_conv49.Conv2D
 block24_conv50.Conv2D
```

Layers of pre-existing architecture that were frozen Fully connected (dense) were then tested.

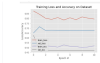
Layers added to pre-existing architecture:

Only dense (fully connected) was added which first could and then layrons were added for training

```
 layer (type)                Output Shape              Param #
=================================================================
 model_2 (Model)             (None, 7, 7, 512)         14714688
 flatten_1 (Flatten)         (None, 25088)             0
 dropout_1 (Dropout)         (None, 25088)             0
 dense_1 (Dense)             (None, 256)               6422784
 dropout_2 (Dropout)         (None, 256)               0
 dense_2 (Dense)             (None, 64)                16448
 dropout_3 (Dropout)         (None, 64)                0
 dense_3 (Dense)             (None, 32)                2
=================================================================
Total params: 21153922
Trainable params: 6439234
Non-trainable params: 14714688
_________________________________________________________________
```

Algorithm training parameters visualization:

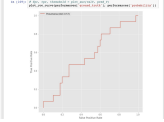
Train and validation trajectoryies versus epochs



The model is converging and this can be observed from the decrease loss and validation loss with epochs.
It reached 90% validation accuracy in just 7 epochs

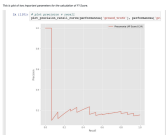
The plot shows the model distinguishes between the classes

```
In [101]: # Box-cox transform plot_pos(ax=ax, pos=1)
          plot_roc_curve(pos_fraction=0.1, groundtruth=y_test, pos_probs=y_pred_prob)
```



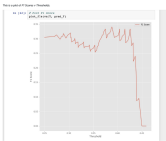
This is a plot of two Important parameters for the calculation of F1 Score

```
In [102]: # plot precision v recall
          plot_precision_recall_curve(performance, ground_score, performance, ax=
```



This is a plot of F1 Score v Threshold.

```
In [103]: # F1v0.5 (0.5)
          plot_f1v0.5(y, pred_f)
```



Final Threshold and Explanation:

A deep protection, with the decision model for this threshold was based the calculation, has Threshold, from F1 partial weightening a precision value of 0.8 and overall value of 0.85.

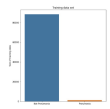
The threshold value found for the best of F1 was chosen because, it is important for the algorithm to pick all positive cases of pneumonia. Missing cases of pneumonia is not acceptable. Recall is more valuable under this circumstance where a negative test means you have a pneumonia and a positive test means

4. Datasets

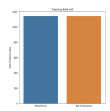
(For this dataset, include visualizations as they are useful and relevant)

Description of Training Dataset:

Data set was split 80/20 percent in frames of stratifying diversity, using the ratio of positive cases of pneumonia to randomly select equal number of negative cases.

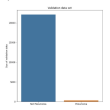


Zoom of train and validation dates after allocating receiver state

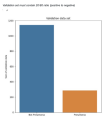


Description of Validation Dataset:

Validation after split 80/20 and 20% of the entire dates in the validation dataset By finding using random sample to add a negative data to the the ratio of 1:1 of positive to negative cases.



Validation set must consist 20-80 ratio (positive & negative)



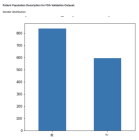
5. Ground Truth

The dataset were selected by qualified radiologist. In it for medical imaging, using a radiologist's labels as our "true" label is often the best ground truth. Radiologists achieve performance in Judgist based on professional digests on expert journal.

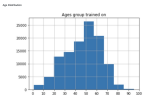
6. FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

Gender distribution:



Age distribution:



Concurrent disease