FDA Documentation

Name: Abdelrahman Rashed

Algorithm Description: Pneumonia Detection Algorithm.

1. **General Information:**

- **Intended Use Statement:** Detection of pneumonia on chest x-rays for patients of different ages.

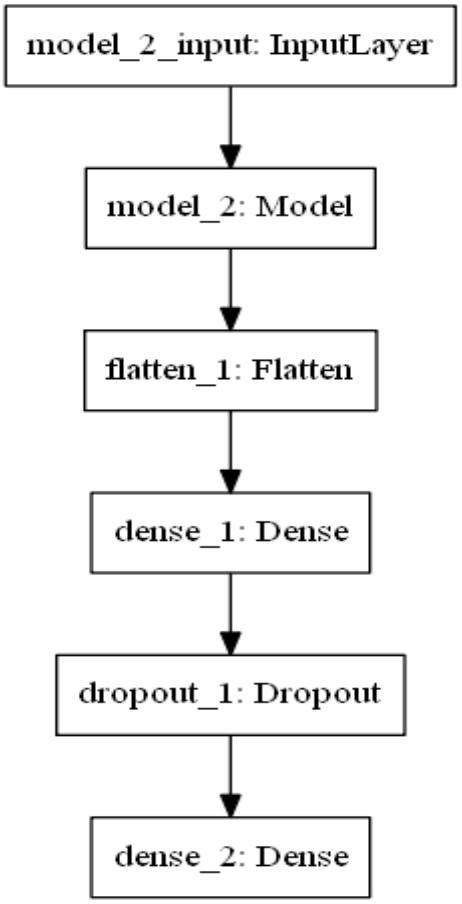
- **Indications for Use:** This algorithm's clinical intended use is for radiologists for the detection and suspicion of pneumonia on chest x-rays.

- **Device Limitations:** The Algorithm is not 100% accurate for detecting the positive Pneumonia cases. It might predict false positive cases of pneumonia. Therefore, the positive cases shall be re-checked by the experts to double confirm them. However, the algorithm is more accurate in detecting 'No Finding' cases.

- **Clinical Impact of Performance:** The algorithm has a good percentage of detecting the "No Pneumonia" cases so it can help in concentrating in the positive cases for further investigation by the experts.

2. Algorithm Design and Function:

- **Flowchart:**



- **DICOM Checking Steps:** I load the Images from the Dicoms files stored in the same project directory. I then extract the image pixels to be plotted then. Finally i print some of the provided data like patient's age, bodypartExamined or Study description.
- **Preprocessing Steps:** First we get the numpy array output from the check_dicom function. Then I started to get the image mean and standard deviation. After that, I evaluate the processed image through subtracting the mean intensity from the actual image then dividing it by the standard deviation. After that I applied resizing to the new preprocessed image.

3. Algorithm Training:

- **Types of augmentation used during training:**

```
my_idg = ImageDataGenerator(rescale = 1./255,
                            width_shift_range = 0.1,
                            height_shift_range = 0.1,
                            shear_range= 0.1,
                            zoom_range = 0.1,
                            horizontal_flip = True,
                           vertical_flip  = False,
                           rotation_range = 20)

return my_idg
```

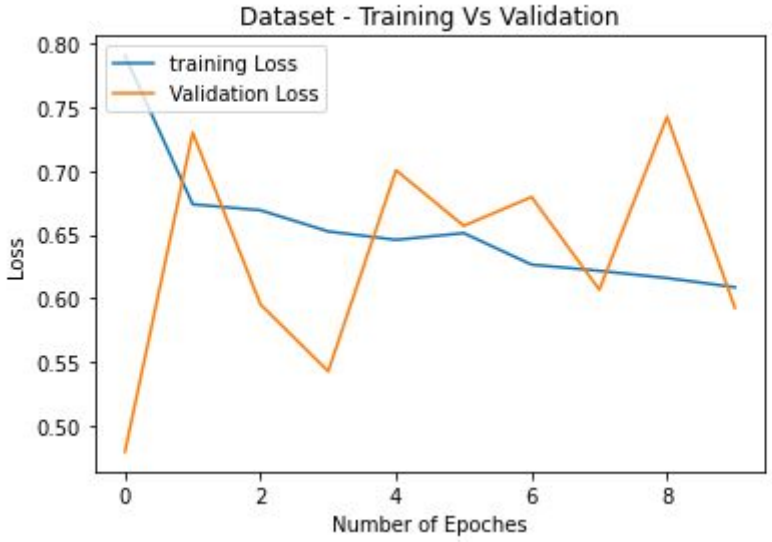
- **Batch size :** (64)

- **Optimizer learning rate:** Adam(lr=0.0001, decay=1e-5)

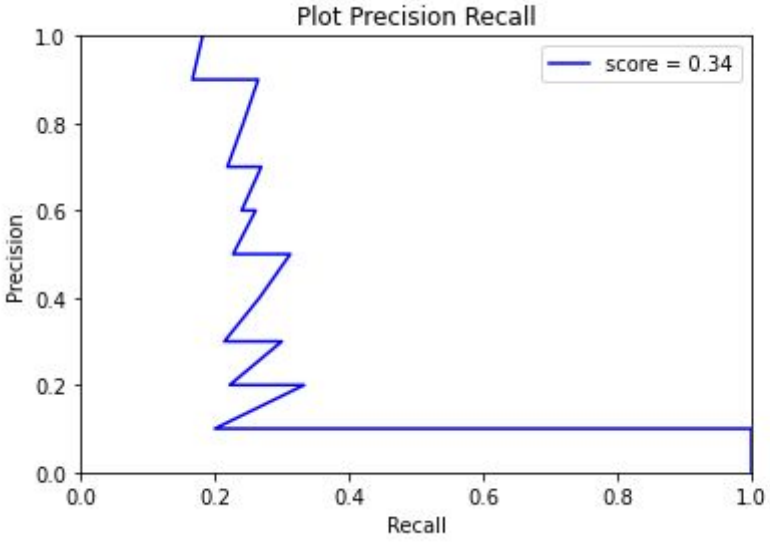
- **Layers of pre-existing architecture that were frozen:** I have designed the algorithm using the pretrained model (VGG16) model. Then after the pre trained model I have added the following layers to be fine-tuned.

```
# Building the model with transfer learning and added new layer for classification
my_model = Sequential()

vgg16_model = load_pretrained_model()

# Addig from the above the VGG16 model
my_model.add(VGG16_Conv_model)

# FC layer
# Flatten the VGG16 model output  -- shape of last block = (7,7,512)
my_model.add(Flatten())

# Add the fully-connected layer (Dense layer) - To combine the recongized feature by VGG16
my_model.add(Dense(1024, activation = 'relu'))

# Add the droup-out layer to avoid overfitting
my_model.add(Dropout(0.2))

# Add a final sigmoid layer for classification
my_model.add(Dense(1, activation= 'sigmoid'))

return my_model
```

- **Algorithm training performance:**

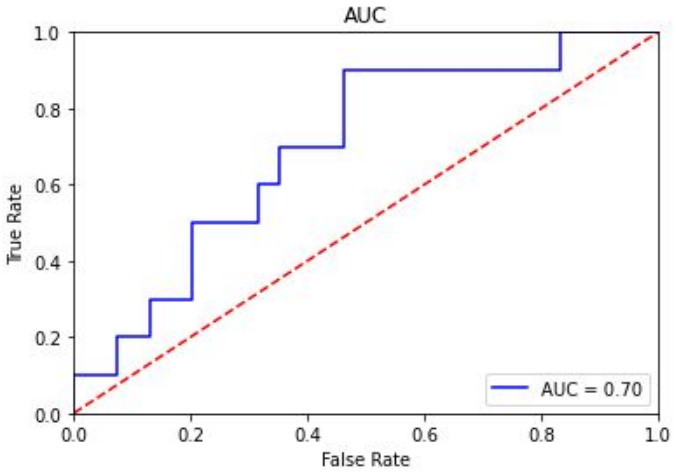


- **P-R curve:**



- **Final Threshold:** (Final threshold = 0.7999999999999999)
- **Final Accuracy:** (Final Accuracy = 0.8125)

- **Accuracy Curve:**



4. Database

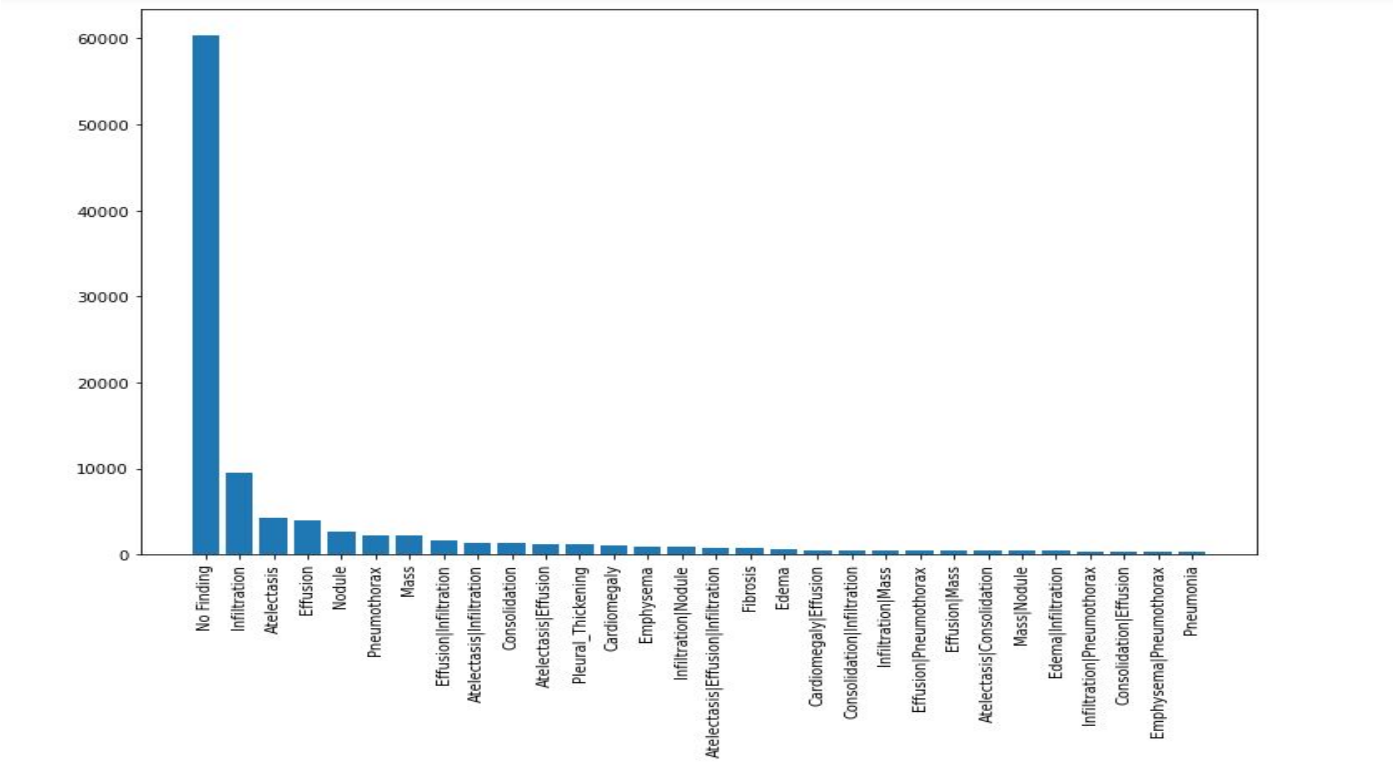
- The NIH dataset contains 112,120 images with disease labels from 30,805 unique patients. The labels are more than 90% accurate and valid for supervised learning. The dataset's labels differentiate between 14 diseases and the 'No Finding' label.

- The names of disease are:
    - Atelectasis
    - Consolidation
    - Infiltration
    - Pneumothorax
    - Edema
    - Emphysema
    - Fibrosis
    - Effusion
    - Pneumonia
    - Pleural_thickening
    - Cardiomegaly
    - Nodule Mass
    - Hernia
    -

- **Training Dataset:** The below images describe the distribution of the diseases in the dataset, Patient Gender Distribution, patients ages distribution and ages of patients suffer from Pneumonia. And Regarding the training set itself my model. I have splitted the dataframe into training dataframe and validation data frame. Where the percentage for

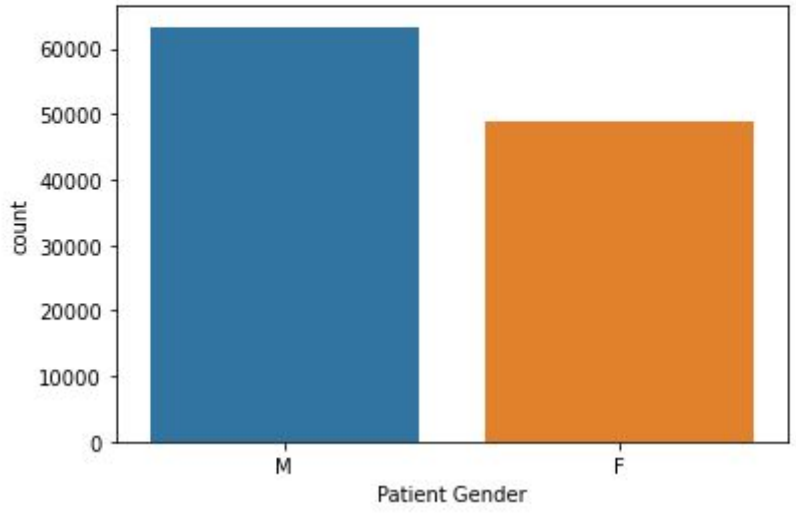
this splitting was 80% for train data and 20% for validation data. I have also modified the training dataset to be a balanced dataset where the number of patients who have “Pneumonia” equals the number of patients who have “No Pneumonia”.

- **Validation Dataset:** For the validation dataset I have created it to be an unbalanced dataset where the number of the patients suffering from “Pneumonia” is the number of the patients that have “No Pneumonia”.
- Below I have plotted some distribution of the data inside the dataset.
- **Dataset diseases distribution:**

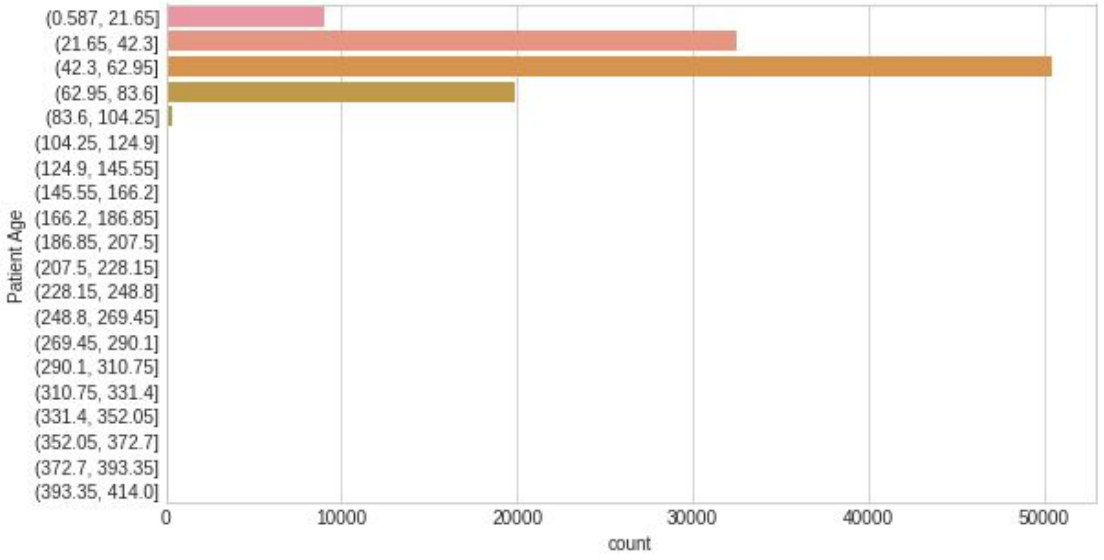


- **Patient Gender Distribution:**

```
Number of Male in the dataset = 63340
Percentages of the Males:  56.49304316803425
Number of Females in the dataset = 48780
Percentages of the Females:  43.50695683196575
```

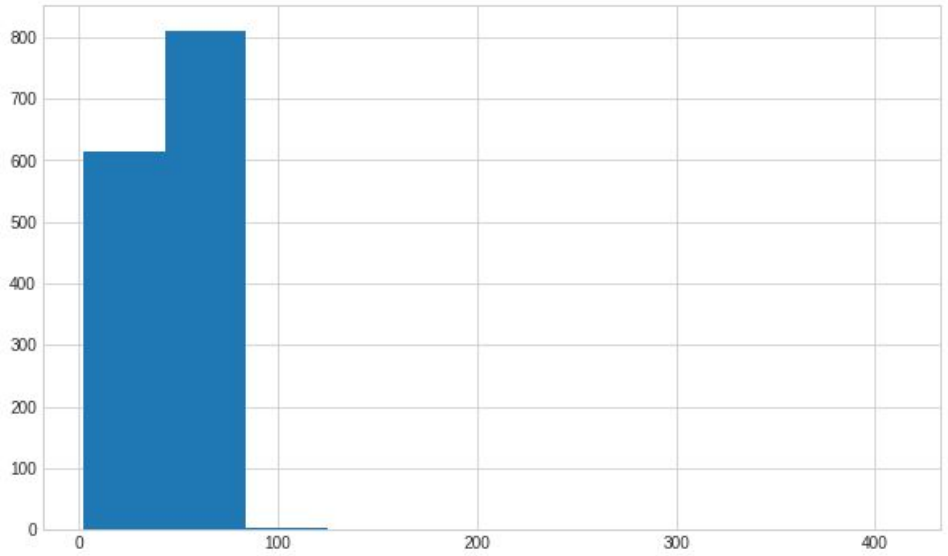


- **Patients Ages Distribution:**



- **Ages of patients suffer from Pneumonia**

```
Out[14]: (array([615., 811.,   4.,   0.,   0.,   0.,   0.,   0.,   0.,   1.]),
          array([  2.,  43.,  84., 125., 166., 207., 248., 289., 330., 371., 412.]),
          <a list of 10 Patch objects>)
```



- Distribution of the age of the patient who suffer from pneumonia

5. Ground Truth:

- The Algorithm is not 100% accurate for detecting the positive Pneumonia cases. It might predict false positive cases of pneumonia. Therefore, the positive cases shall be re-checked by the experts to double confirm them. However, the algorithm is more accurate in detecting 'No Finding' cases.

6. FDA Validation Plan

- **Patient Population Description for FDA Validation Dataset:** The dataset shall have x ray chest images for patients in different ages between [1-100] and with different genders.The validation set shall not have a prior history of any patient.. Also it is possible for these x ray chest images to have different labels (diseases) , not just Pneumonia. Patients with other diseases shall take in consideration for more expert checks.

- **Ground Truth Acquisition Methodology:** Applying the intended use for this algorithm where it is used as a tool to help the radiologist to diagnose Pneumonia. As checking for other diseases shall be taken in consideration as the dataset does not only include

‘Pneumonia’ or ‘No finding’

- **Algorithm Performance Standard:** The silver standard approach of using several radiologists would be more optimal for this Algorithm.