

FDA Submission

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Name of your Device: CheXCNN

Algorithm Description

1. General Information

Intended Use Statement: This algorithm is intended for use in assisting a radiologist with pneumonia screening from chest x-rays.

Indications for Use: It is indicated for use in patients (male and female) within the age bracket 1-95 years with chest x-rays taken in the AP and PA view positions on a ER setting

Device Limitations: The presence of Emphysema or Nodule may reduce the model performance of the algorithm in precision or recall of predicting the presence of pneumonia in a chest x-ray. Conversely, the presence of Edema, Infiltration, or Consolidation in the image may lead to improved performance of the algorithm in precision or recall of predicting the presence of pneumonia from a chest x-ray.

Clinical Impact of Performance: This algorithm's performance shows that it will be useful for screening chest x-rays for pneumonia and may also be used for workflow prioritization.

2. Algorithm Design and Function

DICOM Checking Steps: Check DICOM Headers for:

1. Modality == 'DX'
2. BodyPartExamined=='CHEST'
3. PatientPosition in 'PA' or 'AP' Position

If any of these three categories do not match their respective requirements, then a message will state that the DICOM does not meet criteria.

Preprocessing Steps:

1. Image standardization: $\text{standardized_pixel} = \text{pixel} / 255.0$
2. Image resizing: resize image to (224, 224)

CNN Architecture:

The model architecture :

1. Pre-existing architecture: model_1 (Model)
2. Layers added to pre-existing architecture: flatten_1(Flatten) and dense_1(Dense)

Model: "sequential_1"

Layer (type)	Output shape	Param #
model_1 (Model)	(None, 7, 7, 512)	14714688
flatten_1 (Flatten)	(None, 25088)	0

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dense_1 (Dense)          (None, 1)          25089
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Total params: 14,739,777
Trainable params: 2,384,897
Non-trainable params: 12,354,880

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The Pre-existing architecture "model_1 (Model)"

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Model: "model_1"

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Layer (type)	Output Shape	Param #
input_1 (InputLayer)	(None, 224, 224, 3)	0
block1_conv1 (Conv2D)	(None, 224, 224, 64)	1792
block1_conv2 (Conv2D)	(None, 224, 224, 64)	36928
block1_pool (MaxPooling2D)	(None, 112, 112, 64)	0
block2_conv1 (Conv2D)	(None, 112, 112, 128)	73856
block2_conv2 (Conv2D)	(None, 112, 112, 128)	147584
block2_pool (MaxPooling2D)	(None, 56, 56, 128)	0
block3_conv1 (Conv2D)	(None, 56, 56, 256)	295168
block3_conv2 (Conv2D)	(None, 56, 56, 256)	590080
block3_conv3 (Conv2D)	(None, 56, 56, 256)	590080
block3_pool (MaxPooling2D)	(None, 28, 28, 256)	0
block4_conv1 (Conv2D)	(None, 28, 28, 512)	1180160
block4_conv2 (Conv2D)	(None, 28, 28, 512)	2359808
block4_conv3 (Conv2D)	(None, 28, 28, 512)	2359808
block4_pool (MaxPooling2D)	(None, 14, 14, 512)	0
block5_conv1 (Conv2D)	(None, 14, 14, 512)	2359808
block5_conv2 (Conv2D)	(None, 14, 14, 512)	2359808
block5_conv3 (Conv2D)	(None, 14, 14, 512)	2359808
block5_pool (MaxPooling2D)	(None, 7, 7, 512)	0

```

=====
Total params: 14,714,688
Trainable params: 2,359,808
Non-trainable params: 12,354,880

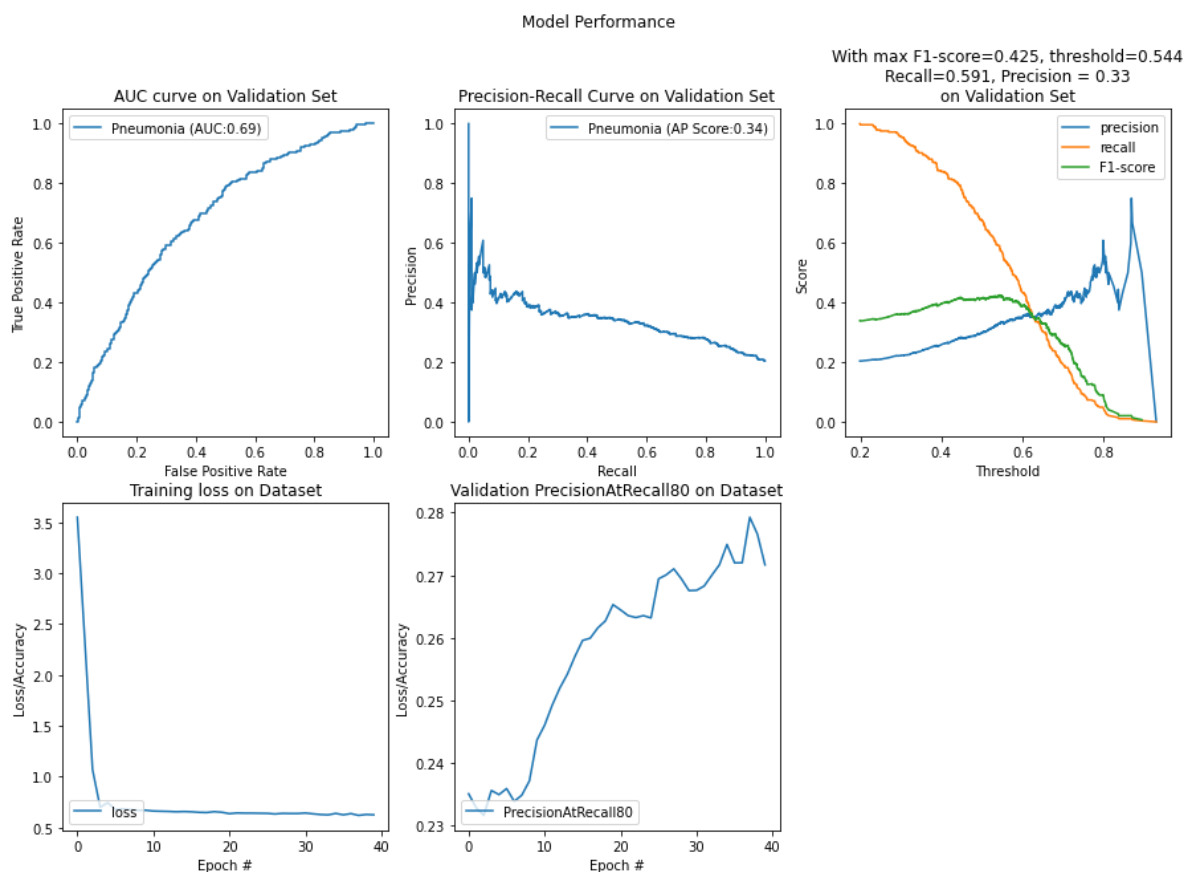
```

The architecture of Pre-existing architecture is VGG16

3. Algorithm Training

Parameters:

- Types of augmentation used during training
 - Horizontal_flip
 - Height_shift_range = 0.1
 - Width_shift_range = 0.1
 - Rotation_range = 5
 - Shear_range = 0.05
 - Zoom_range = 0.05
- Batch_size
 - 256
- Optimizer learning rate
 - Cyclical Learning Rate
 - initial_learning_rate = 4e-6
 - maximal_learning_rate = 2e-4
 - step_size = 27
- Layers of pre-existing architecture that were frozen
 - First 17 layers are frozen
- Layers of pre-existing architecture that were fine-tuned
 - block5_conv3 were fine-tuned
- Layers added to pre-existing architecture
 - flatten_1 (Flatten)
 - dense_1 (Dense)



Note that PrecisionAtRecall80 means max precision when recall ≥ 0.8 .

Final Threshold and Explanation:

Selected threshold = 0.44090602 with

1. Precision = 0.28
2. Recall = 0.8
3. F1-score = 0.41

The criteria to choose the threshold is to find the threshold that maximizes precision when recall ≥ 0.8

4. Databases

Description of Training Dataset:

The training dataset is an imbalanced dataset containing 1,145 pneumonia cases and a total of 89,696 images sampled from 112,120 chest X-ray images with 14 (unique) disease and 'No Finding' labels from 30,805 unique patients.

However, the training dataset for each training epoch contains only 2,304 images and is almost balanced for Pneumonia and Non-Pneumonia labels by the sampling technique as follows.

1. 1,145 images of Pneumonia from training dataset
2. 1,159 images of Non-Pneumonia sampled from the training dataset every epoch

Description of Validation Dataset:

The validation dataset is an imbalanced dataset containing 20% pneumonia cases and a total of 1430 images sampled from 112,120 chest X-ray images with 14 (unique) disease and 'No Finding' labels from 30,805 unique patients.

5. Ground Truth

This NIH Chest X-ray Dataset is comprised of 112,120 X-ray images with disease labels from 30,805 unique patients. 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 FDA validation dataset was acquired from six patients, all men with ages 58, 71 and each of the remaining four being 81 years old.

Ground Truth Acquisition Methodology:

This NIH Chest X-ray Dataset is comprised of 112,120 X-ray images with disease labels from 30,805 unique patients. 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.

Algorithm Performance Standard:

With maximum F1_score = 0.425, CheXCNN performs a bit lower than CheXNet (Rajpuratar, et al., 2017). However, CheXCNN's F1 score is higher those of three radiologists (radioplogist 1 & radioplogist 2 & radiologist 3) in Rajpuratar, et al. (2017).

