FDA Submission

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Device: Hippocampus Volume Quantifier

Algorithm Description

1. General Information

Intended Use Statement: Assisting radiologists in quantifying Hippocampus volume.

Indications for Use:

Screening MRI images of the hippocampus area with a pixel spacing of 1.0 mm and standard units of (mm,s). The coronal and sagittal slice size must be less than (64,64). This algorithm is intended for use on patients from the age of 52-71.

Algorithm Limitation: The algorithm accuracy can deteriorate when performing on patients with ages lees or higher than (52-71). The algorithm shouldn't be used on people with neurological disorders or head injuries due to the lack of these cases n the training dataset.

Computational Limitation:

The algorithm can run on CPU machines and gives an inference time of 7.0s for an MRI study with ~35 axial slices.

Clinical Impact of Performance:

It can save a lot of time checking MRI image slices one at a time and calculate the Hippocampus volume in much less time compared to the time taken by radiologists.

there are many radiograph findings that can be detected nowadays, and the high number of repetitive measurement tasks makes radiologists task more difficult than ever It also makes the overall sensitivity, specificity low in many cases, so an algorithm which quantifying certain finding like Hippocampus volume can be very helpful.

2. Algorithm Design and Function

Preprocessing Steps:

A- For training Process:

1-image pixel values are scaled to be in the range of 0-1 by dividing the maximum pixel value in a volume over all the volume slices.

2- volume is padded with zeros and reshaped to reach a shape of (axial_slices, 64,64)

B- For testing and validation process :

1-image pixels is scaled to be in the range of 0-1

2- volume is padded with zeros and reshaped to reach a shape of (axial_slices, 64,64)

CNN Architecture:

The architecture used in the Algorithm is a U-Net network which is a very efficient architecture in segmentation tasks. All the architecture layers are trained and no pre-trained weights were used.

3. Algorithm Training

Parameters:

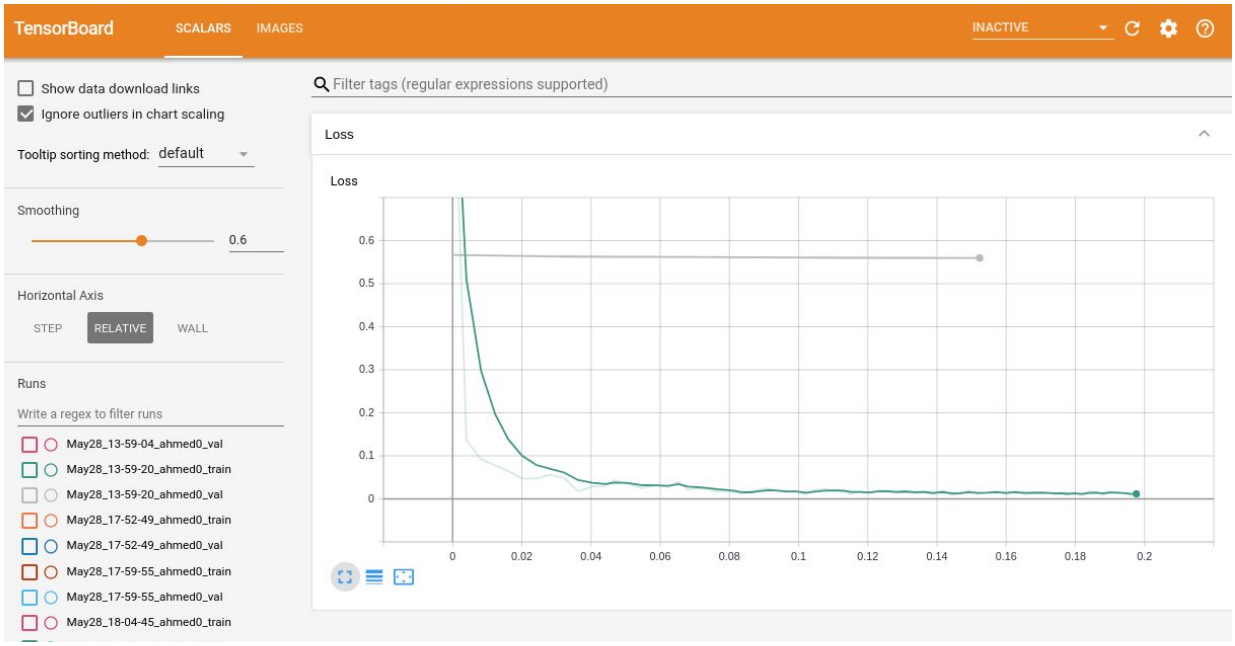
1- Batch size

Chosen batch size=8 for both the training, validation steps with 8 batches per epoch.

2- Optimizer, learning rate

The learning rate 0f 0.0002 and Adam optimizer were used.

3- Algorithm training performance visualization

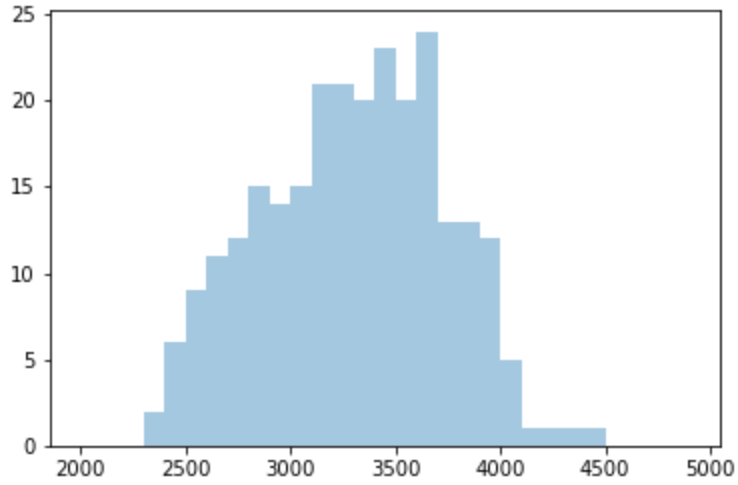


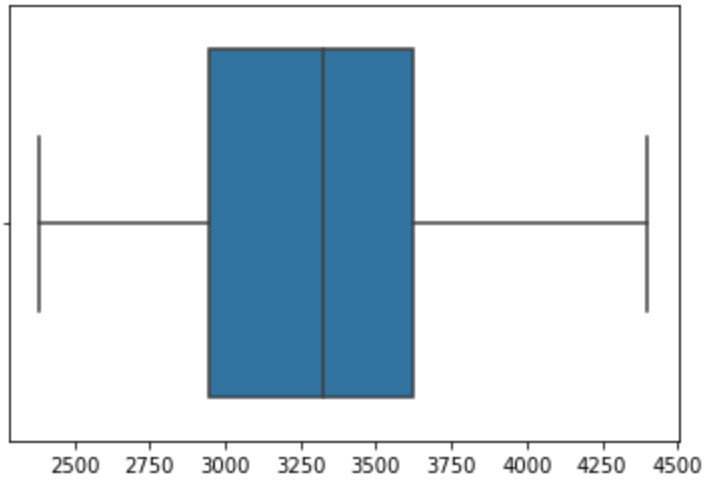
4-Performance:

The output performance gives a mean dice coefficient of 0.5056412541873323, Mean Jaccard of 0.5245832299410406 on the testset.
The performance is expected to be higher if done on the training set and almost the same if done on real-world cases.

4. Dataset

The distribution of Hippocampus volumes over the original dataset:





1- Description of The whole Dataset:

The used dataset is a part of the Medical Decathlon competition. The dataset consisted of MRI acquired in 90 healthy adults and 105 adults with a non-affective psychotic disorder (56 schizophrenia, 32 schizoaffective disorder, and 17 schizophreniform disorder) taken from the Psychiatric Genotype/Phenotype Project data repository at Vanderbilt University Medical Center (Nashville, TN, USA). Patients were recruited from the Vanderbilt Psychotic Disorders Program and controls were recruited from the surrounding community. All participants were assessed with the Structured Clinical Interview for DSM-IV [15]. All subjects were free from significant medical or neurological illness, head injury, and active substance use or dependence. Structural images were acquired with a 3D T1-weighted MPRAGE sequence (TI/TR/TE, 860/8.0/3.7 ms; 170 sagittal slices; voxel size, 1.0 mm3). All images were collected on a Philips Achieva scanner (Philips Healthcare, Inc., Best, The Netherlands). Manual tracing of the head, body, and tail of the hippocampus on images was completed following a previously published protocol [16, 17]. For the purposes of this dataset, the term hippocampus includes the hippocampus proper (CA1-4 and dentate gyrus) and parts of the subiculum, which together are more often termed the hippocampal formation [18]. The

last slice of the head of the hippocampus was defined as the coronal slice containing the uncal apex. The resulting 195 labeled images are referred to as hippocampus atlases.

Finally, the dataset volumes cropped volumes where only the region around the hippocampus has been cut out.

Provided Findings:

Our focus on this project was to calculate the volume of the hippocampus and therefore preprocessing was required before training.

2- preprocessing the Dataset:

The training data set is selected with these points set as the main goal:

1- the volumes of the training set should be representative of the real world.
2- the data shouldn't have any outliers.

To achieve these goals these steps were made :

1- the dataset was cleaned from any outliers regarding the volume of the segmented labels.

2- the dataset was split with a ratio of (0.8/0.1/0.1) for training, test, and validation respectively.

3- volumes are padded with zeros in the to reach a shape of (axial_slices,64,64) and slices are in the top left corner. This process should be done of all training, validation, and test processes.

5. Ground Truth

The ground truth of the dataset was obtained by following the methods in these two papers.

1- Pruessner, J. et al. Volumetry of hippocampus and amygdala with highresolution MRI and three-dimensional analysis software: minimizing the discrepancies between laboratories. Cerebral cortex 10, 433–442 (2000).

2- Woolard, A. & Heckers, S. Anatomical and functional correlates of human hippocampal volume asymmetry. Psychiatry Research: Neuroimaging 201, 48–53 (2012).

The resulted labels values are 0 for background, 1 for anterior segment, 2 for the posterior segment.

6. FDA Validation Dataset :

Patient Population Description for FDA Validation Dataset:

The validation dataset should be collected from MRI brain studies over the hippocampus are from patients with age in between 40-70 to make it more representative of the real clinical needs. The patients shouldn't have any head injuries or significant neurological disorder

Ground Truth Acquisition Methodology:

Because MRI studies are universally considered to be the "gold standard" for Quantifying the Hippocampus volume. a single or multiple radiologist diagnosis will be sufficient to obtain the ground truth.