FDA Submission

Your Name : Sahika Betul Yayli

Name of your Device : HippoVolume.AI

FDA Validation Plan

Intended Use:

The intended use of this algorithm is to assist doctors in observing theprogression of Alzheimer's disease. The algorithm identifies the hippocampal volume from MRI scan, measures posterior, anterior and total volume of the hippocampus by segmentation of tissue.

Training Data Collection:

Training data was obtained from a publicly available dataset: "Hippocampus" dataset from the Vanderbilt University Medical Center, Medical Decathlon competition.

This dataset contains NIFTI files. Original images are T2 MRI scans of the full brain. For every volume, there are one file for the original image and one file for the corresponding segmentation mask. Dataset contains multiple adult patients of both genders.

We used cropped volumes by an algorithm called HippoCrop. Cropped volumes include only the region around the right hippocampus that has been cut out.

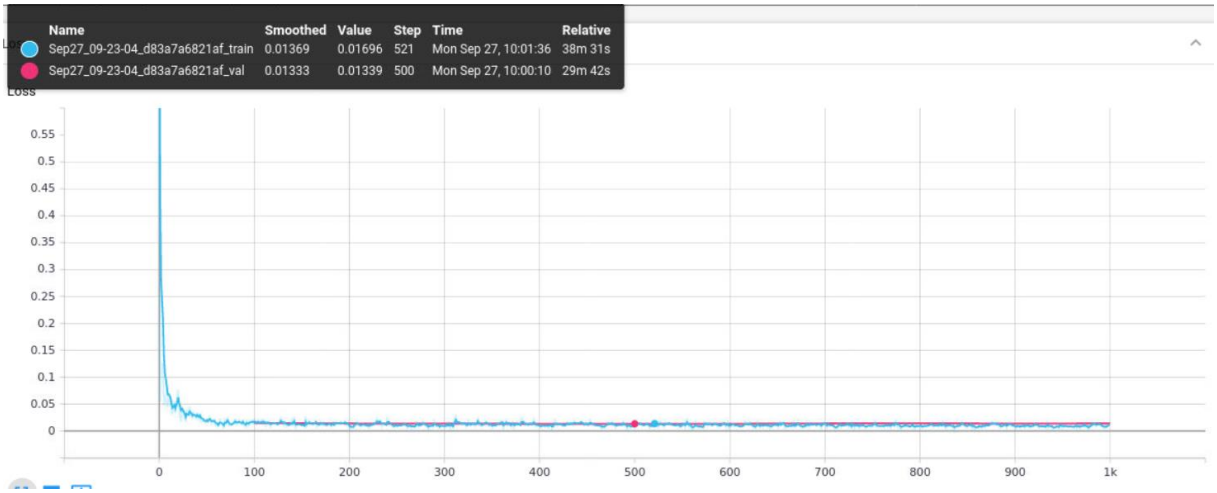
We removed the outlier data which has no responding label and which has the abnormal dimension of slice.

Labels of Training Data:

Labels are generated by marking the hippocampal area of each slice by expert radiologists.

Each data has segmentation masks with three values: 0 for background, 1 for anterior and 2 for posterior region of the hippocampus.

Performance:



As the figure above shows, the training and validation loss is under 0.03 after 3 epochs.

Overall, the mean Dice similarity coefficient is 0.8996 and the mean Jaccard similarity coefficient is

Real-World Performance:

The real-world performance of the algorithm can be estimated by newly generated test dataset. When creating a test dataset, all patients must be adults.

The algorithm will perform well in adult people images, not perform well in young people images.

This algorithm is for only MRI images.