Validation Plan

The developed algorithm is constructed using U-Net deep neural network architecture to segment certain brain regions as a result of MRI scanners.

Intended Use Statement:

The algorithm can assist radiologists in calculating the hippocampal region volume from a cropped MRI brain scan to help in detecting Alzheimer's disease by monitoring the region volume size change.

Indications for Use:

This algorithm require MRI acquired scans where axial positions are considered. It can be integrated into a clinical network workflow to assist in quantifying Hippocampus volume for Alzheimer's progression.

Training Dataset:

The training dataset was acquired from the Medical Decathlon Competition, where it contained 394 3d volumes and masks constructing a T2 MRI full brain sequence. The dataset was also cropped to focus only on the region around the hippocampus.

FDA Validation Dataset:

T2 MRI scans for both ages are the ideal case for dataset. Cropped images as well for the acquired series need to be considered, which will be then converted to NIFTI file format.

Algorithm Accuracy:

As a result of training, the performance was measured using both DICE and Jaccard similarity coefficients, where the results are shown below.

	Overall mean DICE coefficient	Overall mean Jaccard
	1.4663855890522102	0.8129697944977523

The algorithm was also trained for a total number of 10 epochs, with a learning rate of 0.0002, where the training was tracked on Tensorboard as shown below:

Loss
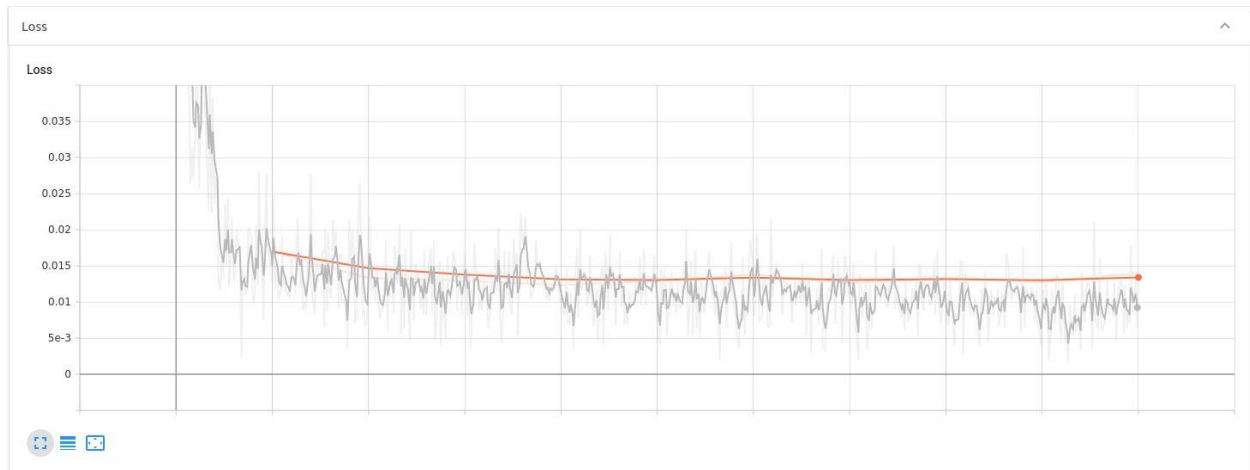
Both Dice and Jaccard coefficients can explain how the algorithm can perform on new unseen data from real-world. As we acquire the new data, it must be acquired from the same modality T2 MRI, as for the labelling, it can be done using the voting silver standard.