Validation Plan

1. General Information

Intended Use:

To assist radiologist in measuring the volume of Hippocampal in patient's brain.

Indications for Use:

It can be used for both male and female patients using MRI images.

Device Limitations:

Require high-power processing computer to run the algorithm.

2. Dataset

Training Data

The dataset is the "Hippocampus" dataset from the [Medical Decathlon competition](). This dataset is a collection of NIFTI files, with one image file, and one file per corresponding segmentation mask. The original images here are T2 MRI scans of the full brain.

Labeling Training Data

The images in the training are labeled with the following convention: - Anterior part of the Hippocampus is labeled as `1` - Posterior part of the Hippocampus is labeled as `2` - All other parts is labeled as `0`

3. Algorithm Performance

Metrics

Two metrics are used to measured the performance of the algorithm: - Dice Similarity Coefficient - Jaccard Similarity Coefficient

Performance on given dataset

The algorithm can achieve a Dice Similarity Coefficient approximately `0.90` and Jaccard Similarity Coefficient approximately `0.82`

Real-world Performance

The real-world ground truth can be established by acquiring silver standard of radiologist reading.

4. Real-world Inference

- The algorithm can only perform on T2 MRI brain scan.
- The algorithm cannot perform on other image format such as CT scan.
- The algorithm can only be used to measure volume of hippocampus of the brain. To apply for other parts, neural network must be re-trained.