

# Validation Plan

## 1. General Information

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### **Intended Use:**

Assisting radiologist to determining the early stages of Alzheimer's disease.

### **Indications for Use:**

The algorithm was trained on the hippocampal volume data which ranges from 2200 to 4500. All patients were scanned for the MRI who was showing early symptoms of Alzheimer's Disease progression. It is used for both male and female patient.

### **Device Limitations:**

Require GPU to run the algorithm.

## 2. Dataset

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### **Training Data**

The dataset is collected by taking MRI scans of different age, gender, and brain hemisphere. It is stored as a collection of NIFTI files, with one file per volume, and one file per corresponding segmentation mask. The original images here are T2 MRI scans of the full brain. In this dataset we are using cropped volumes where only the region around the hippocampus has been cut out.

### **Labelling Training Data**

The dataset is labelled by marking each slice of the MRI scan for the Hippocampal area. Then extended to all slices for calculating total volume. The images in the training are labelled by the following convention: - The Anterior part of the Hippocampus is labelled as 1 - The Posterior part of the Hippocampus is labelled as 2 - All other part (the background) is labelled as 0.

## 3. Algorithm Performance

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### **Metrics**

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

## **Performance**

The algorithm can achieve a Dice Similarity Coefficient of around 0.90 and Jaccard Similarity Coefficient of around 0.82

## **Ground Truth**

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

## **4. Real-world Inference**

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- The algorithm will perform well on T2 MRI scans of the full brain while it cannot perform on CT scans or any other format.
- The algorithm cannot be used to measure volume of any other body parts except the hippocampus of the brain.