Validation Plan

1 Intended Use

Assisting radiologists in quantifying the progression of Alzheimer's Disease (AD) through automated measurement of hippocampal volume from brain MRI scans.

2 Indications for Use

- The algorithm is indicated for use by qualified radiologists in a clinical setting.
- It is to be used on brain MRI scans of patients evaluated for Alzheimer's progression.
- Its usage is not restricted by gender or age.

3 Training Data

The algorithm has been trained on the "Hippocampus" dataset sourced from the Medical Decathlon competition. This dataset consists of NIFTI format volumes along with corresponding segmentation masks. The original images are T2 MRI scans of the full brain. For enhanced efficiency and reduced complexity, the algorithm utilizes cropped volumes wherein the region around the hippocampus—the designated region of interest—has been extracted.

4 Ground Truth

Ground truth annotations are provided alongside the training data. The labeling convention designates the anterior part of the hippocampi as 1, the posterior part as 2, and designates the remaining regions as background (labeled as 0).

5 Performance Metrics

The algorithm's performance is assessed using two key metrics: the Dice Coefficient and the Jaccard Index. These metrics provide a quantitative measure of the algorithm's accuracy in segmenting the hippocampus on brain MRI scans.

6 Algorithm Performance

The algorithm achieved a Dice coefficient score of approximately 0.88 and a Jaccard index of around 0.80 on the provided dataset.

7 Algorithm Limitations

- The algorithm is tailored exclusively for T2 MRI scans and cannot be reliably applied to other types of scans.
- Its training is focused solely on hippocampus segmentation, necessitating re-training for other anatomical patterns.
- Performance may diminish when used on full brain MRIs. As a recommended approach, employing an auxiliary algorithm or manual extraction of the region of interest (hippocampus) prior to algorithm application is advised.
- The algorithm's usage is intended for assistance purposes only and should not replace or serve as a substitute for radiologist decision-making.