Validation Plan

Name of the Device: Hippocampus.AI

Intended Use: Assisting radiologist in localizing hippocampus and quantifying its volume.

Training Data Collection: We are using the "Hippocampus" dataset from the Medical Decathlon competition (http://medicaldecathlon.com/). It consists of 263 training and 131 testing images. This dataset 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.

Labels for Training Data: The training data has been labeled and verified by a group of radiologists

Training Performance of Algorithm and Real-World Performance Estimation: The algorithm performance was measured using Dice Score and Jaccard Distance. In real world, the performance can be estimated by the radiologists.

Data Algorithm Performance: As we have used cropped images, the algorithm may perform will if we give in images that have been cropped to localize hippocampus. The algorithm may not perform well if whole brain images are given.