Validation Plan

Your Name: Jinto Lonappan
Name of your Device: Hippocampal Volume Calculator Assist

Intended Use Statement:
Assist providers (radiologists) in calculating the volume of hippocampal.

Indications for Use:
Algorithm can assist the providers in calculating the volume of hippocampal if the MRI is taken with parameters:
Body Part Examined = BRAIN

Clinical Impact of Performance:
After the training, model had a mean dice score of 0.8954 and a mean Jaccard Index of 0.8124.

While this shows a higher level of accuracy, clinicians should not that the ground truth was calculated based on a smaller dataset and the real-world performance may vary.

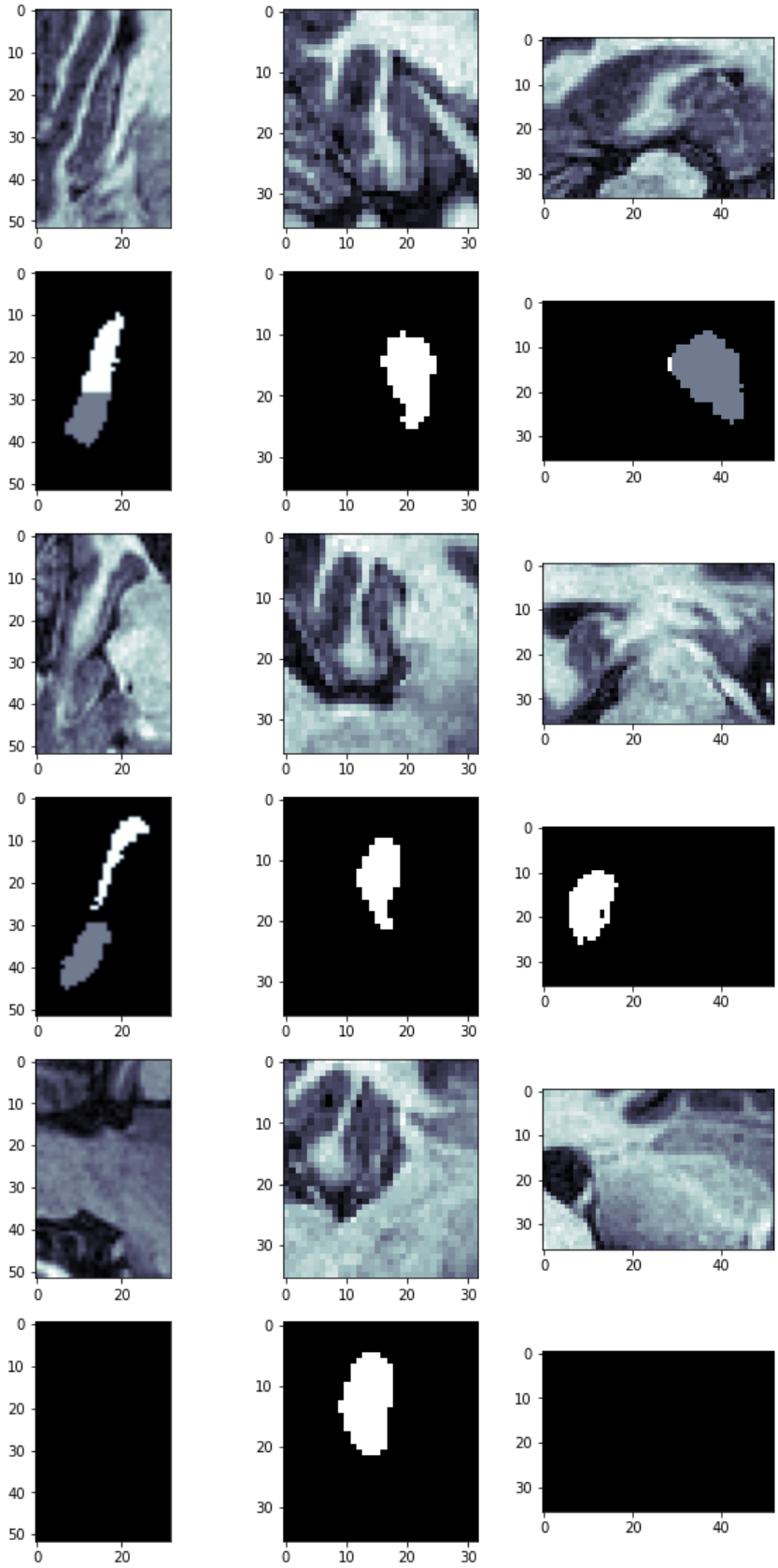
Also, as the validation was performed on axial slice, performance on sagittal and coronal slices may not perform as well as axial slice scans.

Algorithm Design:

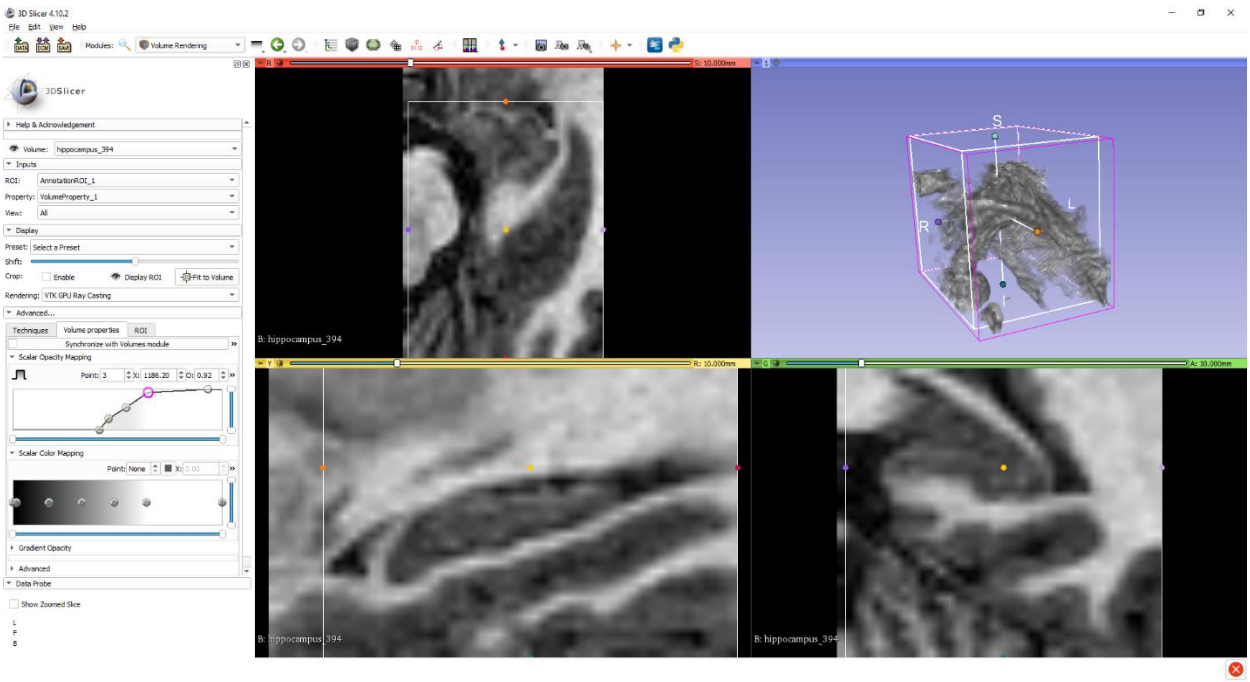
A Recursive U-Net model architecture is used for training and inference. The model is applied on brain scans after normalizing the images using numpy library functions. Ground truth were obtained from the dataset made available as part of Medical Segmentation Decathlon (http://medicaldecathlon.com/)

Training Data Insights:

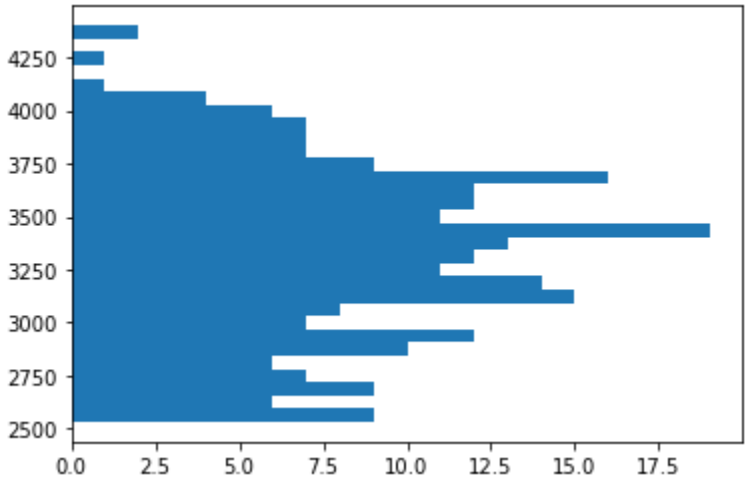
Training data and its labels



Sample Training Data visualized in 3D Slicer Tool:



Range of volume data (label) in training set:



Model Training Performance (Data from Tensorboard):