Hippocampus segmentation software (Validation plan)

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1) Intended use statement

This product will be used for segmenting hippocampal volumes extracted from MRI brain images. The model is built using the U-net architecture. Model usage can speed up critical clinical procedures and help radiologists in their workflow. Specifically, it can be used in patients suffering from Alzheimer's disease.

This product can be used as an integrated part of a PACS server. The PACS server is central to clinical settings. It receives & archives all medical images and allows connected computers to request & send image files.

2) Indications for use

Model can be applied to MRI brain images taken in the axial plane.

3) Training data

Training data was provided by Udacity (260 NIFTI files). It was adapted from the Medical Segmentation Decathlon "Hippocampus" dataset. The original "Hippocampus" dataset consisted of cropped T2 MRI scans of the full brain. The volumes were cropped to only the region around the right hippocampus. This reduces the dataset size and allows for shorter model training times. The project dataset was stored as a collection of NIFTI files, with one file per image volume and one file per corresponding segmentation mask volume.

4) Clinical validation

This model needs to be validated in a real-world setting. This could be achieved by partnering with a medical facility and comparing model's results to radiologist's output or some other gold standard. For example, a team of three radiologists can be used to label the samples.

5) Model performance

Performance was measured by utilizing Dice and Jaccard similarity coefficients. Target was 0.90 Dice and 0.80 for Jaccard.

On the test data, 0.906 was achieved for Dice coefficient, while 0.829 was achieved for Jaccard coefficient.

6) Device limitations

Device will perform worse on uncropped MRI scans. It may also perform worse on T1 MRI scans without contrast media.