

# FDA Validation Plan

## Intended use

The Intended use of this product is to predict anterior and posterior hippocampus volumes of the brain.

## How training data was collected

The training data was collected from T2 MRI scans of the brain, with cropped volumes of the region of the brain where the Hippocampus resides. This data has been sourced from <http://medicaldecathlon.com/>.

## How training data was labelled

The data was manually labelled by Radiologists

## How the training performance of the algorithm was measured

The training performance of the model was primarily measured using the Dice score, and also using the Jaccard Index.

## How is the real-world performance going to be estimated?

To estimate real world performance, we will create a validation dataset of images each labelled by 3 Radiologists, taking the mean volumes of the 3 labelled volumes to establish a silver standard performance score as a ground truth for the model to compare

## What data will the algorithm perform well in the real world and what data it might not perform well on?

The model will perform well on clearly labelled data, for complete volumes of the hippocampus region of the brain. It will not perform well on data from other types of imaging modalities, and images of the brain not cropped around the hippocampus.