Cover Page

Official Title of the Study: To Assess the Utility of the Point Digit in a Clinical Take-home Study

Document Date: August 22, 2019

NCT Number: NCT04755790

Statistical Power and Design

Power calculation:

The primary outcome measure will be the improvement in intra-subject CAPPFUL scores while using the Point Digit system versus no prosthesis. CAPPFUL provides a full-scale score ranging from 0 to 100. The mean and standard deviation of CAPPFUL for partial hand amputees (n=17) is provided in [28] as 71.37±10.15. If we consider a difference in CAPPFUL functional scores of one standard deviation (10.15) as clinically significant, a sample size of at least 11 subjects will be needed to reject the null hypothesis that the means are equal with power of 0.9 and a probability of Type I error of 0.05 (z-test for normally distributed data with known standard deviation). This sample size paired with the CAPPFUL metric will provided actionable evidence to support the Point Digit.

Data analysis:

Data will be gathered by Arm Dynamics and provided to the independent researchers at the Biomechatronics Development Laboratory. The data will be evaluated carefully by study team members without conflicts of interest to determine the distribution of all scores in the population studied and the variability of scores within and between uses of the two systems. We will measure the effectiveness of the *Point Digits* using the primary measures: CAPPFUL and WI. Both outcome measures will be studied over time by comparing the results across stage 0, 1, and 2. We hypothesize that the CAPPFUL and WI measures will increase from stage 0 to stage 2. Average scores across subjects will be studied using One-Factor ANOVAs to determine differences across the testing sessions. Post-hoc analysis (Tukey-Kramer post-hoc analysis) will be performed as necessary. One-sample t-tests will be used to compare the outcome measures with the existing dataset from Arm Dynamics. Pair-wised t-tests may be performed when a subject matches the demographic, functional, or psychological profiles of an existing subject within the dataset. Then, differences can be studied based on the prosthetic components, amputation level, or other subject attributes. A probability of Type I error of 0.05 will be used to determine statistical significance. Sex will not be a factor in this study.