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**Official Title:** Assessment of Penile Vibratory Stimulation Using the Viberect in Men with Mild-Moderate ED

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# Statistical Analysis Plan (SAP)

This was a pilot study and there were no data to suggest the magnitude of the effect of Viberect on ED, we performed power calculations for various scenarios of change in IIEF. The scenarios used a pattern of means with an absolute increase from pre-treatment to 4 weeks of 4 units for IIEF, and plausible conservative (higher than expected) values for the within-subject standard deviation that were increased until power fell below 80%. For IIEF, we evaluated power if the pre-treatment mean was the midpoint of the range of values eligible for study: IIEF = 18 (range 11-25). However, the power was not sensitive to the pre-treatment mean, and showed little variation according to the specific changes in mean score between time points, for a fixed overall change from pre-treatment to 4 weeks. The table below shows power to detect a 4 unit increase in IIEF with 20 patients evaluated at 4 time points, $\alpha = 0.05$, within-subject standard deviation and autocorrelation both constant over time. Power calculations were performed using PASS v. 11 (NCSS Software, Inc., Kaysville, UT), according to the method of Mueller (Mueller 1989).

| **Pattern of means over 4 time points** | | **Within-subject SD** | **Power** |
|---|---|---|---|
| **Pre-test** | **4 weeks** | | |
| IIEF | | | |
| 18 | 20 | 2 | >0.99 |
| 18 | 20 | 3.5 | 0.88 |
| 18 | 20 | 3.8 | 0.81 |

Thus, despite the small size of the study, power is likely to be more than adequate to detect the minimum changes in IIEF (increase 4 units) considered clinically relevant.

Should a measurable positive effect be noted, a more extensive randomized, placebo controlled, blinded and possibly multi-institutional trial be considered. The information obtained from the pilot study a help guide future studies if appropriate.

Pre-treatment IIEF, EHS, EDITS, and TSS scores was planning to be compared to post-treatment scores at 4 weeks. The primary analysis for all scores were repeated measures analysis of variance (RM ANOVA); if there are no missing time points, otherwise, a mixed model was used. The primary endpoint was the TIME effect, i.e. to test for a change from pre-treatment value of IIEF, EHS, EDITS, or TSS. The minimum change considered clinically relevant was an increase in IIEF and EDITS of 4 units and EDITS of 4 units. In addition to absolute change in IIEF or EDITS scores, we evaluated models of percentage change from pre-treatment value. If the overall effect of TIME is statistically significant, we used paired t-tests comparing pre-treatment to

each of the post-treatment values, with a Bonferroni p-value adjustment, to determine the time at which an increase in IIEF and EDITS of at least 4 points can first be detected. Covariates to be evaluated as potential confounding factors include age, comorbidity or cause of ED, body mass index, and other medications.

Data were analyzed using GraphPad Prism ver. 8 (GraphPad Software, San Diago, CA, USA). A P value <.05 was considered statistically significant.