

Cover Letter:

All enclosed below documents are part of the clinical trial NCT03536819

Study Name: Radio-frequency rejuvenation for pelvic floor and vagina

Protocol No.: DO607404A

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SPONSOR: InMode Ltd.

Tabor House

Industrial Park South

Yokneam 20692 ISRAEL

POB 44

Tel +972-4-9097309

Fax +972-4-9096310

I. Data analysis.

A. Analysis Sets

1. Safety Analysis Set

a) The safety analysis set will include all subjects using Votiva procedures at least a single time.

2. Performance Analysis Set

a) Performance analysis set will consist of all subjects providing at least one post treatment performance measurement.

3. Treatment of Missing Values

a) Only observed data will be used; i.e. missing data will not be imputed.

B. Statistical Analysis

1. Means, and standard deviations for each characteristic will be calculated. Paired sample t-test will be computed to assess changes in before treatment and follow-up scores. Statistical significance will be calculated and two-tail significance level of 0.05 will be used. All analyses will be conducted using IBM SPSS 21.0.