1 TITLE PAGE

TITLE OF STUDY:	**Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model**
INVESTIGATIONAL MATERIALS:	**Manual toothbrush:** ADA reference manual soft-bristled toothbrush **Sonic toothbrush:** AutoBrush® 360° U-shaped Sonic Toothbrush

Sponsor:	Lander Enterprises, LLC dba AutoBrush® 5700 Biscayne Blvd Apt 822 Miami, Florida 33137
Protocol No.:	AB-GBP-2023-02
Investigator:	Jeffery L. Milleman, DDS, MPA Salus Research, Inc. 1220 Medical Park Drive, Building #4 Fort Wayne, Indiana 46825
Study period:	First Subject First Visit: 31 May 2023 Last Subject Last Visit: 14 July 2023
GCP Statement:	This study was performed in compliance with ICH Good Clinical Practice (GCP) including the archiving of essential documents.
Date of report:	20 October 2023

ABSTRACT

Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Objective: This single-center, randomized, controlled, examiner-blind, 30-day parallel trial assessed safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA reference soft manual toothbrush. The extent of gingival abrasion and recession was evaluated.

Methods: 77 subjects, aged 5-65 years, with mild -to-moderate plaque and gingivitis levels were assigned to : 1)twice-daily two-minute brushing with ADA reference manual toothbrush (MTB)/fluoride toothpaste; or 2)twice-daily 30-second brushing with AutoBrush® (AB)/fluoride toothpaste. Subjects refrained from oral hygiene for 12-16 hours before each exam visit at Baseline, Day 15 and Day 30, received oral safety examination, assessed for gingivitis according to Modified Gingival Index (MGI), gingival recession, gingival abrasion and supragingival plaque according to Lobene-Soparkar Modified Turesky Plaque Index (LSPI). Subjects presented with existing mild to moderate gingivitis and no dental prophylaxis was performed. Pre-to-Post-brushing plaque assessments were measured at Day 30. Treatment means and between-treatment means were assessed by the ANCOVA model.

Results: No treatment-related oral adverse events nor differences between groups for gingival recession and abrasion were detected. Significant gingivitis and plaque reductions were observed for AB compared to MTB at Days 15 and 30 ($p<0.0001$). Compared to MTB, AB reduced whole mouth MGI scores by 27% and 41%, respectively. AB provided significantly greater improvement in gingivitis levels in the hard-to-reach areas (gumline, proximal sites and most distal surfaces) compared to MTB. Whole mouth plaque scores were reduced 26.5% and 27.7% at Days 15 and 30, respectively for AB and compared to the MTB. Improvement in Day 30 Pre-to-Post-brushing plaque scores for AB were significantly better ($p<0.001$) than MTB for whole mouth, gumline, proximal sites and most distal surfaces at 43%, 82.5%, 27.4% and 69.9%, respectively.

Conclusion: Thirty-second brushing with AutoBrush® toothbrush was superior to the MTB in reducing gingivitis and plaque at Days 15 and 30, and demonstrated highly significant plaque removal at Day 30 Pre- to Post-brush evaluation. Both toothbrushes were well-tolerated and the safety of the AutoBrush® 360 was demonstrated in this 30-day study.

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2 SYNOPSIS REPORT

2.1 OBJECTIVE

The objective of this 30-day, randomized, controlled, examiner-blind, parallel design clinical trial was to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. Safety was assessed through the evaluation of the extent of gingival abrasion and recession, through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms, and monitoring of adverse events (AEs) / serious AEs.

2.2 INTRODUCTION

The effective management of dental plaque and gingivitis continues to be a high priority for the dental health of the public. Dental professionals recommend brushing at least twice a day for two minutes to remove plaque and reduce the risk of tooth decay and gum disease.[1] However, the high prevalence of oral diseases worldwide suggests that consumers do not achieve sufficient plaque removal with their toothbrushing routine.

Clinical studies have shown that improvement in mechanical oral hygiene can be achieved through the use of power toothbrushes.[2, 3, 4, 5, 6, 7, 8, 9, 10, 11] In fact, there are systematic reviews and meta-analyses which have demonstrated that power toothbrushes are more effective in removing plaque than manual toothbrushes.[12, 13] Well-designed clinical studies are needed to validate the efficacy of new toothbrush products and claims of improving plaque control and gingival health. A study by Ebel and co-workers[2] assessed the impact of brushing time, brushing techniques, and brushing systematics of young adults (18 years old) on efficiency of plaque removal with a standard manual toothbrush. They found that participants distributed their brushing time across surfaces unevenly which explained the variance of plaque and bleeding results. Brushing technique appeared to be of minor importance. The researchers concluded that the results indicated that establishing systematic interventions or prophylactic programs should emphasize the importance of brushing all surfaces and not neglecting any teeth.

An innovative U-Shaped sonic power toothbrush has been developed by AutoBrush® that is designed with a full two-sided toothbrush head (mouthpiece) with tapered nylon bristles to clean all tooth surfaces at once in a 30-second period. Each U-shaped brush head contains about 58,000 nylon tapered bristles and are available in six sizes to accommodate a variety of mouth sizes and shapes. Consumers can select the brush head size based on their age: Kids Ages 3 – 5, Kids Ages 6 – 8, Kids Ages 9 – 12, Adult Women Small, Adult Men Regular, Adult XL. The handle supplies 30,000 sonic vibrations per minute and features an on/off button for

selecting the “deep clean” brushing mode. Users are directed to insert the brush head into the handle, wet their toothbrush, and apply foam or regular fluoride toothpaste on each side (upper and lower) of the brush head bristles and insert into the mouth. The on/off button initiates the 30-second timer along with a fun musical tune while users gently move the brush in figure 8 motions to clean all tooth surfaces. See Figure 1.

Figure 1. AutoBrush®

The AutoBrush® company’s mission is to make brushing simpler, better, and more accessible for kids, adults and individuals with disabilities. A recent independent, single-use, examiner blinded, randomized, two-period, cross-over, clinical study evaluated the safety and plaque removal efficacy in 22 children, 5 to 8 years of age who used the AutoBrush® 360° U-shaped Sonic Toothbrush and a marketed children’s manual toothbrush. Supragingival plaque levels were assessed according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). When assigned to the AutoBrush® (AB), subjects used the product for 30 seconds whereas they used the manual toothbrush in their usual manner for 2 minutes. Following single use of the AB, statistically significant reductions were observed for the AB compared to Baseline for whole mouth plaque for 50.6%, gumline levels with 71.2% and proximal levels were reduced by 40.7%. The manual toothbrush provided reductions of 1.9%, 3.5% and 1.1%, respectively. The AB provided 27 times greater whole mouth plaque removal than the manual toothbrush. There were no adverse events in this short-term study and the AutoBrush® was well-tolerated.

Because the AutoBrush® 360° U-shaped Sonic Toothbrush product is considered a specialty toothbrush device with a unique design and functions, this study was conducted in accordance with ADA Council on Scientific Affairs’ Acceptance Program Guidelines: *Toothbrushes* (2020).

The study design followed the recommended 30-day model to evaluate the safety and efficacy of AutoBrush® 360° U-shaped compared to an ADA reference manual soft toothbrush on dental plaque and mild to moderate gingivitis in a 30-day clinical study including children and adults, ages 5 to 65 years old. In addition to efficacy evaluation of the toothbrushes, oral safety was assessed through the examination of the extent of gingival abrasion and recession, as well as oral clinical examinations for soft and hard tissue changes, interviews to determine soft tissue or oral irritation symptoms, and monitoring of subject-reported adverse events (AEs) / serious AEs.

2.3 METHODOLOGY

Prior to the initiation of this study, the protocol, informed consent, assent documents and subject instructions received ethical review and approval from U.S. Investigational Review Board, Inc. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice Guideline (ICH-GCP) E6(R2).

This study was a single-center, randomized, controlled, examiner-blind, 30-day parallel study with volunteers aged 5 to 65 years. Based on the assumption that the sonic power toothbrush group improvement would exceed that of the control group by at least 25% at Days 15 and 30, the calculated total sample size of 90 completed subjects (45 per group) provided 90% power to detect a difference of 0.24 with respect to MGI, and 0.4 with respect to PI when compared to the control group, with an effect size (mean/standard deviation) of 0.7, at the Day 30 assessment. These calculations were based on two-sided tests at the 0.05 significance level.

The study consisted of a Screening visit during which potential subjects provided consent to participate in the study, completed health and dental questionnaires and received a clinical oral examination. Adult subjects, ages 18 – 65 years, read and signed an informed consent form and subjects 5 to 17 years of age signed an assent form indicating their willingness to participate in the study and their parents/legal guardians signed the consent form on their behalf. Generally healthy children and adult subjects were eligible and enrolled in this study after meeting the inclusion criteria.

The Screening visit included assessments in the following order:

- Oral safety to evaluate oral soft and hard tissues (OSHT), and the presence or absence of gingival abrasion, recession or other abnormalities.
- Visual examination for qualifying gingivitis levels according to the Modified Gingival Index (MGI);[14]

Subjects were enrolled if they had at least 18 natural teeth, in the adult dentition, with scorable facial and lingual surfaces. If under the age of 12, they had at least 12 fully erupted teeth, primary or permanent teeth. Partially erupted permanent teeth and primary teeth in process of exfoliation were not included in the tooth count. Teeth that were grossly carious, fully crowned, or extensively restored, orthodontically banded, exhibited general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession were not included in the tooth count. All qualified subjects had a mean gingival index ≥ 1.75, according to the MGI, a mean plaque index ≥ 1.95 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).[15,16] Subjects were excluded if they had significant oral soft tissue pathology; severe periodontal disease or concurrent periodontal treatment; peri/oral piercings or removable partial dentures; self-reported serious medical conditions; under treatment for a heart condition requiring use of a pacemaker; required antibiotic premedication prior to dental procedures; use tobacco products, had antibiotic, anti-inflammatory, anti-coagulant medication or chemotherapeutic antiplaque/antigingivitis therapy within 30 days of screening; or participated in any study involving oral care products concurrently or within 30 days of screening.

Following the Screening Visit, qualified subjects participated in a 7 to 14-day Washout period that allowed subjects to comply with study and lifestyle restrictions prior to the Baseline Visit. During the Washout period, subjects were not permitted to use antimicrobial mouth rinses, dentifrices or other dental products that might affect a subject's plaque or gingivitis status. Subjects used an ADA Accepted fluoride toothpaste (Crest® Cavity Protection, Procter and Gamble Co., Cincinnati, OH, USA) and an ADA reference standard soft bristle manual toothbrush as their only oral hygiene regimen during the washout period.

All subjects who enrolled in the study agreed to refrain from dental treatment during the course of the study, except on an emergency basis, and discontinued use of other oral hygiene products for the duration of the study. Prior to each exam visit, subjects refrained from oral hygiene for 12 to 16 hours and were instructed to avoid eating or drinking 30 minutes prior to the visit. Sipping water was permitted prior to each exam visit. At Baseline, Day 15 and Day 30, subjects confirmed their consent and assent to continue their participation in the study and received clinical assessments in the following order:

- Oral safety (soft and hard tissue examination for evidence of irritation or other abnormalities);
- Gingivitis according to the MGI;
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin.

- Gingival Abrasion as described by Danser[17], Rosema[18] and Van der Weijden[19].
- Supragingival plaque levels according to LSPI.

Subjects meeting baseline inclusion criteria were stratified by age: pediatric dentition group (≥ 5 and < 12) and adult dentition group (≥ 12 and ≤ 65). Eligible subjects were randomly assigned to one of two toothbrush groups, such that each group contains at least 10 pediatric subjects:

2.3.1 Study Materials Assignment and Procedures

Qualified subjects were randomly assigned to one of two treatment groups:

1) **Control Group (Manual Toothbrush)**:Twice daily brushing for two minutes with an ADA reference standard manual soft toothbrush and Crest® Cavity Protection with 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) **Sonic Toothbrush (AutoBrush® 360° U-shaped Sonic Toothbrush)**: Twice daily brushing for 30 seconds with AutoBrush® 360° U-shaped Sonic Toothbrush and Crest® Cavity Protection with 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Subjects were provided verbal and written instructions on the use of their assigned toothbrush and maintained a daily diary to document compliance. For the first use, all subjects brushed with their assigned toothbrush under the supervision of study personnel and twice daily subsequent uses were performed at home unsupervised. Participants between 5 and 8 years of age conducted their toothbrush procedures under the supervision of their parent or guardian. Subjects assigned to the AB group were dispensed the AB base handle and the two-sided toothbrush head (mouthpiece) with nylon bristles, appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. A registered dental hygienist dispensed the test products and ensured that the selected mouthpiece provided adequate coverage over all teeth. The AB has a 30-second cycle time which simulates a full 2-minute brushing for all quadrants of the mouth and was set for “deep clean” mode. Figure 2 displays the product features which are the same for adult devices. Each AB package included the charging base with the charging cord, two-sided brush head (mouthpiece) and the base handle. If assigned to the ADA reference MTB (See Figure 3), subjects brushed their teeth twice daily in their usual manner for 2 minutes. Irrespective of the toothbrush assignment, the fluoride toothpaste volume was dispensed on the brush heads based on acceptable safety standards. Juvenile subjects, age 5 to 8 years, dispensed a smear of toothpaste (~0.25 grams onto the brush head and subjects ≥ 9 years of age used a full ribbon (~1.5 grams).

Figure 2. AutoBrush® Package

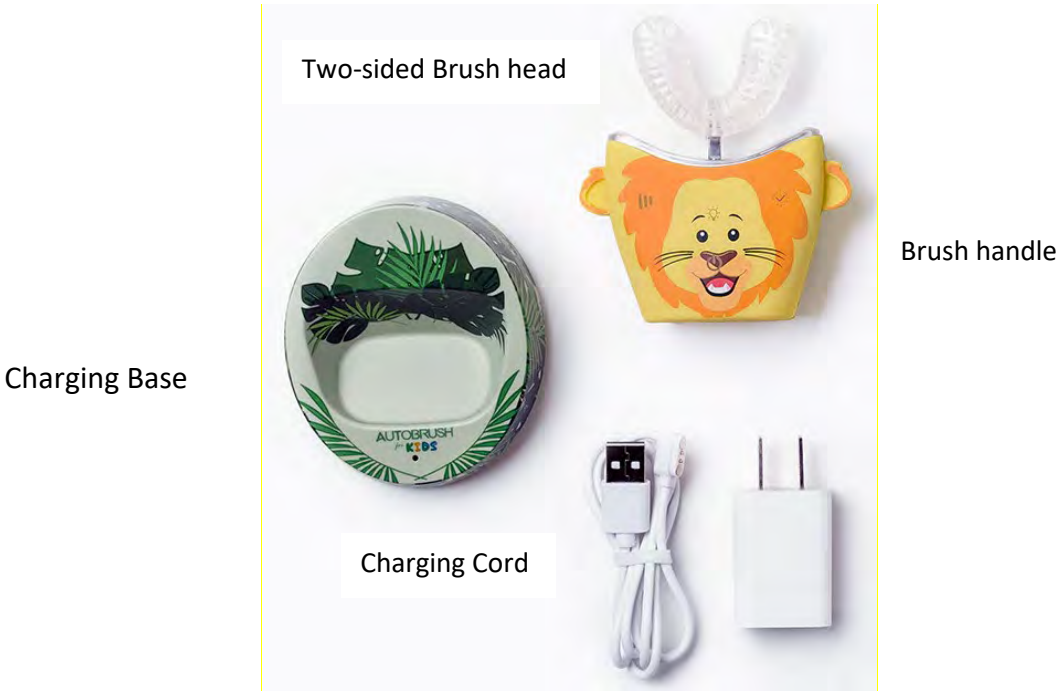
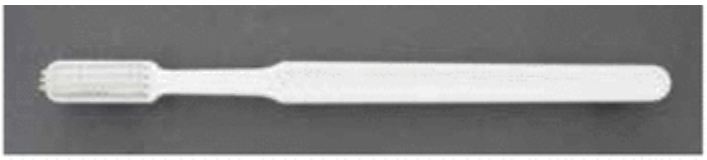


Figure 3. ADA Reference Standard Manual Toothbrush

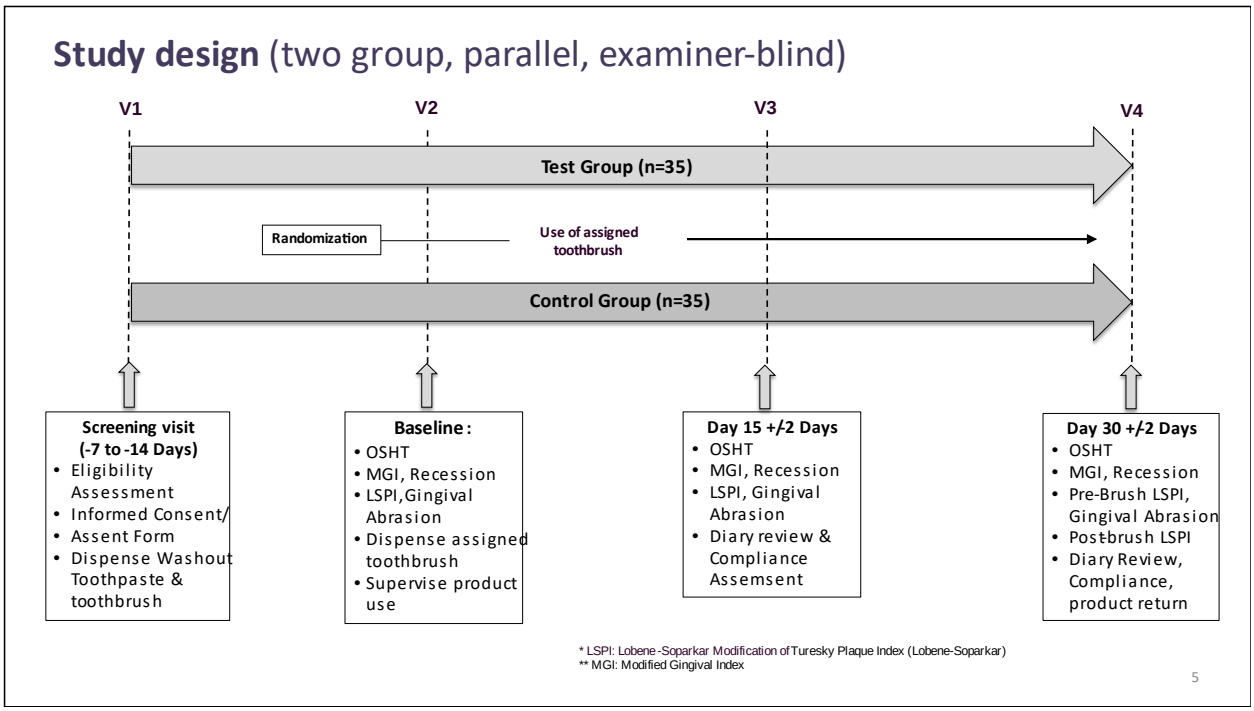


Toothbrush Group assignment process, subsequent product distribution and supervised brushing procedures were conducted in a protected area that ensured blinding of the clinical examiner and the data recorders to subjects' assignments to their toothbrush. Following the Baseline exams, subjects returned at Days 15 and 30 for the same assessments for oral safety, gingival health and plaque. At the Day 30 visit only, subjects received a pre-brushing plaque exam followed by a post-brushing plaque exam to assess the immediate plaque removal with the assigned toothbrush.

Throughout the study, subjects refrained from using any oral care products other than the toothbrush or toothpaste provided to them and avoided the use of other toothbrushes, toothpaste, mouthwashes, chewing gum, breath film, mints, floss or interdental cleaning aids, or other oral care cleaning aids for the duration of this research study. Subjects who routinely use interdental aids were permitted to continue use throughout the study.

Detailed Description of the study design is provided in Figure 4.

Figure 4.



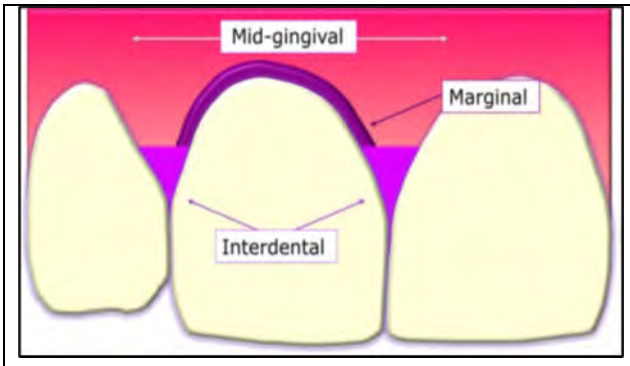
2.3.2 Safety parameters

Safety was assessed with respect to AEs and OSHT abnormalities (oral tolerability). Adverse events (AEs) spontaneously reported by the subjects or observed by the site staff were monitored and recorded from the time of the first test product use until the End of Study (or early termination).

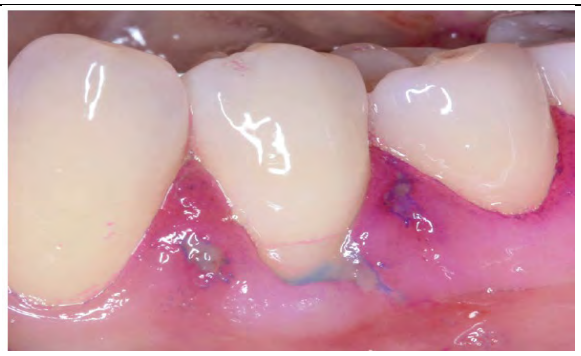
Additional safety measures included:

- Change in gingival recession scores at Day 15 and Day 30. Gingival recession was evaluated at Baseline (Visit 2), Day 15 (Visit 3) and Day 30 (Visit 4) using a manual probe (Hu-Friedy® Michigan-0 with William's markings at 1,2,3,5,7,8,10 mm), at six sites per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual). Recession was measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements indicating recession were recorded.
- Change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30. The development of abraded gingival tissue was evaluated on both the facial and lingual gingival surfaces of each tooth at Baseline, Day 15 and Day 30. The gingival tissues of each tooth were divided into 3 areas on both the facial and lingual surfaces: marginal (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva). Young-2-Tone® disclosing solution was used to help visualize abraded areas of the oral epithelium for each tooth as described by Danser[17] , Rosema[18] and Van der Weijden[19] as illustrated in Figure 5.

Figure 5. Gingival Abrasion Assessment



(From Rosema et al 2014)[18]



(From Faus-Damiá 2015)[20]

2.3.3 Efficacy Parameters

Clinical efficacy assessments were performed by a single examiner at Baseline, Days 15 and 30 in the following sequence: MGI and LSPI.

The primary efficacy variables were the mean change from Baseline in Whole Mouth MGI scores at Day 30 and the mean change in Whole Mouth LSPI scores at Day 30, immediate post-brushing (pre-brushing to Post-brushing scores).

Gingivitis: Gingival inflammation was assessed at Screening, Baseline, Days 15 and 30, according to the Modified Gingival Index (MGI),[14] and was scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual) of all scorable teeth using a scale of 0 – 4. Whole mouth MGI scores were calculated by summing all scores and dividing by the number of scorable sites examined. For more details, see Protocol Section 9.3.1 in Appendix 5.1.1.

Supragingival dental plaque: Plaque was measured at Screening, Baseline, Days 15 and 30 (Pre- and Post-Brushing), according to the Turesky Modification of the Quigley-Hein Plaque Index[15], as further modified by Lobene and Soparkar (LSPI).[16] Plaque was disclosed using Young-2-Tone® disclosing solution and each tooth was scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual), according to a 0 to 5 scale.

2.4 STATISTICAL METHODS

With 35 completed subjects per treatment group, the study had 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level.

All eligible subjects who were randomized into the study and performed at least one use of the study product were included in the safety analysis (e.g., the Safety Population). The Per-protocol (PP) population included subjects who did not have any major protocol violations. Data for safety analysis included all subjects who were randomized and received one of the assigned test products.

2.4.1 Demographic and Baseline Characteristics:

Demographic variables (age, gender, race, and ethnicity) and Baseline characteristics (mean MGI and LSPI) were summarized by treatment group and overall. Demographic and Baseline characteristics were summarized for age, gender, race, mean MGI, and LSPI. Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.

All tests were two-sided and conducted at the 0.05 significance level. No adjustments were made for multiple comparisons or multiple testing.

2.4.2 Safety Analysis

Clinical safety endpoints included AEs and SAEs and gingival recession and gingival abrasion scores. OSHT abnormalities were included as AEs if they appeared or worsened after the initial assessment. All findings regarding OSHT observations, AEs, SAEs, gingival recession, and gingival abrasion were presented in listings. The number and percentage of subjects experiencing adverse events, tabulated by treatment group was planned.

For gingival recession scores, cross tabulations were prepared for each toothbrush group to illustrate findings from visits to subsequent follow up visits (Baseline vs. Day 15, Baseline vs. Day 30, and Day 15 vs. Day 30. The cross tabulations presented the number of measured sites that exhibited each score transition. In addition, the percentage of transitioned scores from an earlier visit are presented. A table was prepared that presented, for each study visit, a summary of the subject-wise mean recession scores for each treatment, and the number and percentage of subjects in each treatment group that presented at least one measured site with recession of 1mm or higher; and that presented at least one measured site with recession of 2mm or higher.

For gingival abrasion, change in number of gingival abrasion values in two of the three defined categories was provided at Day 15 and Day 30: small (≤2 mm), medium (3–5 mm). (It is noted that no subject presented with large lesions [>5 mm] at any timepoint.) Summaries of the subject-wise mean abrasion scores by treatment group and visit included:

- A summary of the scores at the visit, and for post-baseline visits, a summary of the changes from baseline at the visit;

- For each post-baseline visit, based on an analysis of covariance (ANCOVA) model that employed the treatment group as a fixed effect, and that included the corresponding baseline value as a covariate: an estimate of the change from baseline that included the Least-squares mean (LS mean) and its standard error; a 95% confidence interval for the LS mean; and the p-value for the comparison of the LS mean change versus zero; results of a comparison of the AB group versus the MTB control group with respect to the changes from baseline, including the difference between the LS means for the treatments, and its standard error; a 95% confidence interval for the difference; and p-value from the between-treatment comparison.
- Cross tabulations were prepared as described for the gingival recession scores. These cross tabulations were prepared separately for transitions of abrasion scores; and also for transitions of assigned abrasion category scores (as described above). For those sites that presented abrasion scores of 0 (i.e., no abrasion) were assigned a category score of zero. Two additional summary tables were prepared for the gingival abrasion data:
    - A summary indicating, for each treatment and study visit, a categorical distribution of subjects according to the number of measured sites that presented any abrasion (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites), the number of measured sites that presented Category 1 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
    - the number of measured sites that presented Category 2 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
    - The number and percentage of subjects with at least 1 site presenting an abrasion lesion of 1mm or higher, presenting an abrasion lesion of 2mm or higher, presenting an abrasion lesion of 3mm or higher.

Further details are presented in the Statistical Report, Appendix 5.2.

2.4.3 Efficacy Analysis

For each efficacy variable, a summary of the subject-wise mean scores by treatment group and visit was provided, presenting the same content as described above for the analysis of subject-wise mean gingival abrasion scores.

Data listings were provided for all efficacy variables.

The primary efficacy variables were:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing (Pre- to Post-Brushing scores).

Secondary Efficacy Variables:

- MGI at Day 15:
  - Whole mouth mean change.
  - Gumline (marginal).
  - Proximal.
  - Mean distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
  - Gumline.
  - Proximal.
  - Distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
  - Whole mouth.
  - Gumline.
  - Proximal.
  - Distal score of the last posterior tooth in each quadrant.
- LSPI scores at Day 30
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Analyses were performed at Days 15 and 30 for each efficacy variable, using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons were made at the 0.05 level, 2-sided. At Days 15 and 30 post ANCOVA pairwise comparisons between each of the two group were made using a two-sided Dunnett's test, which controls the error rate for the simultaneous comparisons. Differences between the means, simultaneous 95% confidence intervals and test results was presented.

2.4.3.1 Changes in Conduct of Planned Analysis

Any changes in the planned analyses that were described in Section 11 of Protocol Amendment No. 1 (Appendix 5.1.1) and described in the Statistical Report (Appendix 5.2) are summarized here.

- Demographics data comparisons between the toothbrush groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables instead of the Fisher's Exactness Test.
- Summary tables of site-wise assessment of gingival recession transition of scores (mm) for each toothbrush from Baseline to Day 15 Visit, Baseline to Day 30 Visit, Day 15 to Day 30. The protocol did not stipulate any summary of site-wise scores. Cross-

tabulations were added to present a clear picture of changes in site-wise recession findings over the course of the study.

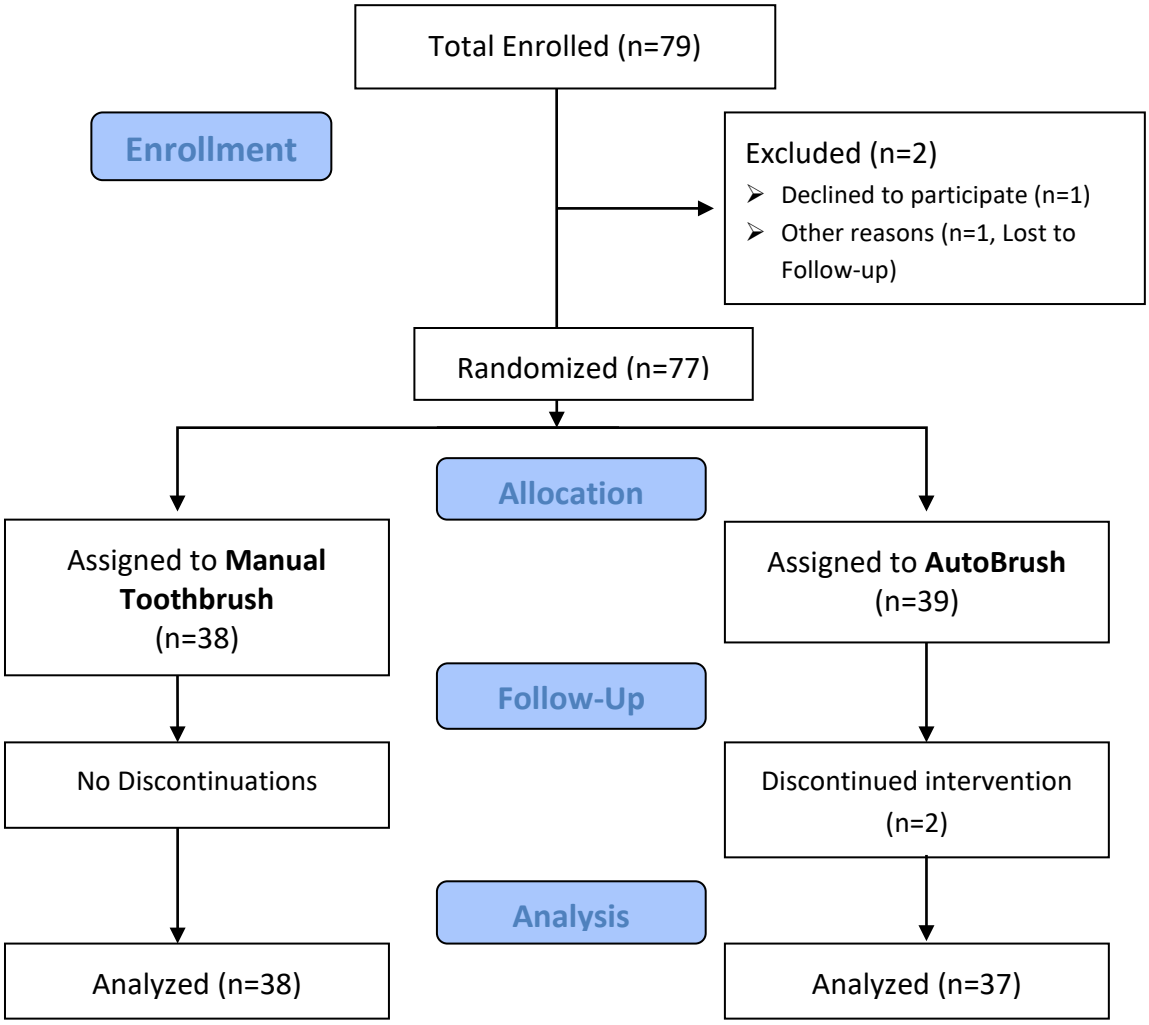
- Analysis methodology for subject-wise mean recession scores was not mentioned in the protocol but the analysis employed an ANCOVA model, the ANCOVA methodology represents more of a clarification, as opposed to a change.
- For gingival recession, the number and percentage of subjects in each treatment group at each study visit with at least one measured site with recession of 1mm or higher; and one measured site with recession of 2mm or higher was added to the analysis to enhance the understanding of the possible impact of the toothbrushes on gingival recession.
- For gingival abrasion, data summaries are presented for cross-tabulations of site-wise score transitions between pairs of visits and cross-tabulations of site-wise abrasion category transitions between pairs of visits. The protocol did not mention this methodology but these cross-tabulations help to present a clear picture of changes in site-wise gingival abrasion findings over the course of the study.
- The protocol proposed analysis of mean change in gingival abrasion scores for each of the 3 categories was replaced by the cross-tabulations described above. The cross-tabulations provide a clearer picture of the possible changes in gingival abrasion that could occur within each treatment group over the course of the study.
- Not described in the protocol, categorical distributions were presented of subjects according to numbers of sites with specific abrasion findings by treatment and visit since this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.
- Although not described in the protocol, analysis of subject-wise mean abrasion scores employed an ANCOVA model as a useful adjunct to the other data analyses on gingival abrasion scores.
- Analysis of subject-wise mean abrasion scores employing an ANCOVA model. Dunnett's test was not employed since there are only two study treatments, there is no need to employ Dunnett's test for this study.
- No analyses were performed on AEs since only one subject was present with an AE so there was no need for statistical analysis.

A detailed description of the changes in statistical analysis methods is provided in the Statistical Report in Appendix 5.2.

3 SUMMARY RESULTS AND CONCLUSIONS

Subject recruitment and screening commenced May 31, 2023, and the study was completed July 14, 2023. Subject flow through the study is presented in Figure 6. Of the 79 subjects screened, 77 subjects met the study entrance criteria and were randomized to one of the two treatment groups. Two subjects randomized to the AB group withdrew from the study prior to Day 15 and 75 subjects completed all study visits. A summary of subject disposition is provided in Table 4.1.

Figure 6. Flow Diagram



Source: Table 4.1, Listing 5.3.2

Demographics characteristics for the 75 subjects who completed the study are provided in **Table 1** and Table 4.2. Subjects ranged in age from 5 to 64. Although the mean age was slightly

larger in the Control group, this difference was not statistically significant. This study population evaluated the effect of the two toothbrushes in subjects with primary/mixed dentition and adult dentition. Each toothbrush group contained at least 10 subjects with primary and mixed dentitions. Both toothbrush groups were roughly 40% male, and consisted predominately of White subjects. Fewer than 4% of the subjects in the study were Hispanic/Latino. The whole mouth MGI was slightly higher for the Control group (MTB); p = 0.0475. Mean LSPI at baseline was comparable in the groups.

Table 1: Demographic and Baseline Characteristic (Per-Protocol Population*)

Parameters	AutoBrush® (AB) (n=37)	Manual Toothbrush (MTB) (n=38)	Total (N=75)
Age, mean (SD), years	27.08 (17.02)	30.66 (18.02)	28.89 (17.51)
Range	5.0, 55.0	7.0, 64.0	5.0, 64.0
			p=0.3800**
Gender			
Male, n (%)	14 (37.8%)	16 (42.1%)	30 (40.0%)
Female, n (%)	23 (62.2%)	22 (57.9%)	45 (60.0%)
			p=0.7061†
Race, n (%)			
American Indian /Alaskan Native	0	2 (5.3%)	2 (2.7%)
Black or African American	1 (2.7%)	0	1 (1.3%)
White	34 (91.9%)	36 (94.7%)	70 (93.3%)
Native Hawaiian or other Pacific Islander	0	0	0
Asian	0	0	0
Other	2 (5.4%)	0	2 (2.7%)
			p=0.1686†
Ethnicity, n (%)			
Hispanic/Latino	1 (2.7%)	2 (5.3%)	3 (4.0%)
Non-Hispanic/Non-Latino	36 (97.3%)	36 (94.7%)	72 (96.0%)
			p=0.5716†
Baseline whole mouth MGI, mean (SD)	2.47 (0.32)	2.61 (0.27)	2.54 (0.30)
			0.0475**
Baseline whole mouth LSPI, mean (SD)	3.05 (0.47)	2.99 (0.39)	3.02 (0.43)
			p=0.5196**

Source: Table 4.2, Table 4.3.1, Table 4.4.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and LSPI, p-values from two-sided t-tests are presented;

† For gender, race, and ethnicity, p-values from chi-squared tests are presented.

Compliance: Based on review of completed diaries and interviews with subjects, all 75 subjects were in compliant with their twice daily use of their assigned toothbrush. All subjects attended

study visits as scheduled and there were no protocol deviations. All subjects, study staff and investigators were compliant with the clinical trial protocol and Good Clinical Practice (GCP) requirements.

3.1 SAFETY RESULTS

3.1.1 Adverse Events

There were no treatment-related oral adverse events observed or reported during the study demonstrating that all treatment materials were well tolerated in this study. Only one adverse event was observed during the OHST exam for one subject who presented with an oral aphthous ulcer on the labial mucosa. The event was considered unrelated to the study product. The adverse event was not serious, was moderate in severity, and resolved within 14 days without sequelae. See **Appendix 5.3.7** for additional details.

3.1.2 Gingival recession

Participation in this study was restricted to subjects with gingival recession levels ≤ 2 mm. The pre-existing gingival recession measurements (mm) averaged 0.046mm and 0.047mm for the AB and MTB, and remained unchanged at Day 15 and Day 30. At the Baseline visit, 18 subjects (48.6%) in the AB group presented with at least 1 site with 1mm gingival recession or higher and only 6 subjects (16.2%) had recession levels of 2mm. In the MTB group, 22 subjects (57.9%) had recession levels of 1 mm and 9 subjects (23.7%) had recession level of 2mm. No site presented a recession score greater than 2mm at any follow up visit (see Table 4.5.7) At each post-baseline visit, each measured site presented the same recession score as noted at the Baseline. Detailed information of recession scores at each visit is presented in Tables 4.5.1-23T-4.5.6-34C and includes the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites that presented scores of 0mm, 1mm, and 2mm. Thus, there was no obvious negative impact on gingival recession associated with either study toothbrush.

3.1.3 Gingival Abrasion

Categorical summary: At Baseline, the percentage of subjects presenting at least one site with gingival abrasion was 94.6% in the AB group, and 84.2% for the MTB group (Table 4.6.13). The percentage of subjects presenting any level of gingival abrasion at follow up visits tended to be numerically higher in the MTB group. At Day 15, 75.7% of subjects in the AB group presented at least one gingival site with abrasion while there were 94.7% of subjects in the MTB group. By Day 30, the percentage of subjects with at least one abrasion site decreased to 56.8% for AB group and 73.7% for the MTB group. At the Baseline visit, there was a little more than 50% of subjects had at least one site with Category 2 abrasion lesion (3mm or higher). At Day 15 and Day 30, the AB group showed a reduction in the percentage of subjects with at least one

Category 2 lesion, 5.4% and 0, respectively. The MTB group had 34.2% and 21.1% of subjects with any Category lesion at Day 15 and Day 30, respectively.

Analysis of mean abrasion scores: Statistically significant reductions from Baseline were observed for both toothbrush groups, p<0.001 (Table 4.6.14) for Day 15 and Day 30 follow up visits. The Baseline mean scores were low for each group, 0.051 for the AB group and 0.066 for the MTB group. At Day 15, the mean scores were lower for the AB group (0.016) compared to the MTB group (0.045). At Day 30, means scores for AB (0.009) and the MTB group (0.022). At Days 15 and 30, the AB group provided significantly greater reductions in abrasion compared to the MTB group, p<0.002.

Site-wise score transitions: For each of the toothbrushes with sites presenting with no gingival abrasion at Baseline, over 97% presented no abrasion at the Day 15 and follow up visits. See Tables 4.6.1-23T – 4.6.6-34C. For sites that presented any abrasion at Baseline, most sites transitioned to lower abrasion levels at the follow up exams. There was no notable transition of abrasion scores for either toothbrush at any time point.

Site-wise transitions of Category scores**:** Examined sites that did not present gingival abrasion were assigned to abrasion Category 0, Category 1 represented sites with small (≤2 mm) abrasions, and Category 2 represented sites with medium (3–5 mm) abrasions. Category score transitions was similar to the site scores previously described. For both toothbrush groups, the number of Category 1 and 2 lesions transitioned to lower categories at each follow up visit (Tables 4.6.7-23T – 4.6.12-34C).

3.2 EFFICACY RESULTS

3.2.1 Primary Efficacy Endpoints

Participants enrolled in this study with mild-to-moderate gingivitis (baseline MGI score of 1.8 to 3.0). Summary data for the primary efficacy variables is provided in Table 2 and Figure 7 for mean changes in whole mouth MGI scores at Day 30 and the mean changes in whole mouth LSPI scores at Day 30, immediate post-brushing (Day 23 Pre- to Post-brushing) .

3.2.1.1 Day 30 Gingivitis Efficacy

At Baseline, gingivitis levels were slightly, but significantly higher for the MTB control group, with mean whole mouth MGI scores of 2.47 and 2.61 for the AB and MTB groups, respectively (p=0.0475). Brushing for 30 days resulted in statistically significant improvement in MGI levels relative to the Baseline scores for the AB group only, p<.0001. Compared to the MTB control group, the mean difference between the AB group and the MTB was 0.958. The AB demonstrated significantly greater whole mouth mean MGI reductions by 40.9% (p<0.0001) compared to the MTB after 30 days of brushing.

3.2.1.2 Day 30 Plaque Removal Efficacy After Single Brushing

Subjects presented with appreciable levels of supragingival plaque at Baseline with overall mean whole mouth LSPI of 3.02, ranging from 2.3 to 4.0, which did not differ significantly (p=0.52). Following the single brushing at Day 30 (Pre-Brushing to Post-Brushing), both toothbrushes significantly reduced whole mouth LSPI (0.62 vs. 0.28). The mean difference between the two groups was 0.33 compared to the MTB group, AB group had 43.22% greater whole mouth plaque removal compared to the MTB (p<0.0001).

Results are illustrated in Figure 7 and greater details of MGI and LSPI results are provided in Table 4.3.1 and 4.4.1, respectively.

Table 2. Summary for Primary Efficacy Variables: Day 30 Whole Mouth MGI, Day 30 Pre- to Post-Brush Whole Mouth LSPI

	Summary of Scores at Visit			Summary of Changes from Baseline			
MGI	**n**	**Mean (S.D.)**	**% Diff. vs. Control ‡**	**n**	**Mean (S.D.)**	**p-value vs. Baseline***	**p-value vs. Control†**
AutoBrush® Group							
Baseline	37	2.471 (0.316)	--	37	--	--	--
Day 30	37	1.502 (0.373)	40.96%	37	-0.969 (0.369)	<.0001	<.0001
Manual Toothbrush Group							
Baseline	38	2.607 (0.266)	n/a	38	--	--	--
Day 30	38	2.544 (0.279)	n/a	38	-0.063 (0.203)	0.4127	n/a
	Summary of Scores at Visit			**Summary of Changes from Pre-Brushing**			
LSPI	**n**	**Mean (S.D.)**	**% Diff. vs. Control ‡**	**n**	**Mean (S.D.)**	**p-value vs. Pre-Brushing$^{\Omega}$**	**p-value vs. Control$^{\Upsilon}$**
AutoBrush® Group							
Day 30 Pre-Brushing	37	2.17 (0.34)	--	37	--	--	--
Day 30 Post-Brushing	37	1.55(0.36)	43.03%	37	-0.62 (0.21)	<0.0001	<0.0001
Manual Toothbrush Group							
Day 30 Pre-Brushing	38	3.01 (0.37)	n/a	38	--	--	--
Day 30 Post-Brushing	38	2.73 (0.28)	n/a	38	-0.283 (0.18)	<0.0001	<0.0001

‡ Percentage difference between the mean follow-up visit score and the corresponding mean score for the Control group. A positive value of % difference reflects a lower score for the Test group being summarized.

* within-group p-value comparing the mean score at the follow-up visit versus the mean score at baseline.

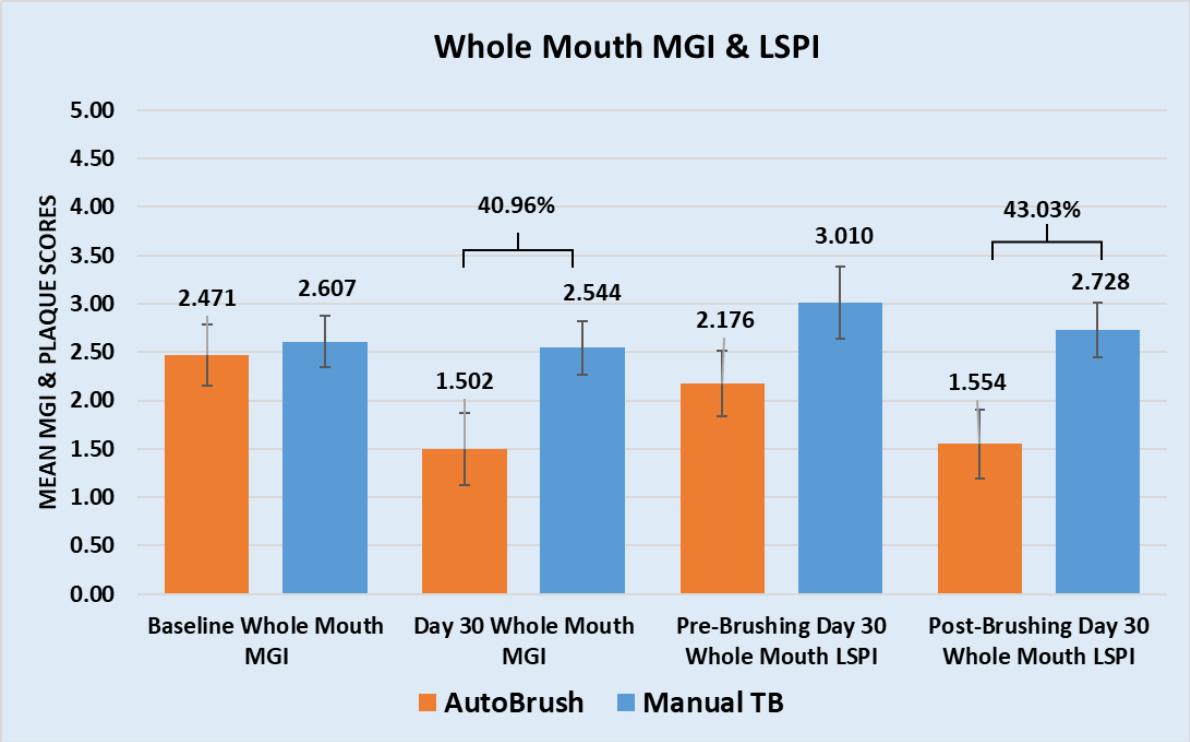
†between-group p-value comparing the mean change from baseline for the indicated test group versus the corresponding change for the Control group

$^{\Omega}$ within-group p-value comparing the mean score at the post-brushing visit versus the Pre-brushing mean score at Day 30

$^{\Upsilon}$ between-group p-value comparing the mean change from Pre-Brushing for the indicated test group versus the corresponding change for the Control group

Source: Table 4.3.1, Table 4.4.1

Figure 7. Day 30 Whole Mouth MGI and Pre- to Post-Brush Whole Mouth LSPI Results



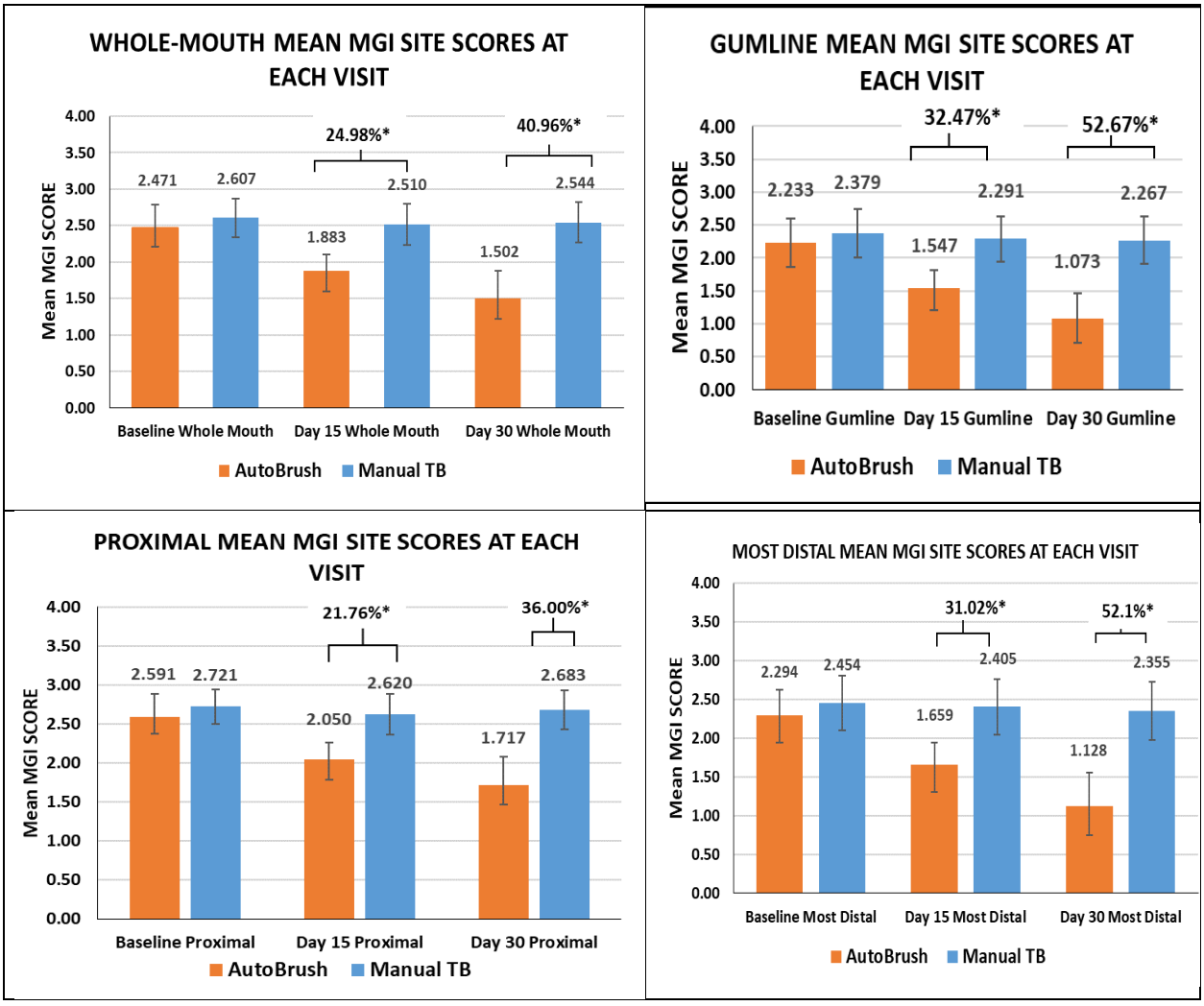
Source: Table 4.3.1, Table 4.4.1

3.2.2 Secondary Efficacy Variables

3.2.2.1 Gingivitis

After 15 days of brushing with the assigned toothbrushes, statistically significant improvement in whole mouth MGI levels relative to the Baseline scores were seen for both the AB group and the MTB group, $p<0.0001$ and $p=0.0307$, respectively. Between group comparisons were favorable for the AB group compared to the MTB with a mean difference of -0.958 and 24.98% greater improvement in whole mouth MGI, $p<0.0001$ (Table 4.3.1; Figure 7). Analysis of the hard-to-reach areas (gumline, proximal, and most distal surfaces) are provided in Tables 4.3.2, 4.3.3 and 4.3.4 and described in Figure 8. At Days 15 and 30, statistically significant improvement from Baseline was observed only for the AB group for all hard-to-reach areas with the MTB providing significant changes only at Day 15 in the proximal areas. Compared to the MTB at Days 15, the AB provided greater reductions in gingivitis of 32.5%, 21.7% and 31.02% ($p<0.0001$), respectively, for gumline, proximal and most distal areas. Similar results were observed for Day 30 with the AB product reducing gingivitis levels for the three hard-to-reach areas by 52.7%, 36.0% and 52.1%, respectively, $p<0.0001$, compared to the MTB.

Figure 8. MGI Results for Whole Mouth and Hard-to-Reach Areas



*Differences compared to control, p <0.0001

Source: Table 4.3.1, Table 4.3.2,Table 4.3.3, Table 4.3.4

3.2.2.2 Plaque Reductions at Day 15 and Day 30

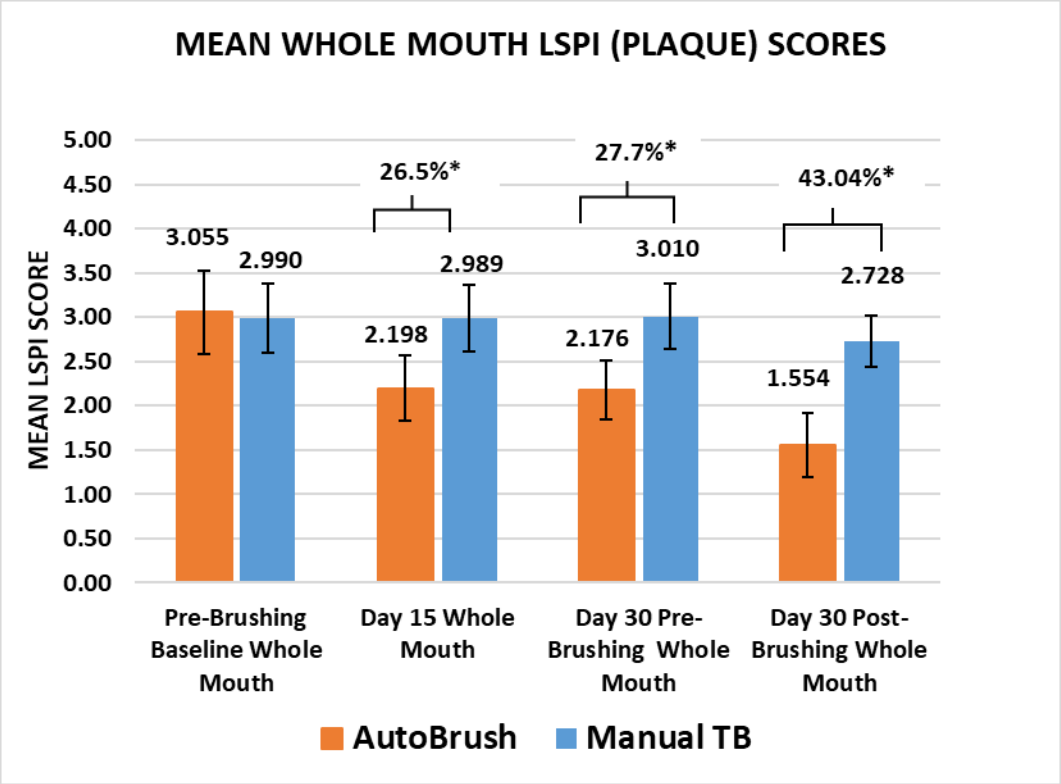
At Baseline, there were no differences between the two groups with whole mouth mean LSPI Baseline scores of 3.09 and 2.99, respectively, for AB and MTB (p=0.5196; Table 1). Only the AB group showed significant (P< 0.001) reductions from Baseline in whole mouth, gingival margin, proximal and most distal area plaque scores at Day 15 and Day 30 (p<0.0001). The AB group removed significantly more plaque than MTB at Day 15 for whole mouth mean scores as well as at Day 15 and Day 30 for gumline, proximal and most distal surfaces (p<0.0001). After 15 days of brushing, the AB was found to have significantly greater plaque removal for whole mouth scores (26.5%), gumline areas (45.4%), proximal (18.3%), and most distal surface regions (31.02%). At Day 30, significantly greater reductions continued in the hard-to-reach areas (gumline, proximal and most distal areas) for the AB group compared to the MTB group with reductions of 45.4%, 19.7% and 28.2%, in the hard-to-reach areas, respectively. Details of LSPI

results (whole mouth, gumline, proximal, and most distal regions) are provided in Table 4.4.1, 4.4.2, 4.4.3, and 4.4.4 and are illustrated in Figure 9, Figure -10, Figure 11 and Figure 12.

3.2.2.3 Plaque Reduction After Day 30 Single Brushing

Following the single brushing at Day 30 (Pre-Brushing to Post-Brushing), both toothbrushes significantly reduced LSPI in the hard-to-reach-areas (gumline and proximal), p<0.000. However, only the AB group significantly reduced plaque compared to the Pre-brushing levels. Compared to the MTB group, the AutoBrush® provided 85.2%, 27.4% and 68.8% greater plaque removal on the gumline, proximal and most distal regions, respectively (p<0.0001).

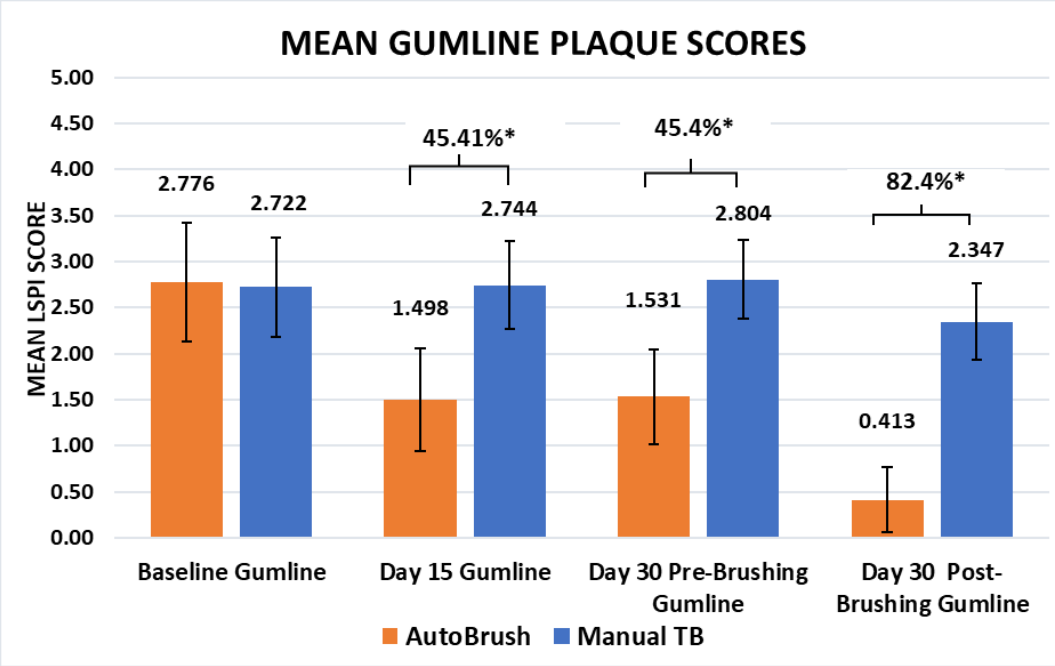
Figure 9. Mean Whole Mouth Plaque scores at Each Visit



*Differences compared to control, p <0.0001

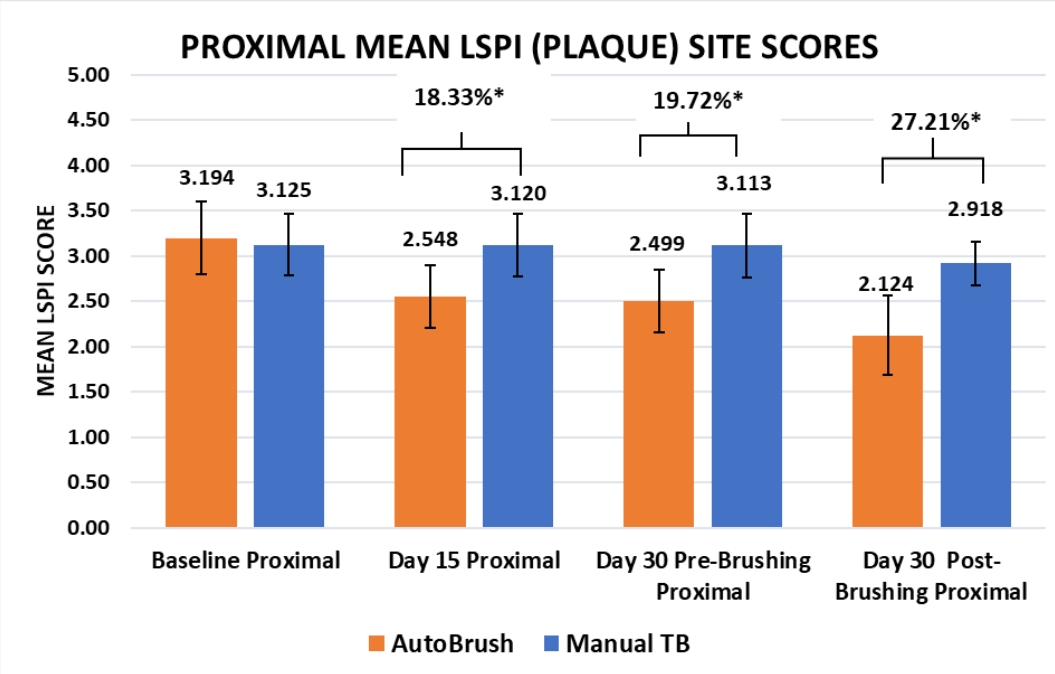
Source: Table 4.4.1

Figure 10. Mean Gumline Plaque Scores at Each Visit



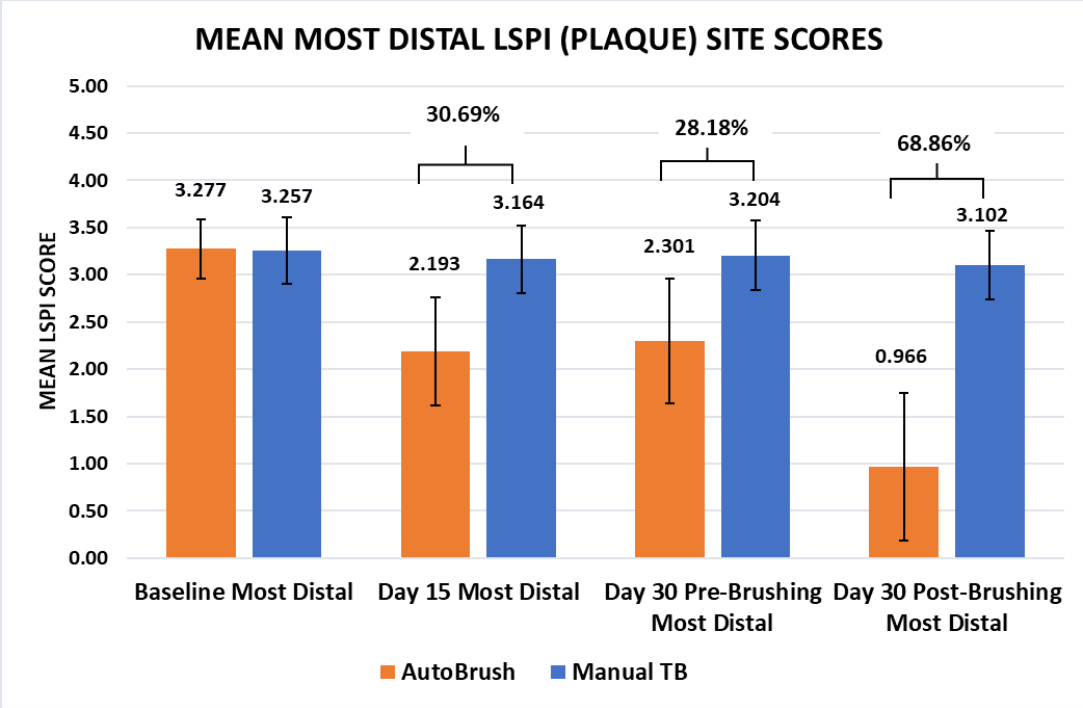
*Differences compared to control, p <0.0001
Source: Table 4.4.2

Figure 11. Mean Proximal Plaque Scores at Each Visit



*Differences compared to control, p <0.0001
Source: Table 4.4.3

Figure 12. Mean Most Distal Plaque Scores at Each Visit



*Differences compared to control, p <0.0001
Source: Table 4.4.4

3.3 DISCUSSION

This 30-day, examiner-blind clinical trial was designed to assess both the safety and efficacy of an innovative U-shaped sonic toothbrush, AutoBrush®, on plaque and gingivitis, compared to an ADA reference soft manual toothbrush. A reasonable concern for new toothbrush designs, manual or power, is the potential to cause soft tissue damage in the form of gingival abrasion or gingival recession. Analysis of recession measurements in this study revealed no change from Baseline at any subsequent timepoint, Day 15 or Day 30. The initial levels of recession were extremely small, which makes sense considering this study recruited a gingivitis population with an initial level of recession less than 2 mm. Similar to recession, the initial levels of gingival abrasion were quite small and the Baseline levels reflect any potential damage caused by the ADA reference toothbrush that subjects used during the 7 to 14 day washout period. Up to 168 sites were assessed for gingival abrasion in a mouth will a full complement of 28 teeth. The extremely low mean abrasion scores at Baseline and all subsequent timepoints represent a remarkably low level of toothbrush trauma initially and throughout the study. The incidence of abrasion lesions actually reduced for each toothbrush from Baseline with the greatest change seen for the AB group. The majority of the gingival abrasion lesions were small in size and were likely superficial and reversible given that we observed a reduction in the small number of abrasions for both toothbrushes from Baseline to Day 30.

Any potential safety signal was addressed through the evaluation of the extent of gingival abrasion and recession, as well as through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. Only one subject presented with an AE related to an oral aphthous ulceration was deemed unrelated to the assigned toothbrush, the MTB. There were no other reported AEs or SAE during the study. Both toothbrushes were well-tolerated and did not contribute to any toothbrush trauma such as gingival abrasion and gingival recession.

A revealing measure of the efficacy of a toothbrush is the improvement in plaque-induced gingivitis. In a diverse population of participants aged 5-65 years, results of this study reflect the ability of the innovative AutoBrush® U-shaped sonic power toothbrush to improve gingival health vs. an ADA reference standard MTB and provide a corresponding level of plaque reduction. After 15 and 30 days of brushing, the AutoBrush® U-shaped sonic toothbrush surpassed the ADA reference MTB with respect to improvement in whole mouth gingivitis scores. Similar results were seen in the hard-to-reach areas (gumline, proximal and most distal surfaces). This study assessed gingivitis and plaque levels on the distal surfaces of the most distal tooth in each quadrant of the mouth. Considering the population included individuals with adult dentition, and primary or mixed dentition, the most distal tooth in each mouth could be a primary molar, or 6-year or 12-year permanent molar. Gingivitis reductions for the most distal and posterior surfaces in the mouth demonstrate the reach of the AutoBrush® in the most posterior parts of the mouth to remove plaque and thereby reduced gingival inflammation.

Plaque removal efficacy mirrored the gingivitis reduction with significant improvements for the AutoBrush® compared to the MTB at all timepoints. The cumulative benefit in plaque reduction that was observed at Days 15 and 30 when assessing the pre-brushing LSPI scores suggests that the AutoBrush® effectively disrupted dental plaque colonies, helping to minimize further accumulation of plaque bacteria and thereby reduced and inhibited gingival inflammation. In this study, we also assessed the immediate post-brushing effect following the pre-brushing plaque assessment on Day 30. This measurement helps to explain why gingivitis improvements were seen at Day 30 since plaque removal is key to preventing and reducing gingivitis. For all areas of the mouth (whole-mouth, gumline, proximal and most distal), the AutoBrush® removed significantly more plaque than the ADA reference MTB.

In a recent, unpublished, single-use clinical study with 22 children, aged 5-8 years, 30 seconds use of the AutoBrush® significantly reduced whole mouth plaque levels compared to a children's MTB, used for two minutes, by 50%. Hard-to-reach areas, such as gumline and

proximal, had plaque levels reduced by 69.7% by 40.7%. Effective plaque removal in children is a constant challenge since efficiency can be impacted by a child's age and dexterity. A recent systematic review concluded that there was strong evidence that use of an electric toothbrush provided meaningful improvement in plaque levels compared to a manual toothbrush in children as young as 2 years of age up to 17 years.[21] Toothbrushing research in a pediatric population has been limited to assessment of plaque removal efficacy with no substantial assessment on gingivitis.

It is noteworthy that a 30-second brushing with the AutoBrush® provided significantly greater improvement in plaque removal and gingivitis compared to a two minute brushing with a manual toothbrush. In a 30-second time period, the unique toothbrush was able to disrupt plaque biofilm and reduce gingivitis, even in hard-to-reach areas. Similar benefits have been seen with power toothbrushes, such as sonic and oscillating-rotating design, which are achieved with two-minute brushing periods. It is well-known that power toothbrushes are more effective than manual toothbrushes in removing plaque and reducing gingivitis.[12–13]

The introduction of the AutoBrush® 360 U-Shaped toothbrush represents a disruption to the power toothbrush market with plaque and gingivitis benefits achieved with 30-second toothbrushing versus two minutes with a manual toothbrush. The company's mission is to make brushing simpler, better, and more accessible for kids, adults and individuals with disabilities.

3.4 CONCLUSION

In conclusion, the AutoBrush® 360° U-shaped Sonic Toothbrush demonstrated a superior reduction in plaque and showed a beneficial improvement in gingival health compared with the manual toothbrush. The results of this study demonstrate the safety of the AutoBrush® and benefits in providing clinically measurable improvement in plaque removal and gingival health.

Results from this study of the comparative safety and efficacy of the AB® indicate that this new power toothbrush for children and adults is safe and is significantly more effective than an ADA reference soft manual toothbrush. There was no gingival abrasion and recession reported during the study, and no reported adverse events were considered related to either toothbrush product.

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4 TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

4.1 Disposition of Study Subjects (All Randomized Subjects)

Table 1
Disposition of Study Subjects
(All Randomized Subjects)

	AutoBrush® Toothbrush (N = 39)	Manual Toothbrush (N = 38)	Overall (N = 77)
Randomized	39	38	77
Completed Study	37 (94.9%)	38 (100%)	75 (97.4%)
Discontinued*	2 (5.1%)	0 (0.0%)	2 (2.6%)

Source: Listings 1 and, 2

* All randomized subjects who discontinued the study did so for the reason: Subject withdrew from study.

4.2 Demographics and Baseline Characteristics (Subjects in the Per-Protocol Population)

Table 2
Demographics and Baseline Characteristics
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush (N = 37)	Manual Toothbrush (N = 38)	Overall (N = 75)	Between Treatment Comparisons**
Age (years)				
n	37	38	75	
Mean (SD)	27.08 (17.02)	30.66 (18.02)	28.89 (17.51)	0.3800
Median	27.00	35.50	33.00	
Min, Max	(5.0, 55.0)	(7.0, 64.0)	(5.0, 64.0)	
Gender				
Male	14 (37.8%)	16 (42.1%)	30 (40.0%)	0.7061
Female	23 (62.2%)	22 (57.9%)	45 (60.0%)	
Race				
American Indian /Alaskan Native	0	2 (5.3%)	2 (2.7%)	0.1686
Black or African American	1 (2.7%)	0	1 (1.3%)	
White	34 (91.9%)	36 (94.7%)	70 (93.3%)	
Native Hawaiian or other Pacific Islander	0	0	0	
Asian	0	0	0	
Other	2 (5.4%)	0	2 (2.7%)	
Ethnicity				
Hispanic/Latino	1 (2.7%)	2 (5.3%)	3 (4.0%)	0.5716
Non-Hispanic/Non-Latino	36 (97.3%)	36 (94.7%)	72 (96.0%)	

Source: Listings 1, 2, 3, 4.1, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and PI, p-values from two-sided t-tests are presented.
For gender, race, and ethnicity, p-values from chi-squared tests are presented.

Table 2 (Cont'd)
Demographics and Baseline Characteristics
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush (N = 37)	Manual Toothbrush (N = 38)	Overall (N = 75)	Between Treatment Comparisons**
Whole Mouth MGI at Baseline				
Subjects with Non-Missing Data	37	38	75	
Mean (SD)	2.47 (0.32)	2.61 (0.27)	2.54 (0.30)	0.0475
Median	2.50	2.62	2.54	
Min, Max	(1.8, 3.0)	(1.9, 3.0)	(1.8, 3.0)	
Subjects with Missing Data	0	0	0	
Whole Mouth PI at Baseline				
Subjects with Non-Missing Data	37	38	75	
Mean (SD)	3.05 (0.47)	2.99 (0.39)	3.02 (0.43)	0.5196
Median	2.95	2.92	2.94	
Min, Max	(2.4, 4.0)	(2.3, 3.9)	(2.3, 4.0)	
Subjects with Missing Data	0	0	0	

Source: Listings 1, 2, 3, 4.1, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and PI, p-values from two-sided t-tests are presented.
For gender, race, and ethnicity, p-values from chi-squared tests are presented.

4.3 Modified Gingival Index Findings

4.3.1 Whole Mouth Modified Gingival Index Findings

Table 3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.471 (0.3159)	2.607 (0.2664)
Median	2.500	2.621
Min, Max	1.81, 3.00	1.89, 3.00
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 4.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.883 (0.2214)	2.510 (0.2826)
Median	1.826	2.514
Min, Max	1.45, 2.35	1.92, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.588 (0.2412)	-0.098 (0.2111)
Median	-0.577	-0.086
Min, Max	-1.22, -0.18	-0.53, 0.34
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.617 (0.0319)	-0.069 (0.0315)
95% CI	(-0.681, -0.553)	(-0.132, -0.007)
p-value comparing LS Mean versus 0	<.0001	0.0307
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.548 (0.0454)	n/a
95% CI	(-0.638, -0.457)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.502 (0.3732)	2.544 (0.2796)
Median	1.476	2.560
Min, Max	0.71, 2.29	1.80, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.969 (0.3692)	-0.063 (0.2030)
Median	-0.970	-0.028
Min, Max	-1.69, 0.35	-0.58, 0.32
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.995 (0.0462)	-0.038 (0.0456)
95% CI	(-1.087, -0.903)	(-0.128, 0.053)
p-value comparing LS Mean versus 0	<.0001	0.4127
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.958 (0.0658)	n/a
95% CI	(-1.089, -0.827)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.3.2 Gumline Surfaces

Table 3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.233 (0.3726)	2.379 (0.3686)
Median	2.214	2.365
Min, Max	1.52, 3.00	1.43, 3.00
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 4.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.547 (0.2633)	2.291 (0.3459)
Median	1.500	2.245
Min, Max	1.07, 2.05	1.48, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.686 (0.2933)	-0.088 (0.2710)
Median	-0.667	-0.134
Min, Max	-1.61, -0.09	-0.60, 0.57
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.719 (0.0383)	-0.056 (0.0378)
95% CI	(-0.795, -0.643)	(-0.131, 0.020)
p-value comparing LS Mean versus 0	<.0001	0.1462
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.663 (0.0543)	n/a
95% CI	(-0.772, -0.555)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.073 (0.3961)	2.267 (0.3569)
Median	1.071	2.234
Min, Max	0.25, 2.02	1.35, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.160 (0.4433)	-0.112 (0.2657)
Median	-1.182	-0.093
Min, Max	-1.93, 0.50	-0.79, 0.43
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.194 (0.0536)	-0.079 (0.0529)
95% CI	(-1.301, -1.088)	(-0.184, 0.027)
p-value comparing LS Mean versus 0	<.0001	0.1418
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.116 (0.0761)	n/a
95% CI	(-1.267, -0.964)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.3.3 Proximal Surfaces

Table 3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.591 (0.2985)	2.721 (0.2230)
Median	2.630	2.730
Min, Max	1.91, 3.00	2.13, 3.00
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 4.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.051 (0.2098)	2.619 (0.2629)
Median	2.000	2.622
Min, Max	1.62, 2.50	2.13, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.539 (0.2307)	-0.103 (0.2005)
Median	-0.545	-0.005
Min, Max	-1.03, -0.16	-0.60, 0.29
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.567 (0.0310)	-0.075 (0.0306)
95% CI	(-0.629, -0.506)	(-0.136, -0.014)
p-value comparing LS Mean versus 0	<.0001	0.0165
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.492 (0.0442)	n/a
95% CI	(-0.580, -0.404)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.717 (0.3656)	2.683 (0.2495)
Median	1.696	2.736
Min, Max	0.94, 2.43	2.02, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.873 (0.3416)	-0.039 (0.1811)
Median	-0.864	-0.005
Min, Max	-1.57, 0.28	-0.50, 0.26
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.895 (0.0434)	-0.017 (0.0428)
95% CI	(-0.982, -0.809)	(-0.102, 0.068)
p-value comparing LS Mean versus 0	<.0001	0.6894
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.878 (0.0619)	n/a
95% CI	(-1.002, -0.755)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.3.4 Most Distal Surfaces

Table 3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.294 (0.3349)	2.454 (0.3493)
Median	2.250	2.438
Min, Max	1.63, 3.00	1.25, 3.00
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 4.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.659 (0.2836)	2.405 (0.3564)
Median	1.625	2.375
Min, Max	1.00, 2.25	1.75, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.635 (0.3010)	-0.049 (0.3243)
Median	-0.625	0.000
Min, Max	-1.38, -0.13	-0.63, 0.75
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.674 (0.0449)	-0.012 (0.0443)
95% CI	(-0.763, -0.584)	(-0.100, 0.076)
p-value comparing LS Mean versus 0	<.0001	0.7889
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.662 (0.0640)	n/a
95% CI	(-0.789, -0.534)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.128 (0.4315)	2.355 (0.3784)
Median	1.125	2.375
Min, Max	0.38, 2.00	1.50, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.166 (0.5078)	-0.099 (0.3105)
Median	-1.250	0.000
Min, Max	-2.00, 0.38	-0.75, 0.63
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.210 (0.0630)	-0.055 (0.0621)
95% CI	(-1.336, -1.085)	(-0.179, 0.069)
p-value comparing LS Mean versus 0	<.0001	0.3763
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.155 (0.0896)	n/a
95% CI	(-1.333, -0.976)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 4.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.4 Analysis of Plaque Index Findings

4.4.1 Whole Mouth Plaque Index Findings

Table 4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	3.055 (0.4699)	2.990 (0.3916)
Median	2.946	2.919
Min, Max	2.38, 4.01	2.35, 3.90
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.198 (0.3637)	2.989 (0.3823)
Median	2.256	3.020
Min, Max	1.38, 2.95	2.40, 3.83
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.857 (0.4731)	-0.001 (0.2634)
Median	-0.783	-0.015
Min, Max	-1.77, 0.14	-0.67, 0.58
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.840 (0.0513)	-0.017 (0.0506)
95% CI	(-0.942, -0.738)	(-0.118, 0.083)
p-value comparing LS Mean versus 0	<.0001	0.7319
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.823 (0.0722)	n/a
95% CI	(-0.966, -0.679)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.176 (0.3368)	3.010 (0.3695)
Median	2.194	3.027
Min, Max	1.30, 2.81	2.39, 3.92
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.879 (0.5303)	0.020 (0.2665)
Median	-0.788	0.003
Min, Max	-1.84, 0.14	-0.64, 0.67
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.858 (0.0524)	-0.000 (0.0517)
95% CI	(-0.963, -0.754)	(-0.103, 0.103)
p-value comparing LS Mean versus 0	<.0001	0.9948
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.858 (0.0737)	n/a
95% CI	(-1.005, -0.711)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.554 (0.3568)	2.728 (0.2846)
Median	1.506	2.735
Min, Max	0.73, 2.30	2.19, 3.46
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.623 (0.2074)	-0.283 (0.1816)
Median	-0.595	-0.260
Min, Max	-1.19, -0.03	-0.93, 0.00
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-0.618 (0.0305)	-0.287 (0.0301)
95% CI	(-0.678, -0.557)	(-0.347, -0.228)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.330 (0.0429)	
95% CI	(-0.416, -0.245)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.4.2 Gumline Surfaces

Table 4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.776 (0.6422)	2.722 (0.5355)
Median	2.705	2.712
Min, Max	1.73, 4.00	1.52, 3.79
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.498 (0.5574)	2.744 (0.4806)
Median	1.478	2.808
Min, Max	0.50, 2.70	1.96, 3.70
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.278 (0.5904)	0.022 (0.3684)
Median	-1.315	0.000
Min, Max	-2.33, -0.11	-0.87, 0.98
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.266 (0.0678)	0.010 (0.0669)
95% CI	(-1.401, -1.131)	(-0.124, 0.143)
p-value comparing LS Mean versus 0	<.0001	0.8832
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.276 (0.0953)	n/a
95% CI	(-1.466, -1.086)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	1.531 (0.5093)	2.804 (0.4302)
Median	1.521	2.820
Min, Max	0.35, 2.66	2.20, 3.87
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.245 (0.6525)	0.082 (0.3671)
Median	-1.354	0.009
Min, Max	-2.21, 0.20	-0.74, 1.02
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.229 (0.0664)	0.066 (0.0655)
95% CI	(-1.362, -1.097)	(-0.064, 0.197)
p-value comparing LS Mean versus 0	<.0001	0.3155
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.296 (0.0933)	n/a
95% CI	(-1.482, -1.110)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.413 (0.3566)	2.347 (0.4114)
Median	0.295	2.356
Min, Max	0.00, 1.68	1.54, 3.31
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.118 (0.3755)	-0.457 (0.2495)
Median	-1.056	-0.473
Min, Max	-2.13, -0.09	-1.24, 0.00
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-1.116 (0.0520)	-0.459 (0.0513)
95% CI	(-1.219, -1.012)	(-0.562, -0.357)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.656 (0.0731)	
95% CI	(-0.802, -0.510)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.4.3 Proximal Surfaces

Table 4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	3.194 (0.4000)	3.125 (0.3430)
Median	3.096	3.071
Min, Max	2.57, 4.02	2.58, 3.95
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.548 (0.3434)	3.112 (0.3457)
Median	2.589	3.123
Min, Max	1.73, 3.13	2.51, 3.89
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.646 (0.4550)	-0.012 (0.2285)
Median	-0.554	-0.030
Min, Max	-1.49, 0.27	-0.57, 0.50
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.627 (0.0495)	-0.031 (0.0488)
95% CI	(-0.726, -0.529)	(-0.128, 0.066)
p-value comparing LS Mean versus 0	<.0001	0.5285
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.596 (0.0696)	n/a
95% CI	(-0.735, -0.457)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.499 (0.3462)	3.113 (0.3474)
Median	2.537	3.133
Min, Max	1.75, 3.09	2.42, 3.95
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.696 (0.5203)	-0.011 (0.2346)
Median	-0.616	-0.010
Min, Max	-1.68, 0.22	-0.61, 0.53
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.673 (0.0533)	-0.033 (0.0526)
95% CI	(-0.779, -0.566)	(-0.138, 0.071)
p-value comparing LS Mean versus 0	<.0001	0.5266
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.639 (0.0750)	n/a
95% CI	(-0.789, -0.490)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.124 (0.4407)	2.918 (0.2413)
Median	2.152	2.946
Min, Max	0.95, 3.00	2.48, 3.53
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.375 (0.2048)	-0.196 (0.1691)
Median	-0.352	-0.181
Min, Max	-0.80, 0.00	-0.77, 0.07
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-0.368 (0.0290)	-0.202 (0.0286)
95% CI	(-0.426, -0.311)	(-0.259, -0.145)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.167 (0.0409)	
95% CI	(-0.248, -0.085)	
Between-treatment p-value	0.0001	

Source: Listings 1, 2, and 5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.4.4 Most Distal Surfaces

Table 4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	3.277 (0.3134)	3.257 (0.3499)
Median	3.250	3.250
Min, Max	2.75, 4.38	2.50, 4.13
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.193 (0.5725)	3.164 (0.3561)
Median	2.375	3.125
Min, Max	1.00, 3.50	2.63, 4.13
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.084 (0.5729)	-0.092 (0.2561)
Median	-1.000	-0.063
Min, Max	-2.38, 0.38	-0.63, 0.50
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.081 (0.0704)	-0.096 (0.0695)
95% CI	(-1.221, -0.940)	(-0.234, 0.043)
p-value comparing LS Mean versus 0	<.0001	0.1723
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.985 (0.0989)	n/a
95% CI	(-1.182, -0.788)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	2.301 (0.6617)	3.204 (0.3681)
Median	2.500	3.250
Min, Max	0.75, 3.63	2.75, 4.13
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.976 (0.6554)	-0.053 (0.2812)
Median	-0.875	-0.125
Min, Max	-2.63, 0.50	-0.75, 0.63
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.973 (0.0808)	-0.056 (0.0797)
95% CI	(-1.134, -0.812)	(-0.215, 0.103)
p-value comparing LS Mean versus 0	<.0001	0.4834
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.917 (0.1136)	n/a
95% CI	(-1.143, -0.690)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.966 (0.7860)	3.102 (0.3628)
Median	0.750	3.000
Min, Max	0.00, 3.00	2.38, 4.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-1.334 (0.6588)	-0.102 (0.1740)
Median	-1.375	-0.125
Min, Max	-2.50, 0.00	-0.38, 0.38
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-1.333 (0.0790)	-0.103 (0.0779)
95% CI	(-1.491, -1.176)	(-0.259, 0.052)
p-value comparing LS Mean versus 0	<.0001	0.1892
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.230 (0.1110)	
95% CI	(-1.451, -1.009)	
Between-treatment p-value	<.0001	

Source: Listings 1, 2, and 5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.5 Clinical Safety Findings; Gingival Recession

4.5.1 Table 5.1-23T Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 5.1-23T

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)			
Frequency Row Pct	0	1	2	Total
0	5395 100.00	0 0.00	0 0.00	5395
1	0 0.00	217 100.00	0 0.00	217
2	0 0.00	0 0.00	22 100.00	22
Total	5395	217	22	5634

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from recx23t

4.5.2 Table 5.1-23C Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit - For Subjects Using the Manual Toothbrush

Table 5.1-23C

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)			
Frequency Row Pct	0	1	2	Total
0	5459 100.00	0 0.00	0 0.00	5459
1	0 0.00	201 100.00	0 0.00	201
2	0 0.00	0 0.00	31 100.00	31
Total	5459	201	31	5691

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.3 Table 5.1-24T Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 5.1-24T

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5395 100.00	0 0.00	0 0.00	5395
1	0 0.00	217 100.00	0 0.00	217
2	0 0.00	0 0.00	22 100.00	22
Total	5395	217	22	5634

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.4 Table 5.1-24C Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 5.1-24C

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5459 100.00	0 0.00	0 0.00	5459
1	0 0.00	201 100.00	0 0.00	201
2	0 0.00	0 0.00	31 100.00	31
Total	5459	201	31	5691

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.5 Table 5.1-34T Site-wise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 5.1-34T

Sitewise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5395 100.00	0 0.00	0 0.00	5395
1	0 0.00	217 100.00	0 0.00	217
2	0 0.00	0 0.00	22 100.00	22
Total	5395	217	22	5634

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.6 Table 5.1-34C Site-wise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 5.1-34C

Sitewise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5459 100.00	0 0.00	0 0.00	5459
1	0 0.00	201 100.00	0 0.00	201
2	0 0.00	0 0.00	31 100.00	31
Total	5459	201	31	5691

Source: Listings 1, 2, and 6
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.7 Table 5.2 Summary of Gingival Recession Findings

Table 5.2
Summary of Gingival Recession Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.046 (0.0830)	0.047 (0.0667)
Median	0.000	0.021
Min, Max	0.00, 0.35	0.00, 0.24
Subjects with Missing Data	0	0
Number of Subjects With at Least 1 Site:		
Presenting Recession 1mm or Higher	18 (48.6%)	22 (57.9%)
Presenting Recession 2mm or Higher	6 (16.2%)	9 (23.7%)

Source: Listings 1, 2, and 6

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: As seen in Table 5.1, each measured site presented the same recession score at every visit. Consequently the summary presented in this table is limited to the Baseline Visit.

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4.6 Clinical Safety Findings; Gingival Abrasion

4.6.1 Table 6.1-23T Site-wise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.1-23T

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)					
Frequency Row Pct	0	1	2	3	4	Total
0	5415 98.89	46 0.84	13 0.24	1 0.02	1 0.02	5476
1	42 91.30	4 8.70	0 0.00	0 0.00	0 0.00	46
2	60 95.24	2 3.17	1 1.59	0 0.00	0 0.00	63
3	32 96.97	1 3.03	0 0.00	0 0.00	0 0.00	33
4	2 66.67	1 33.33	0 0.00	0 0.00	0 0.00	3
5	1 100.00	0 0.00	0 0.00	0 0.00	0 0.00	1
Total	5552	54	14	1	1	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx23t

4.6.2 Table 6.1-23C Site-wise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit - For Subjects Using the Manual Toothbrush

Table 6.1-23C

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)						
Frequency Row Pct	0	1	2	3	4	5	Total
0	5431 97.68	65 1.17	44 0.79	13 0.23	4 0.07	3 0.05	5560
1	36 94.74	2 5.26	0 0.00	0 0.00	0 0.00	0 0.00	38
2	72 87.80	2 2.44	7 8.54	1 1.22	0 0.00	0 0.00	82
3	36 90.00	0 0.00	2 5.00	2 5.00	0 0.00	0 0.00	40
4	8 100.00	0 0.00	0 0.00	0 0.00	0 0.00	0 0.00	8
5	4 66.67	1 16.67	1 16.67	0 0.00	0 0.00	0 0.00	6
Total	5587	70	54	16	4	3	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx23c

4.6.3 Table 6.1-24T Site-wise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.1-24T

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5446 99.45	19 0.35	11 0.20	5476
1	45 97.83	0 0.00	1 2.17	46
2	63 100.00	0 0.00	0 0.00	63
3	30 90.91	0 0.00	3 9.09	33
4	3 100.00	0 0.00	0 0.00	3
5	1 100.00	0 0.00	0 0.00	1
Total	5588	19	15	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx24t

4.6.4 Table 6.1-24C Site-wise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 6.1-24C

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)					
Frequency Row Pct	0	1	2	3	4	Total
0	5497 98.87	25 0.45	33 0.59	4 0.07	1 0.02	5560
1	37 97.37	0 0.00	0 0.00	1 2.63	0 0.00	38
2	77 93.90	2 2.44	2 2.44	1 1.22	0 0.00	82
3	38 95.00	1 2.50	0 0.00	1 2.50	0 0.00	40
4	7 87.50	1 12.50	0 0.00	0 0.00	0 0.00	8
5	5 83.33	0 0.00	1 16.67	0 0.00	0 0.00	6
Total	5661	29	36	7	1	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx24c

4.6.5 Table 6.1-34T Site-wise Abrasion Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.1-34T

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5519 99.41	19 0.34	14 0.25	5552
1	53 98.15	0 0.00	1 1.85	54
2	14 100.00	0 0.00	0 0.00	14
3	1 100.00	0 0.00	0 0.00	1
4	1 100.00	0 0.00	0 0.00	1
Total	5588	19	15	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx34t

4.6.6 Table 6.1-34C Site-wise Abrasion Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 6.1-34C

Sitewise Abrasion Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score) / Frequency / Row Pct	score4(Day 30 Score) 0	1	2	3	4	Total
0	5522 98.84	26 0.47	33 0.59	5 0.09	1 0.02	5587
1	68 97.14	0 0.00	1 1.43	1 1.43	0 0.00	70
2	50 92.59	3 5.56	1 1.85	0 0.00	0 0.00	54
3	15 93.75	0 0.00	1 6.25	0 0.00	0 0.00	16
4	4 100.00	0 0.00	0 0.00	0 0.00	0 0.00	4
5	2 66.67	0 0.00	0 0.00	1 33.33	0 0.00	3
Total	5661	29	36	7	1	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

Executed on 22SEP2023 at 16:41 from abrx34c

4.6.7 Table 6.2-23T Site-wise Abrasion Category Transitions Between Baseline and the Day 15 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.2-23T

Sitewise Abrasion Category Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat3

cat2(Baseline Category)	cat3(Day 15 Category)			
Frequency Row Pct	0	1	2	Total
0	5415 98.89	59 1.08	2 0.04	5476
1	102 93.58	7 6.42	0 0.00	109
2	35 94.59	2 5.41	0 0.00	37
Total	5552	68	2	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 15 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx23t

4.6.8 Table 6.2-23C Site-wise Abrasion Category Transitions Between Baseline and the Day 15 Visit - For Subjects Using the Manual Toothbrush

Table 6.2-23C

Sitewise Abrasion Category Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat3

cat2(Baseline Category)	cat3(Day 15 Category)			
Frequency Row Pct	0	1	2	Total
0	5431 97.68	109 1.96	20 0.36	5560
1	108 90.00	11 9.17	1 0.83	120
2	48 88.89	4 7.41	2 3.70	54
Total	5587	124	23	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 15 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx23c

4.6.9 Table 6.2-24T Site-wise Abrasion Category Transitions Between Baseline and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.2-24T

Sitewise Abrasion Category Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat4

cat2(Baseline Category)	cat4(Day 30 Category)		
Frequency Row Pct	0	1	Total
0	5446 99.45	30 0.55	5476
1	108 99.08	1 0.92	109
2	34 91.89	3 8.11	37
Total	5588	34	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx24t

4.6.10 Table 6.2-24C Site-wise Abrasion Category Transitions Between Baseline and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 6.2-24C

Sitewise Abrasion Category Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat4

cat2(Baseline Category)	cat4(Day 30 Category)			
Frequency Row Pct	0	1	2	Total
0	5497 98.87	58 1.04	5 0.09	5560
1	114 95.00	4 3.33	2 1.67	120
2	50 92.59	3 5.56	1 1.85	54
Total	5661	65	8	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx24c

4.6.11 Table 6.2-34T Site-wise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the AutoBrush® Toothbrush

Table 6.2-34T

Sitewise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat3 by cat4

cat3(Day 15 Category)	cat4(Day 30 Category)		
Frequency Row Pct	0	1	Total
0	5519 99.41	33 0.59	5552
1	67 98.53	1 1.47	68
2	2 100.00	0 0.00	2
Total	5588	34	5622

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx34t

4.6.12 Table 6.2-34C Site-wise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit - For Subjects Using the Manual Toothbrush

Table 6.2-34C

Sitewise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat3 by cat4

cat3(Day 15 Category)	cat4(Day 30 Category)			
Frequency Row Pct	0	1	2	Total
0	5522 98.84	59 1.06	6 0.11	5587
1	118 95.16	5 4.03	1 0.81	124
2	21 91.30	1 4.35	1 4.35	23
Total	5661	65	8	5734

Source: Listings 1, 2, and 7
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

Executed on 22SEP2023 at 16:41 from abrcx34c

4.6.13 Categorical Summary of Gingival Abrasion Findings (Table 6.3)

Table 6.3
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	2 (5.4%)	6 (15.8%)
1 - 4	23 (62.2%)	16 (42.1%)
5 - 8	10 (27.0%)	11 (28.9%)
9 or more	2 (5.4%)	5 (13.2%)
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	2 (5.4%)	6 (15.8%)
1 - 4	29 (78.4%)	22 (57.9%)
5 - 8	6 (16.2%)	8 (21.1%)
9 or more	0	2 (5.3%)
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	16 (43.2%)	17 (44.7%)
1 - 4	20 (54.1%)	18 (47.4%)
5 or more	1 (2.7%)	3 (7.9%)
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	35 (94.6%)	32 (84.2%)
Presenting Abrasion 2mm or Higher	31 (83.8%)	31 (81.6%)
Presenting Abrasion 3mm or Higher	21 (56.8%)	21 (55.3%)

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

Table 6.3
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	9 (24.3%)	2 (5.3%)
1 - 4	25 (67.6%)	24 (63.2%)
5 - 8	3 (8.1%)	9 (23.7%)
9 or more	0	3 (7.9%)
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	9 (24.3%)	3 (7.9%)
1 - 4	26 (70.3%)	26 (68.4%)
5 - 8	2 (5.4%)	8 (21.1%)
9 or more	0	1 (2.6%)
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	35 (94.6%)	25 (65.8%)
1 - 4	2 (5.4%)	13 (34.2%)
5 or more	0	0
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	28 (75.7%)	36 (94.7%)
Presenting Abrasion 2mm or Higher	11 (29.7%)	26 (68.4%)
Presenting Abrasion 3mm or Higher	2 (5.4%)	13 (34.2%)

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

Table 6.3
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	16 (43.2%)	10 (26.3%)
1 - 4	21 (56.8%)	26 (68.4%)
5 - 8	0	2 (5.3%)
9 or more	0	0
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	16 (43.2%)	10 (26.3%)
1 - 4	21 (56.8%)	26 (68.4%)
5 - 8	0	2 (5.3%)
9 or more	0	0
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	37 (100%)	30 (78.9%)
1 - 4	0	8 (21.1%)
5 or more	0	0
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	21 (56.8%)	28 (73.7%)
Presenting Abrasion 2mm or Higher	14 (37.8%)	23 (60.5%)
Presenting Abrasion 3mm or Higher	0	8 (21.1%)

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

4.6.14 Analysis of Gingival Abrasion Findings (Table 6.4)

Table 6.4
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.051 (0.0335)	0.066 (0.0660)
Median	0.051	0.051
Min, Max	0.00, 0.15	0.00, 0.32
Subjects with Missing Data	0	0

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 6.4
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.016 (0.0154)	0.045 (0.0380)
Median	0.012	0.035
Min, Max	0.00, 0.06	0.00, 0.14
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.035 (0.0414)	-0.021 (0.0588)
Median	-0.037	-0.026
Min, Max	-0.14, 0.06	-0.18, 0.12
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.041 (0.0046)	-0.015 (0.0045)
95% CI	(-0.051, -0.032)	(-0.024, -0.006)
p-value comparing LS Mean versus 0	<.0001	0.0017
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.027 (0.0065)	n/a
95% CI	(-0.040, -0.014)	
Between-treatment p-value	0.0001	

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 6.4
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush® Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	37	38
Mean (SD)	0.009 (0.0092)	0.022 (0.0215)
Median	0.007	0.021
Min, Max	0.00, 0.03	0.00, 0.11
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	37	38
Mean (SD)	-0.042 (0.0365)	-0.044 (0.0554)
Median	-0.043	-0.021
Min, Max	-0.15, 0.03	-0.26, 0.02
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.049 (0.0024)	-0.038 (0.0024)
95% CI	(-0.054, -0.044)	(-0.043, -0.033)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.011 (0.0034)	n/a
95% CI	(-0.018, -0.004)	
Between-treatment p-value	0.0020	

Source: Listings 1, 2, and 7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

5 APPENDICES

5.1 Study Information

5.1.1 Protocol and Protocol Amendments

Protocol Amendment No. 1 attached

AUT0BRUSH

Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

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Clinical Protocol

Protocol No. AB-GBP-2023-02

AMENDMENT 1
22 May 2023

STATEMENT OF COMPLIANCE

This trial will be conducted in compliance with the protocol and in accordance with Good Clinical Practice (GCP) as required by the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).
- International Council for Harmonisation; Good Clinical Practice E6(R2) (ICH-GCP); U.S. Food and Drug Administration (FDA) March 2018. International E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry, Current Step 4 version dated 9 November 2016.
- Clinical Investigations of Medical Devices for Human Subjects – Good Clinical Practice, ISO 14155:2020, consistent with FDA Guidance, "Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions; Guidance for Industry and Food and Drug Administration Staff (February 21, 2018).

All study personnel will be trained on study procedures and will be knowledgeable in GCP guidelines on protection of subject interests, health and confidentiality.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol, its attachments and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and ICH guidelines.

Principal Investigator:

Signed: _____ Date: _____

Jeffery L. Milleman, DDS, MPA
Salus Research, Inc.
1220 Medical Park Drive, Building #4
Fort Wayne, Indiana 46825
(260) 755-1099

Sponsor Representative:

Signed: _____ Date: _____

Chris Lander
Lander Enterprises, LLC dba AutoBrush
1919 Pacific Hwy PH01
San Diego, California 92101

SIGNATURE PAGE

The signature below constitutes the approval of this protocol, its attachments and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and ICH guidelines.

Principal Investigator:

Signed: DocuSigned by: Jeffery L. Milleman BFD78C5DD95940A... Date: 22 May 2023 | 12:52:35 PM ED

Jeffery L. Milleman, DDS, MPA
Salus Research, Inc.
1220 Medical Park Drive, Building #4
Fort Wayne, Indiana 46825
(260) 755-1099

Sponsor Representative:

Signed: DocuSigned by: Chris Lander 4A6752A557264E6... Date: 22 May 2023 | 12:52:38 PM

Chris Lander
Lander Enterprises, LLC dba AutoBrush
1919 Pacific Hwy PH01
San Diego, California 92101

TABLE OF CONTENTS

SUMMARY OF CHANGES – AMENDMENT 1

1. Corrections made to the Schedule of Activities table on page 42
2. Changed the photo of the AutoBrush® 360° U-Shaped Sonic Toothbrush
3. Corrections made to the Subject Instructions
4. Correction made to the inequality symbols in Section 6.3

List of Abbreviations

AE	Adverse Event/Adverse Experience
ADA	American Dental Association
ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CRF	Case Report Form
DCF	Data Clarification Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
LSPI	Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index
MGI	Modified Gingival Index
PI	Principal Investigator

QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience

1 PROTOCOL SUMMARY

TITLE: Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Protocol Number: AB-GBP-2023-02

Study Duration: Each subject will participate in a 30-day clinical trial.

Description of Test Agents:

1) Control group: American Dental Association (ADA) Accepted manual soft bristle toothbrush with Crest Cavity Protection toothpaste used twice daily for 2 minutes (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) AutoBrush® 360° U-shaped Sonic Toothbrush with Crest Cavity Protection toothpaste used twice daily for 30 seconds (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Objective:

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial is to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

Study population: Approximately 80 healthy volunteers, 5 - 65 years of age will be enrolled so that 70 subjects (35 per group) complete the study; at least 20 subjects aged 5-12 years old so that 10 pediatric subjects are randomized to each group; ~40 subjects aged 5 – 65 will be randomized to each group.

Sponsor:

Chris Lander
Lander Enterprises, LLC dba AutoBrush
1919 Pacific Hwy PH01
San Diego, California 92101

Key Inclusion Criteria:

1) Generally healthy males and females at least 5 – 65 years of age.
2) Volunteers must read and sign an informed consent form. If under the age of 18, volunteer must provide assent to participate, and consent must be obtained from a parent or legal guardian prior to being enrolled into the study.
3) Regular manual toothbrush user and able to brush their own teeth daily.
4) A minimum of 18 natural teeth, in the adult dentition, with scorable facial and lingual surfaces.

a) If under the age of 12, must have at least 12 fully erupted teeth, primary or permanent teeth. NOTE: Partially erupted permanent teeth and primary teeth that are loose or in process of exfoliation will **not** be included in the tooth count.
b) Teeth that are grossly carious, orthodontically banded, exhibiting general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession will not be included in the tooth count.

5) A plaque index score ≥ 1.80 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI), following 12 to 16 hours plaque accumulation period at Baseline.
6) A gingival index score ≥ 1.75 according to the Modified Gingival Index at Baseline.
7) Willingness to abstain from all other oral hygiene procedures for the 30-day trial period.
8) No current active orthodontic treatment (e.g., orthodontic banding or appliances).
9) No evidence of major hard or soft tissue lesions or trauma.
10) Not currently using any form of tobacco products.

Study Design:

This single-center, randomized, controlled, double-blind, 30-day, parallel study will include an oral screening examination visit consisting of assessments in the following order:

- Oral soft and hard tissue exam will be assessed through soft and hard tissue, presence or absence of gingival abrasion, recession or other abnormalities.
- Gingivitis according to the Modified Gingival Index (MGI).

At Baseline, Day 15 and Day 30, the following exams will be performed in the following order:

- Oral soft and hard tissue exam will be assessed through soft and hard tissue examination for irritation, gingival abrasion, recession or other abnormalities.
- Gingivitis according to the Modified Gingival Index (MGI).
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements, indicating recession, will be recorded.
- Gingival Abrasion: Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium. If abrasion is present, number of sites with gingival abrasion lesions will be recorded as small (≤2 mm), medium (3–5 mm) and large (>5 mm).
- Supragingival plaque levels, determined according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). Plaque will be disclosed using the Young-2-Tone® disclosing solution and each tooth will be scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual).

- At Day 30, a post-brushing plaque assessment will be performed to assess plaque removal immediately following the use of the assigned toothbrush.

Prior to each exam visit, subjects will refrain from oral hygiene for 12 to 16 hours and will not eat or drink 30 minutes prior to the visit, except for small sips of water. Following informed consent and assent procedures (subjects aged 5 to 17) and collection of baseline demographics, qualified subjects will receive an oral examination and assessment for MGI, gingival recession, gingival abrasion and LSPI. Subjects will be enrolled into the study with existing mild to moderate gingivitis and there will be no dental prophylaxis performed during the study.

Subjects meeting study entrance criteria will be randomly assigned to one of two treatment groups:

1) Twice daily brushing for two minutes with an ADA Accepted manual soft toothbrush with Crest Cavity Protection 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) Twice daily brushing for 30 seconds with AutoBrush® 360° U-shaped Sonic Toothbrush and Crest Cavity Protection 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Subjects will be provided verbal and written instructions on the use of their assigned oral care brushing. The first product use will be performed at the clinical site under the supervision of study personnel. Subjects assigned to the AutoBrush® 360° U-shaped Sonic Toothbrush will brush their teeth for 30 seconds with Crest Cavity Protection toothpaste. Subjects aged 5 to 8 years will dispense a pea-sized amount (~ 0.25 grams) or smear the paste into the two-sided brush head (mouthpiece). Subjects aged 9 to 65 years of age will dispense a ribbon of paste (~ 1.5 grams) into the two-sided brush head. Subjects using the manual toothbrush will be instructed to brush in their usual manner for two minutes. Subjects aged 5 to 8 years old will dispense/smear a pea-size amount of paste (~0.25 grams) on to the toothbrush bristles and subjects 9 to 65 years of age will dispense a full ribbon (~1.5 grams) of toothpaste. All subjects will maintain a daily diary to document compliance with the use of their assigned.

The use of a Washout period prior to Baseline will be included in this design so that subjects avoid use of antimicrobial mouth rinses, dentifrices or other dental products that might affect a subject's plaque or gingivitis status. Subjects will be asked to use the provided marketed fluoride toothpaste, e.g., Crest Cavity Protection toothpaste and ADA Accepted soft bristle toothbrush as their only oral hygiene regimen during the washout period. A 7 to 14-day washout period is appropriate to allow subjects to comply with

study and lifestyle restrictions prior to the Baseline Visit. Following the Baseline exams, subjects will return at Day 15 and Day 30 for the same assessments for oral safety, gingival inflammation, gingival recession, gingival abrasion and supragingival plaque. During the study, subjects will refrain from using any oral care products other than the toothbrush and toothpaste products provided to them and will avoid the use of chewing gums and mints. Individuals who use an interdental daily cleaning device will be allowed to continue and will document use on their daily diary.

Safety:

Safety will be assessed through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. Lips, gingiva, buccal, labial, and sublingual mucosae, tongue, hard and soft palate, uvula and oropharynx will be examined for signs of reddening and inflammation, ulceration, soft tissue abrasion and recession, white patches and desquamation/sloughing of mucosal tissues and findings will be recorded on the Oral Exam CRF, with determination of severity (mild, moderate, or severe). Oral soft tissue findings will be tabulated and summarized by treatment group for each exam visit. The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity. The development or advancement of gingival recession and abrasion will be evaluated for safety purposes.

Efficacy Endpoints:

Primary Efficacy variables:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.

Secondary Efficacy Variables:

- MGI at Day 15:
  - Whole mouth mean change.
  - Gumline (marginal).
  - Proximal (marginal).
  - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
  - Pre- and Post- brushing Whole mouth.
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
  - Gumline.

- Proximal.
- Distal score of the last posterior tooth in each quadrant.

- LSPI scores at Day 30
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Safety Endpoints:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events will be tabulated by treatment group.

Statistical Analyses:

Based on published studies comparing a sonic toothbrush to a manual toothbrush, sufficient subjects will be screened so that 80 will be randomized to treatment to ensure a total of 70 subjects (35 per treatment group) complete the Day 30 assessments. With 35 subjects per treatment group the study is calculated to have 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level. These calculations are based on two-sided tests at the 0.05 significance level.

For each efficacy variable summary statistics using appropriate descriptive statistics (mean, median, minimum, maximum) by treatment group and overall will be provided at each visit.

Analyses will be performed for Day 15 and Day 30 for each efficacy variable, analyses will be performed using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons will be made at the 0.05 level, 2-sided. Differences between the means, simultaneous 95% confidence intervals and test results will be presented.

2 KEY ROLES

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Sponsor:	Chris Lander Lander Enterprises, LLC dba AutoBrush 1919 Pacific Hwy PH01 San Diego, California 92101
Monitor:	Sylvia L. Santos, RDH, MS SLS Clinical Research Consulting, LLC Phone: 201-572-9223 sersantos@verizon.net
Study site:	Salus Research 1220 Medical Park Drive, Building #4 Fort Wayne, IN 46825 Tel: (260) 755-1099 www.SalusResearch.us

3 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

The effective management of dental plaque and gingivitis continues to be a high priority for the dental health of the public. Dental professionals recommend brushing at least twice a day to remove plaque and reduce the risk of tooth decay and gum disease.[1] However, the high prevalence of oral diseases worldwide suggests that consumers do not achieve sufficient plaque removal with their manual toothbrushing routine.

Clinical studies have shown that improvement in mechanical oral hygiene can be achieved through the use of power toothbrushes.[2, 3, 4, 5, 6, 7, 8, 9, 10, 11] In fact, there are systematic reviews and meta-analyses which have demonstrated that power toothbrushes are more effective in removing plaque than manual toothbrushes.[12, 13] Well-designed clinical studies are needed to validate the efficacy of new toothbrush products and claims in improving plaque control and gingival health.

An innovative U-Shaped sonic power toothbrush has been developed by AutoBrush® that is designed with brush handle that fits comfortably in the palm of the handa full mouthpiece (double sided) with tapered nylon bristles to clean all surface areas of the teeth at once in a 30 second period. The user is directed to dispense a small amount of fluoride toothpaste into the mouthpiece, insert into the mouth and push the on/off button. The only manipulation needed by the user is to move the hanThe company's mission is to make brushing simpler, better, and more accessible for kids, adults and individuals with disabilities. A recent independent, single-use, examiner blinded, randomized, two-period, cross-over, clinical study evaluated the safety and plaque removal efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush, compared to a marketed children's manual toothbrush. Twenty-two children, 5 to 8 years of age, were randomized to receive each toothbrush product and completed all phases of the study. Supragingival plaque levels were assessed according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). When assigned to the AutoBrush, subjects used the product for 30 seconds whereas they used the manual toothbrush in their usual manner for 2 minutes. Following single use of the AutoBrush, statistically significant reductions were observed for the AutoBrush compared to Baseline for whole mouth plaque for 50.6%, gumline levels with 71.2% and proximal levels were reduced by 40.7%. The manual toothbrush provided reductions of 1.9%, 3.5% and 1.1%, respectively. The AutoBrush provided up to 27 times greater whole mouth plaque removal than the manual toothbrush. Results of this single-use study suggests that the new AutoBrush u-shaped sonic toothbrush can be a valuable tools in the oral hygiene regimen for individuals seeking efficient and effective plaque removal in shorter period of time without the requirement for manual dexterity.

This 30-day study is designed to compare the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush to an ADA Accepted manual soft toothbrush on plaque and gingivitis in a 30-day clinical study.

4 OBJECTIVE

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial is to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

4.1 Endpoints

4.1.1 Safety

Safety will be assessed through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. Soft tissue exams will focus on the potential impact on gingival recession and gingival abrasion.

Safety endpoints include:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

4.1.2 Efficacy

Efficacy endpoints will be:

- Primary Efficacy variables:
  - Whole mouth mean change in MGI scores at Day 30.
  - Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.
- Secondary Efficacy Variables:
  - Whole mouth mean change in MGI scores at Day 15.
  - Mean change in distal score of the last posterior tooth in each quadrant.
  - Mean change in LSPI scores at Day 15 and Day 30 (immediate post-brushing) for:
    - Gumline LSPI scores (marginal)
    - Proximal LSPI scores (mesial and distal).
    - Mean change in distal score of the last posterior tooth in each quadrant.
  - Mean change in LSPI scores at Day 15 and Day 30 (Pre-brushing) for:

- Gumline LSPI scores (marginal)
- Proximal LSPI scores (mesial and distal).

5 STUDY DESIGN

This single-center, randomized, controlled, examiner-blind, 30-day parallel study will consist of a Screening/Baseline visit during which potential subjects (age 5-65 years) will read and sign an informed consent form, complete health and dental questionnaires and a receive a clinical oral examination. For subjects 5 to 17 years of age, subjects' parents/legal guardians will read and sign the consent form and subjects will sign an assent form.

Screening visit will include assessments in the following order:

- Oral safety will be assessed through soft and hard tissue examination (OSHT), presence or absence of gingival abrasion, recession or other abnormalities.
- Visual examination for qualifying gingivitis levels according to the Modified Gingival Index (MGI);[14]

Qualified subjects will participate in a 7 to 14-day Washout period prior to Baseline so that subjects avoid use of antimicrobial mouth rinses, dentifrices or other dental products that might affect a subject's plaque or gingivitis status. Subjects will be asked to use the provided marketed fluoride toothpaste, e.g., Crest Cavity Protection toothpaste and ADA Accepted soft bristle toothbrush as their only oral hygiene regimen during the washout period. A 7 to 14-day washout period is appropriate to allow subjects to comply with study and lifestyle restrictions prior to the Baseline Visit.

Prior to each exam visit, subjects will refrain from oral hygiene for 12 to 16 hours and will not eat or drink 30 minutes prior to the visit. Sipping water will be permitted prior to each exam visit. The Baseline visit will include confirmation of consent and assent to participate in the study, review of inclusion and exclusion criteria, and exams in the following order:

- OSHT
- MGI
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin.
- Gingival Abrasion as described by Danser[15] , Rosema[16] and Van der Weijden[17].
- Supragingival plaque levels, determined according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).[18, 19]

Subjects meeting study entrance criteria will be stratified by age: pediatric dentition group (≥ 5 and < 12) and adult dentition group (≥ 12 and ≤ 65), randomly assigned to one of two treatment groups, such that at least each group contains at least 10 pediatric subjects:

1) Control group: ADA Accepted manual soft bristle toothbrush with Crest Cavity Protection toothpaste used twice daily for 2 minutes (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) AutoBrush® 360° U-shaped Sonic Toothbrush with Crest Cavity Protection toothpaste used twice daily for 30 seconds (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Subjects will be provided verbal and written instructions on the use of their assigned toothbrush. The first assigned brushing will be performed at the clinical site under the supervision of study personnel. All subjects will maintain a daily diary to document compliance with the use of their assigned toothbrush product.

Following the Baseline exams, subjects will return at Days 15 and 30 for the same assessments for oral safety, gingival health and plaque. At the Day 30 visit only, subjects will receive a pre-brushing plaque exam followed by a post-brushing plaque exam to assess the immediate effect of plaque removal with the assigned toothbrush.

During the study, subjects will refrain from using any oral care products other than the toothbrush or toothpaste provided to them and will avoid the use of other toothbrushes, toothpaste, mouthwashes, chewing gum, breath film, mints, floss or interdental cleaning aids, or other oral care cleaning aids for the duration of this research study. Subjects who routinely use interdental aids will be permitted to continue use throughout the study.

6 STUDY POPULATION

Approximately 80 healthy male and female volunteers, 5 - 65 years of age, will be enrolled so that 70 subjects (35 per group) complete the study. At least 20 subjects aged 5-12 years old will be enrolled so that 10 pediatric subjects are randomized to each group. To participate in this study, all subjects will fulfill the inclusion and exclusion criteria as outlined in sections 6.1 and 6.2.

6.1 Inclusion Criteria

To be eligible for study participation, subjects must meet the following criteria:

1) Be generally healthy males and females at least 5 to 65 years of age.
2) If under age 18, willing to provide assent to participate and consent from a parent or legal guardian prior to being entered into the study.

3) If 18 years of age or older, is able to read, sign and receive a copy of the signed informed consent form.
4) Be regular manual toothbrush users and able to brush their own teeth on a daily basis.
5) Be in good health based on medical history review by the investigator.
6) Be willing to refrain from all oral hygiene for approximately 12-16 hours prior to each study visit and discontinue eating and drinking for approximately 30 minutes prior to each study visit, with the exception of sips of water.
7) Have a minimum of 18 natural teeth, in the adult dentition, with scorable facial and lingual surfaces. If under the age of 12, must have at least 12 fully erupted teeth, primary or permanent teeth. **NOTE**: Partially erupted permanent teeth and primary teeth that are loose or in process of exfoliation will not be included in the tooth count. Teeth that are grossly carious, orthodontically banded, exhibiting general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession will not be included in the tooth count.
8) Present with a gingival index score ≥ 1.75 according to the Modified Gingival Index at Baseline.
9) Present with a plaque index score ≥ 1.80 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index, following a 12 to 16-hour plaque accumulation period at Baseline.
10) Be willing and able to refrain from dental treatment during the course of the study, except on an emergency basis.

6.2 Exclusion Criteria

Subjects presenting with any of the following will not be included in the study:

1) A history of adverse effects, oral soft or hard tissue sensitivity, to any ingredient in the test materials.
2) Self-reported serious medical conditions.
3) Self-reported as pregnant or nursing.
4) Under treatment for a heart condition requiring use of pacemaker.
5) Have any condition, in the opinion of the investigator, that would place the subject at increased risk or preclude the subject's full compliance with or completion of the study.
6) Require antibiotic premedication prior to dental procedures.
7) Have had antibiotic, anti-inflammatory, anti-coagulant medication or chemotherapeutic antiplaque/antigingivitis therapy within 30 days of screening exams.
8) Have participated in any study involving oral care products, concurrently or within the 30 days of screening exams.

9) Unwilling to discontinue use of other oral hygiene products for the duration of the study.
10) Present use of any tobacco products.
11) Presence of severe periodontal disease or being actively treated for periodontal disease.
12) Have grossly carious, fully crowned, or extensively restored teeth.
13) Have orthodontic appliances, peri/oral piercings, or removable partial dentures.
14) Have significant oral soft tissue pathology based on a visual examination.

If the subject reports taking medication, a history of allergy, and/or a chronic disease which in the opinion of investigator will not affect the clinical parameter(s) being assessed or the safety of the subject, the subject may be enrolled in the study and the conditions will be noted on the Subject's source document.

6.3 Subject Identification, Screening and Enrollment

Subjects will be recruited from the local population utilizing the recruitment materials approved by the IRB. Subject screening, enrollment, product assignments, and dental assessments will be conducted at the clinic site. The investigator will maintain a screening and enrollment log of all subjects who sign an ICF for this study and for all children who signed assent form and a parent/legal guardian signed ICF for this study. The log will include unique subject identification numbers/screening numbers (1001-1080) and dates of subject screening, enrollment and completion (or early termination). Once a number has been assigned to a subject, it cannot be reassigned to another subject. For subjects who fail screening, the reason(s) for non-participation will be recorded on the log. The Investigator will also maintain a confidential identification list containing each enrolled subject's name and corresponding unique subject number, to enable records to be identified.

6.4 Treatment Assignment Procedures

Up to 80 qualified subjects will be randomly assigned to one of two treatment groups. Qualified subjects will be stratified by age: pediatric dentition group (≥ 5 and ≤ 12) and adult dentition group (>12 and ≤ 65), such that at least 20 pediatric subjects will be enrolled, and 10 pediatric subjects are randomized to each group. Upon qualification, each enrolled subject will be sequentially issued a unique subject randomization number (001-080), which determines the treatment assignments according to a randomization scheme prepared by the Sponsor. Subjects will be randomized to one of two treatment groups:

1) Control Group: Twice daily brushing with an ADA Accepted manual soft toothbrush (age-appropriate) and Crest® Cavity Protection dentifrice.
2) Sonic Toothbrush Group: Twice daily brushing with AutoBrush® 360° U-shaped Sonic Toothbrush (age-appropriate) and Crest® Cavity Protection dentifrice.

Subjects assigned to the AutoBrush group will be dispensed a toothbrush head appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. For subjects assigned to the manual toothbrush group: subjects aged 5 to 8 years will receive the ADA Accepted children's soft toothbrush; for subjects ≥ 9 and ≤ 65 years will receive ADA Accepted manual toothbrush. The Investigator or designee will maintain randomization worksheets documenting the subject assignment to treatment groups.

6.4.1 Withdrawal

Every effort will be made within the bounds of safety and subject choice to have each subject complete the study. A discontinuation occurs when an enrolled subject ceases participation in the study, regardless of the circumstances, prior to completion of the protocol. The reason for a subject discontinuation from the study will be reported in the case report form. The investigators must attempt to determine the primary reason for discontinuation. A study subject will be discontinued from participation in the study if:

- Any clinical adverse event (AE), intercurrent illness, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The subject meets any exclusion criteria (either newly developed or not previously recognized).

Subjects are free to withdraw from participation in the study at any time upon request. A discontinuation must be immediately reported to the sponsor's clinical monitor or the designated representative if it is due to a serious adverse event. The final evaluation required by the protocol will be performed at the time of study discontinuation.

6.4.2 Termination of Study

This study may be prematurely terminated if, in the opinion of the investigator or the sponsor, there is sufficient reasonable cause. Written notification, documenting the reason for study termination, will be provided to the investigator or sponsor by the terminating party.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Plans to modify, suspend or discontinue the development of the experimental test article.

If the study is prematurely terminated or suspended, the sponsor will promptly inform the investigators/institutions, of the termination or suspension and the reason(s) for the termination or suspension. The IRB will also be informed promptly and provided the reason(s) for the termination or suspension by the investigator/institution.

7 INVESTIGATIONAL PRODUCT

7.1 Study Material Description

7.1.1 ADA Accepted Soft Manual Toothbrush

Juvenile subjects, age 5 to 8 years, assigned to the manual toothbrush group will be dispensed the ADA Accepted children's manual soft toothbrush. Subjects who are ≥ 9 and ≤ 65 years of age will be dispensed the ADA Accepted adult's soft manual toothbrush. Subjects assigned to the manual toothbrush will brush their teeth twice daily in their usual manner for 2 minutes. Only the first product use in the office will be supervised by a Salus staff member.

Manual Toothbrush Control:	**ADA Accepted Soft Manual Toothbrushes**
Kids Ages 5-8 years	ADA Accepted Children's Soft Toothbrush
Kids and adults ≥ 9 and ≤ 65 years	ADA Accepted Adult's Soft Toothbrush
Packaging	Single packaging

7.1.2 AutoBrush® 360° U-shaped Sonic Toothbrush

Subjects assigned to the AutoBrush group will be dispensed the AutoBrush base and the two-sided toothbrush head (mouthpiece) with nylon bristles, appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. The brush has a 30 seconds cycle time which simulates a full 2-minute brushing for all quadrants of the mouth. Only the first product use in the office will be supervised by a Salus staff member. The figure below displays the product features which are the same for adult devices.

Sonic Toothbrush:	**Sonic Rechargeable Toothbrush**
Trade name for Kids Ages 5-8	AutoBrush® 360° U-shaped Sonic Toothbrush
	
Trade name for kids and adults ≥ 9 and ≤ 65 years	AutoBrush® 360° U-shaped Sonic Toothbrush

	
Manufacturer	Lander Enterprises, LLC dba AutoBrush
Packaging	Single packaging

Ancillary supplies for the 30-day phase of the include a single tube of Crest® Cavity Protection dentifrice (0.243% sodium fluoride, Procter & Gamble, Cincinnati, OH, USA), at least 4.6 oz. tube. For the 7 to 14-day washout period, subjects will receive the appropriate size ADA Accepted soft manual toothbrush and a tube of the Crest Cavity Protection toothpaste for use twice daily for two minutes.

7.2 Packaging, Labeling and Storage

All products must be stored by the clinical site at room temperature. Manual toothbrushes, AutoBrush® 360° U-shaped Sonic Toothbrushes and Crest® Cavity Protection toothpaste will be supplied in the original marketed packages with no overwrap. Each subject will receive a carrying bag that will contain the label noting the relevant randomization number and instructions for use.

7.2.1 Manual toothbrush control group

Label for subjects 5-8 years old with instructions to dispense approximately 0.25 grams of toothpaste on to the bristles:

Protocol: AB-GBP-2023-02 **Subject Randomization#:_____**

INSTRUCTIONS FOR USE for Ages 5 – 8 years old
UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:

1) Wet your toothbrush and dispense a smear of toothpaste onto the brush head.
2) Brush in your usual manner with your assigned toothbrush for two minutes
3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
4) Rinse brush head after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale
If you have questions, contact the Salus Research Emergency number: 260-413-7777

For subjects ≥ 9 and ≤ 65 years to dispense approximately 1.5 grams (full ribbon) of toothpaste on to the bristles:

Protocol: AB-GBP-2023-02 **Subject Randomization#:_____**

INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 and < 18 years

(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):
1) Wet your toothbrush and dispense a full ribbon of toothpaste onto the brush head. 2) Brush in your usual manner with your assigned toothbrush for <u>two</u> minutes 3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 4) Rinse brush head after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. **For Investigational Use Only – Not for Sale**
If you have questions, contact the Salus Research Emergency number: 260-413-7777

7.2.2 AutoBrush® 360° U-shaped Sonic Toothbrush group

Instructions for use will be similar for all age groups with the exception of the amount of toothpaste used for the 5- to 8-year-old subjects.

The following label for subjects 5-8 years old to dispense approximately 0.25 grams of toothpaste on to the bristles:

Protocol: AB-GBP-2023-02 **Subject Randomization#:_____** **INSTRUCTIONS FOR USE for Ages 5 – 8 years old.** **UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:**
1) Follow package instructions for charging the AutoBrush base device. 2) To assemble the AutoBrush, firmly attach the nylon brush head onto the AutoBrush base. 3) Wet your toothbrush and dispense a smear of paste onto each side of the brush head. 4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base). *** **<u>DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON</u>** 5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds. 6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 7) Remove the brush head from the base, rinse and air dry after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. For Investigational Use Only – Not for Sale
If you have questions, contact the Salus Research Emergency number: 260-413-7777

For subjects ≥ 9 and ≤ 65 years to dispense approximately 1.5 grams (full ribbon) of toothpaste on to the bristles:

Protocol: AB-GBP-2023-02 **Subject Randomization#:_____** **INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 <18 years** **(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) <u>AND</u> ADULTS (≥ 18 years):**
1) Follow package instructions for charging the AutoBrush base device. 2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base. 3) Wet your toothbrush and dispense a ribbon of toothpaste onto each side of the brush head. 4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base). *** **<u>DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON</u>** 5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds. 6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 7) Remove the brush head from the base, rinse and air dry after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. For Investigational Use Only – Not for Sale If you have questions, contact the Salus Research Emergency number: 260-413-7777

7.3 Dosage, Preparation and Administration of Investigational Product

At Screening visit, all subjects will receive the regular fluoride toothpaste and an ADA accepted age-appropriate size toothbrush for use during the 7 to 14-Day Washout Period.

Following Baseline exam procedures, subjects will be instructed to use their assigned toothbrush twice daily as detailed in their instructions attached to their daily diary.

7.4 Accountability Procedures for the Investigational Product(s)

Lander Enterprises, LLC will provide the investigator with sufficient amounts of the study test materials. The investigator must ensure that deliveries of investigational product from the sponsor are received by the responsible person, that all receipts are recorded in writing and that the product is stored in a secure area under recommended storage conditions. It is also the responsibility of the investigator to ensure that the integrity of packaged study product not be jeopardized prior to dispensing. The investigator will dispense the test material only to subjects included in this study following the procedures specified in the study protocol. Each subject will be administered only the test material carrying his/her randomization number.

All dispensing will be documented. The investigator is responsible for ensuring all full, partially full, and empty test material containers are disposed at the end of the study. The investigator must maintain accurate and adequate records including dates of receipt and return of test material shipments, and quantities received/returned from/to Lander Enterprises, LLC as well as, dates and amounts dispensed to the study subjects.

7.5 Assessment of Subject Compliance with Investigational Product

Compliance will be assessed at the Days 15 and 30 visits through review of the subjects' daily diaries. Subjects will be required to maintain a daily diary to record the time of completion of their assigned morning and evening toothbrushing. Toothpaste will be weighed prior to being dispensed at Visit 2 and once it is returned at Visit 4.

7.6 Concomitant Medications/Non-Drug Therapy

Any medication the subject takes during the study is considered concomitant medication. All concomitant medications and non-drug therapy (e.g., tooth extraction, endodontic treatment, etc.) must be recorded in the subject's medical source document.

8 STUDY PROCEDURES, EVALUATION AND SCHEDULE

The schedule of observations and assessments is provided in Sec. 16, Table 1, Study Flow Chart.

8.1 Screening (Visit 1)

Prior to randomization to treatment groups, the following procedures will be performed:

- Parent or legal guardian will read and sign the informed consent form prior to enrollment of juvenile subjects.
- Juvenile subject will provide assent to participate.
- Informed consent for adult subjects.
- Collection of medical and dental history.
- Inclusion/Exclusion Criteria checklist.
- Clinical exams:
  - OSHT.
  - Visual screening for qualifying levels of gingivitis.
  - Visual screen for gingival abrasion and recession.
- Dispense Washout toothpaste and toothbrush.
- Study staff review and dispense daily diary and home use written instructions.
- Appoint subjects for next visit.

8.2 Baseline (Visit 2)

- Confirm continuing Informed consent and assent.
- Query to update medical and oral health and record adverse events and concomitant medications.
- Review and update Inclusion/Exclusion Criteria checklist.
- Clinical exams:
  - OSHT.
  - Modified Gingival Index (MGI).
  - Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin.
  - Gingival Abrasion evaluation using Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium.
  - Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).
  - Identify subjects with qualifying levels of gingivitis and plaque: MGI ≥ 1.75, LSPI ≥ 1.80.

If subject meets entry criteria, the following procedures will be performed:

- Randomization to test groups.
- Supervise initial use of assigned test products.
- Dispense assigned test materials.

- Study staff review and dispense daily diary and home use written instructions.
- Appoint subjects for next visit.

8.3 Day 15 (± 2 days) – Midpoint Exams (Visit 3)

- Query to update medical and oral health and record adverse events and concomitant medications.
- Assess compliance with study instructions and use of test materials.
- Oral soft and hard tissue examination for safety.
- Clinical exams:
  - OSHT.
  - MGI.
  - Gingival Recession evaluation.
  - Gingival Abrasion Assessment.
  - LSPI.
- Appoint subjects for next visit.

8.4 Day 30 (± 2 days) – Final Exams (Visit 4)

- Query to update medical and oral health and record adverse events and concomitant medications.
- Assess compliance with study instructions and use of test materials.
- Oral soft and hard tissue examination for safety.
- Clinical exams:
  - OSHT.
  - MGI.
  - Gingival Recession evaluation.
  - Gingival Abrasion Assessment.
  - Pre-Brushing LSPI.
  - Subjects perform last brushing with their assigned toothbrush.
  - Post-Brushing LSPI.
- Discharge subject and provide final instructions for follow-up of ongoing adverse events, as applicable.

During the study, subjects will follow their usual dietary habits, but will be instructed to refrain from using any oral care products other than the test materials provided to them.

8.5 Early Termination Visit

If a subject discontinues from the study for any reason prior to the final visit, the following procedures should be conducted:

- Record adverse events and concomitant medications.
- Oral soft and hard tissue examination.
- Schedule follow-up visit for any ongoing adverse events.

9 STUDY PROCEDURES/EVALUATIONS

9.1 Demographics

Demographic information will be collected at the Screening/Baseline Visit and will include the subject's race, gender, age and tobacco use.

9.2 Safety Assessments

9.2.1 Oral Examinations

An oral examination will be conducted to monitor the changes to the soft and hard tissues. Examination of the oral hard tissues (teeth), all facial, lingual/palatal, mesial/distal and occlusal surfaces, will be completed by direct observation, using retraction aids as appropriate.

Oral soft tissue examination will be accomplished throughout the study by direct observation and palpation with retraction aids, as appropriate. The examination will include evaluation of the labial mucosa (including lips), buccal mucosa, mucogingival folds, gingival mucosa, hard palate, soft palate, uvula, tonsillar area, pharyngeal area, tongue, sublingual area, submandibular area and salivary glands. Results of the examination will be documented with details of any abnormalities. Any abnormality or worsening of a pre-existing condition observed by the clinical examiner or reported by the subject following the Visit 1 OSHT examination will be recorded as an AE.

Observations such as reddening/inflammation, ulceration, white patches and desquamation/sloughing of mucosal tissues will be documented, with determination of severity (mild, moderate or severe):

Mild:	The oral condition is easily tolerated and does not interfere with daily activity
Moderate:	The oral condition causes enough discomfort to interfere with daily activity.
Severe:	The oral condition results in an incapacity to work or do usual activity and requires medical/dental intervention.

Clinically significant findings will be recorded as adverse events and an assessment will be made regarding the relationship to test materials.

9.2.2 Gingival Recession

Gingival recession will be evaluated at Baseline (Visit 2), Day 15 (Visit 3) and Day 30 (Visit 4). Gingival recession is marked by the apical migration of the gingival margin away from the cemento-enamel junction (CEJ). The clinical recession measurements will be carried out at six sites per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual). Recession will be measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements indicating recession, will be recorded.

9.2.3 Gingival Abrasion

Gingival Abrasion as described by Danser[15] , Rosema[16] and Van der Weijden[17]. Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium. The gingival tissues of each tooth will be divided into 3 areas on both the facial and lingual surfaces, as illustrated in Fig. 1: marginal (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva). If abrasion is present, the site will be recorded as small (≤2 mm), medium (3–5 mm) and large (>5 mm). If no abrasion is present, the site will be recorded as "0".

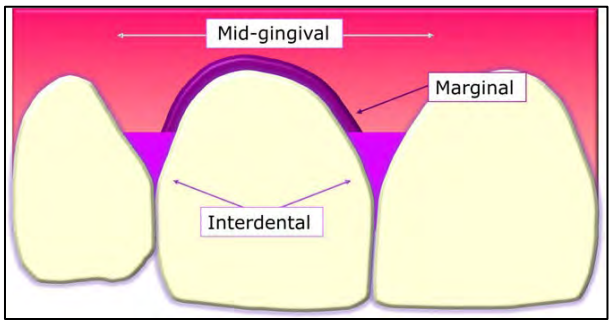

Figure 1. (From Rosema et al 2014)

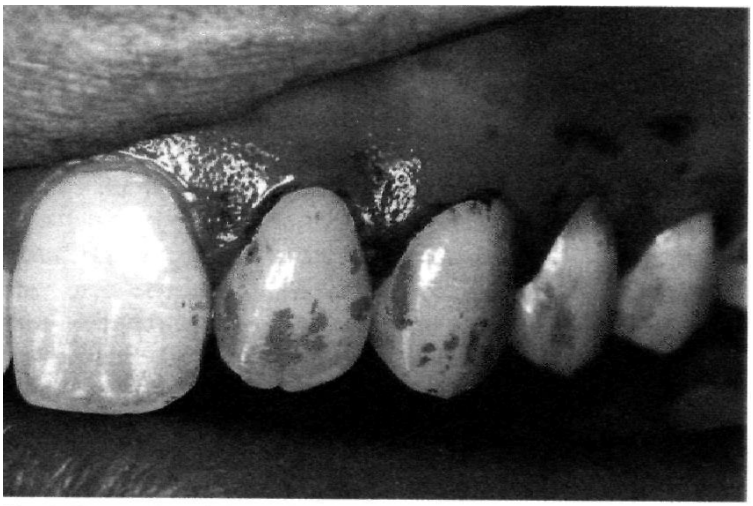

Figure 2. (from Danser et al, 1998a)

9.3 Efficacy Assessments

Clinical efficacy assessments will be performed by a single examiner at Baseline, Days 15 and 30 in the following sequence: MGI and LSPI.

9.3.1 Gingival Inflammation

Gingival inflammation will be assessed at Screening, Baseline, Days 15 and 30, according to the Modified Gingival Index (MGI),[14] and will be scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual) of all scorable teeth using a scale of 0 – 4 as noted below:

0 = Normal (absence of inflammation).
1 = Mild inflammation (slight change in color, little change in texture) of any portion of the entire gingival unit.
2 = Mild inflammation of the entire gingival unit.
3 = Moderate inflammation (moderate glazing, redness, edema, and/or hypertrophy) of the gingival unit.
4 = Severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit.

Whole mouth MGI scores will be calculated by summing all scores and dividing by the number of scorable sites examined.

9.3.2 Plaque Index

Supragingival dental plaque will be assessed according to the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Soparkar (LSPI).[18,19] Plaque will be disclosed using a red disclosing solution and each tooth will be scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual), according to the criteria noted below:

0 = No plaque.
1 = Separate flecks or discontinuous band of plaque at the gingival (cervical) margin.
2 = Thin (up to 1 mm), continuous band of plaque at the gingival margin.
3 = Band of plaque wider than 1 mm but less than 1/3 of tooth surface area.
4 = Plaque covering 1/3 or more, but less than 2/3 of tooth surface area.
5 = Plaque covering 2/3 or more of tooth surface area.

At Day 30 visit only, subjects will brush with their assigned toothbrush at the clinical test site and will be re-disclosed for a second plaque assessment (post-treatment).

A whole mouth plaque index will be calculated for each subject by adding all the individual scores and dividing this sum by the number of measurements. To understand the plaque

removal efficacy of each toothbrush in hard-to-reach areas, separate subsets of the plaque index will be calculated for gingival margin (gumline) and the proximal surfaces. Gumline LSPI scores will be calculated by summing the number of gingival margin (buccal and lingual) scores and dividing by the number of measurements. Proximal LSPI scores (mesial and distal) will be calculated by summing the number of proximal site scores (distobuccal, mesiobuccal, distolingual and mesiolingual) and dividing by the number of measurements.

9.4 Examiner Repeatability Exercises

A single trained dental examiner will perform the oral examinations and MGI and LSPI assessments. Prior to Baseline exams, at least 10 subjects will be assessed for gingival inflammation and plaque levels, according to the MGI and LSPI with at least 10 minutes between repeat examinations. Repeatability will be evaluated through the demonstration of at least 80% frequency of agreement of assessments. Re-training and/or recalibration (followed by a repeat of the exercise) will be performed if the evaluated level of reliability is judged to be low.

NOTE: Repeatability exercises will not be needed if the examiner has used MGI and LSPI in a clinical trial within two months prior to the start of this study.

10 ADVERSE EVENT REPORTING AND DOCUMENTATION

Adverse events will be determined by visual examination of the oral cavity by the dental examiner. In addition, clinical research center personnel will ask subjects about the occurrence of any adverse events during their participation in this study. All observed or volunteered adverse events, regardless of treatment group or suspected causal relationship to study product, will be recorded on the adverse event page(s) of the case report form.

10.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a clinical study subject administered an investigational product and that does not necessarily have a causal relationship with the study product. An AE is therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease (new or exacerbated) temporally associated with the use of a study product, whether or not related to that study product.

An unexpected AE is one of a type not identified in nature, severity, or frequency in the investigational product safety summary or of greater severity or frequency than expected based on the information in the study product safety summary.

The Investigator will probe, via discussion with the subject, for the occurrence of AEs during each subject visit and record the information in the site's source documents. Adverse events will be recorded in the subject CRF. Adverse events will be described by duration (start and stop dates), severity, outcome, treatment and relation to study product, or if unrelated, the cause.

Pre-existing conditions will not be regarded as AEs if the condition follows a normal course of recovery unless it worsens after exposure to the study product.

10.2 Definition of a Serious Adverse Event (SAE)

The Investigator or other study personnel must immediately (within 24 hours) inform the Sponsor of all Serious Adverse Events (SAEs) that occur in study subjects.

An SAE is any untoward medical occurrence that at any dose:

- Results in death.
- Is life-threatening.
- Requires hospitalization, or prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity.
- Is a congenital anomaly or birth defect.

Important medical event/experience that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Note: Classification of an AE as 'serious' is based on the outcome of the event and is a factor in determining reporting requirements.

10.3 Medical Device Incidents

Medical devices are being provided by the Sponsor for use in this study; the medical devices in this study include the plaque disclosing solution (Class I medical device), the standard ADA manual toothbrush and the AutoBrush® 360° U-shaped sonic toothbrush (Class I medical device).

A medical device incident is any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a subject/user/other person or to a serious deterioration in his/her state of health.

Not all incidents lead to death or serious deterioration in health. The nonoccurrence of such a result might have been due to other fortunate circumstances or to the intervention of health care personnel.

Medical device incidents, including those resulting from malfunctions of the devices, must be detected, documented, and reported by the investigator on the Incident Report Form.

10.4 Unanticipated adverse device effect (UADE)

An unanticipated adverse device effect is any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device, if that effect problem, or death was not previously identified in nature, severity, or degree of incidence in the study plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

10.5 Recording an Adverse Event

All serious adverse events will be recorded and reported immediately to the Study Sponsor. An AE shall be documented when a subject reports an untoward event or when subjects are asked directly about concurrent illnesses and concomitant medication or from answers on subject-completed diary forms. When an AE is discovered or reported, the PI or designee shall complete the AE/SAE Case Report Form. The Principal Investigator shall review all AEs/SAEs and determine the severity, relationship (of the AE/SAE to the test article/investigational product), and outcome. The PI also will determine whether the subject will remain in the study.

Severity, relationship and outcome will be defined as follows:

Severity	**Description**
Mild	Awareness of signs or symptoms, but easily tolerated.
Moderate	Discomfort to a degree that the AE/SAE causes interference with normal daily life activities and/or requires medication.
Severe	Incapacity with regard to work or usual daily life activities. Requires medical attention/intervention.

Relationship	**Description**
Unrelated	Clearly evident relationship to other etiologies such as concomitant medications or conditions or subject's known clinical state.
Possible	Uncertain association. Other etiologies are also possible.
Probable	Causal relationship cannot be ruled out.
Definite	AE/SAE with a clear-cut temporal association

Outcome	Description
Not recovered/Not resolved	AE/SAE had not resolved by end of study. (Does not mean AE/SAE was not followed until resolution.)
Resolved without sequelae	AE/SAE completely resolved by end of study (or ongoing yet unrelated to study, therefore resolved for purposes of study).
Resolved with sequelae	AE/SAE resolved by end of study, but aftereffect or disease or injury is present. e.g., a stroke that resulted in partial paralysis; the stroke resolved, but residual paralysis.
Death	

10.6 Follow-up

Study-related adverse events will be monitored to resolution by the Investigator for at least 30 days following study completion or discontinuing use of the study product.

Serious Adverse Events/Experiences will be followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

10.6.1 Follow-up of Incidents

During the study:

- All incidents will be followed until resolution of the event, until the condition stabilizes, until the condition is otherwise explained, or until the subject is lost to follow-up. This applies to all subjects, including those withdrawn prematurely. The investigator is responsible for ensuring that follow-up includes any supplemental investigations as may be indicated to elucidate as completely as practical the nature of the incident.
- New or updated information will be recorded on the originally completed form with all changes signed and dated by the investigator.

After the study:

- Investigators are not obligated to actively seek reports of incidents in former subjects. However, if the investigator learns of any incident at any time after a subject has been discharged from the study, and such incident is reasonably related to a medical device provided for the study, the investigator will promptly notify the Study Manager and Sponsor.

10.7 Reporting Adverse Events

The Investigator will report all serious adverse events immediately to the Sponsor monitor, Sylvia L. Santos, RDH, MS at 201-572-9223, and will complete a Serious Adverse Event Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and sent by email within 24 hours of site awareness to the attention of Sylvia L. Santos at sersantos@verizon.net.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by email within 72 hours of site awareness to the attention of Sylvia L. Santos at sersantos@verizon.net.

The Sponsor's representative or monitor will be notified within the time frame specified above, after any adverse event has been reported to the Investigator or Investigator's staff.

10.8 Reporting of Medical Device Incidents and Malfunctions

10.8.1 Incident reporting:

- All incidents must be reported to the Sponsor monitor within 24 hours (or sooner if possible) of the investigator or designee becoming aware of the situation.
- Any medical device incident occurring during the study will be documented in the subject's medical records, in accordance with the investigator's normal clinical practice, and on the appropriate Incident Report Form. In addition, for incidents fulfilling the definition of an AE or an SAE, the appropriate AE CRF page or SAE form will be completed and reported as per the AE and SAE reporting sections.
- The Incident Report Form will be completed as thoroughly as possible and signed by the investigator before transmittal to the Sponsor. It is very important that the investigator describes any corrective or remedial actions taken to prevent recurrence of the incident.
- The completed Incident Report Form should be scanned and emailed to the Study Monitor as soon as possible, but not later than 24 hours after study site personnel learn of the event. If there is an SAE, the completed SAE pages should be sent together with this report form. However, if a copy of the SAE report is sent with this form, this does not replace the procedure to report an SAE. The original Incident Report Form will remain with the subject's records.
- The Study Monitor should be notified of the situation by telephone or email.
- The Study Monitor will be responsible for forwarding the Incident Report Form to the Sponsor.
- The initial report will be followed up with more information as relevant, or as requested by the Sponsor.

10.8.2 Malfunction reporting:

The investigator will follow the following directions regarding device failure (malfunction):

- Notify the Study Monitor immediately.
- Schedule the subject to return to the site promptly to return the failed device.
- Record any incidents on the CRF and Incident Report Form following instructions given in the section above.
- Return the failed device to the Sponsor as soon as possible, including documentation of the details of the failure.

10.8.3 Regulatory and Ethics Reporting Requirements for Incidents

- The investigator will promptly report all incidents occurring with any medical device provided for use in the study within 24 hours. The Sponsor has a legal responsibility to notify appropriate regulatory bodies and other entities about certain safety information relating to medical devices being used in clinical studies. Prompt notification of incidents by the investigator to the Sponsor is essential in order to meet legal obligations and ethical responsibility towards the safety of subjects.
- The investigator, or responsible person according to local requirements, will comply with the applicable local regulatory requirements relating to the reporting of incidents to the IRB.

10.9 Reporting Unanticipated Adverse Device Effects

Investigators are required to submit a report of a UADE to the Sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the Investigator first learns of the event.

Sponsors must immediately conduct an evaluation of a UADE and must report the results of the evaluation to FDA, all reviewing IRBs, and participating Investigators within 10 working days after the Sponsor first receives notice of the effect.

11 STATISTICAL CONSIDERATIONS

This section outlines the basic statistical approach for the study.

Data will be electronically and/or manually recorded on Case Report Forms (CRFs). Salus Research will be responsible for data entry, and statistical analysis of the data will be performed by LRM Statistical Consulting, LLC.

11.1 Data Sets Analyzed

All eligible subjects who are randomized into the study and perform at least one use of the study product will be included in the safety analysis (e.g., the Safety Population). The Per-protocol (PP) population will include subjects who do not have major protocol violations possibly altering the study outcome (e.g., low compliance, visit window violations etc.). Subjects will be classified into analysis sets prior to opening of the product code.

No accounting of missing data will be made. The Sponsor will be informed of dropouts in the final study report. Data for discontinued subjects will be included in the safety analysis. Subjects discontinued due to an adverse event will be included in the safety analysis. Data for safety analysis will include all subjects who were randomized and received one of the assigned test products.

11.1.1 Exclusion of Data from Analysis

Any of the following will be considered a protocol violation and will be exclude from analysis:

- Violation of inclusion or exclusion criteria that can affect efficacy.
- Medical history which impacts efficacy.
- Use of prohibited treatment or medication before or during the study, which can affect the assessment of efficacy. The assessments affected will be determined prior to database lock.
- Not receiving randomized treatment.
- Noncompliance with randomized treatment.

11.2 Sample Size Considerations

Based on published studies comparing a sonic toothbrush to a manual toothbrush,[5, 6, 8, 9, 10, 11] sufficient subjects will be screened so that 80 will be randomized to treatment to ensure a total of 70 subjects (35 per treatment group) complete the Day 30 assessments. With 35 subjects per treatment group the study is calculated to have 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level. These calculations are based on two-sided tests at the 0.05 significance level. Assuming an estimated attrition rate of 5%, 80 subjects will be screened and randomized.

11.3 Safety Review

Oral soft tissue findings will be tabulated and summarized by treatment group for each exam visit. The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity.

Safety endpoints include:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

11.4 Demographic and Baseline Characteristics

Demographic and Baseline characteristics will be summarized for age, gender, race, mean MGI, and LSPI. Data will be summarized using appropriate descriptive statistics (mean, median, minimum, maximum) by treatment group and overall. Categorical demographic and baseline data will be evaluated using Fisher's Exactness Test and continuous demographic and baseline data will be evaluated using ANOVA. All tests will be two-sided and conducted at the 0.05 significance level. No adjustments for multiple comparisons or multiple testing will be made.

11.5 Efficacy Review

11.5.1 Primary Efficacy Endpoint

The primary efficacy endpoint:

- Mean change in Whole Mouth MGI scores at Day 30.
- Mean change in Whole Mouth LSPI scores at Day 30, immediate post-brushing.

11.5.2 Secondary Efficacy Endpoint

- MGI at Day 15:
    - Whole mouth.
    - Gumline (marginal).
    - Proximal (marginal).
    - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
    - Pre- and Post- brushing Whole mouth
    - Pre- and Post- brushing Gumline.
    - Pre- and Post- brushing Proximal.
    - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
    - Gumline.
    - Proximal.

    - Distal score of the last posterior tooth in each quadrant.
- LSPI scores at Day 30
    - Pre- and Post- brushing Gumline.
    - Pre- and Post- brushing Proximal.
    - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

For each efficacy variable summary statistics using appropriate descriptive statistics (mean, median, minimum, maximum) by treatment group and overall will be provided at each visit.

Analyses will be performed at Days 15 and 30 for each efficacy variable, analyses will be performed using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons will be made at the 0.05 level, 2-sided. Tables comparing treatment groups will provide differences in the least squares mean, the standard error of the differences, the confidence interval for the difference, and the p-value. At Days 15 and 30 post ANCOVA pairwise comparisons between each of the three active treatments and the negative control will be made using a two-sided Dunnett's test, which controls the error rate for the simultaneous comparisons. Differences between the means, simultaneous 95% confidence intervals and test results will be presented.

12 DATA HANDLING AND RECORD KEEPING

Data that is manually recorded on CRFs or source documents will be entered into an Excel spreadsheet and transmitted to the statistician for statistical analysis. The investigator site will be responsible for data entry into an Excel spreadsheet as well as transmission of the data to the statistician for statistical analysis. The investigator's study coordinator and consultant statistician will agree on data entry format. The data entry personnel will perform a 100% QC of data entered into the Excel Spreadsheet against the paper CRFs. Following data entry verification and prior to statistical analysis, the spreadsheet will be transmitted to the AutoBrush study manager and study monitor for review to detect data entry issues/errors, logical data inconsistencies, missing data, protocol deviations, outliers and develop any necessary data queries. Following the satisfaction completion of data queries, the data entry file will be supplied to the statistician under password protection. A follow-up email will be provided to the statistician revealing the password.

The investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each subject participating in the study. Data captured in source documents includes subject information, original records of clinical findings, observations, medical histories, prior and concomitant medication records,

inclusion/exclusion eligibility checklist, records of subject visits and phone calls, progress notes, subjects' diaries or evaluation checklists, test product dispensing and accountability records.

A Case Report Form (CRF) will be completed for each subject enrolled in the study and will include documenting subject demographics and subject's study completion status. All information recorded on the CRFs for this study must be consistent with the subject's source documentation records. The Investigator or designee must review all entries for completeness and correctness.

The Investigator or designee agrees to make all CRFs and source documents available to the Sponsor's Study Monitor for full inspection. After resolution of the monitor's queries, a copy of the final CRF will be placed in the investigator's study file and the original will be taken by the site monitor and provided to the Sponsor.

The sponsor will review the CRFs and additional source documents for completeness and adherence to the protocol.

12.1 Study Records Retention

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the Sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

12.2 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, Good Clinical Practice (GCP) requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be promptly reported to the Sponsor and must be addressed in study subject source documents. In addition, protocol deviations must be sent to the local IRB per their guidelines. The site PI/study staff are responsible for knowing and adhering to their IRB requirements.

13 ETHICS

13.1 Institutional Review Board

This study will be reviewed by U.S. Investigational Review Board, Inc. which is an appropriately constituted Institutional Review Board (IRB) as outlined in 21 CFR Part 56 and is registered with the US Department of Health and Human Services (DHHS) as #IRB00007024. The IRB will review the protocol, any amendments, the informed consent form (ICF), the assent form, subject instructions and questionnaires, safety information, Investigator's curriculum vitae (CV) and advertisements.

Approval by the Board must be obtained prior to the initiation of the study. Approval by the Board must be obtained prior to the initiation of the study.

13.2 Ethical Conduct of the Study

This study will be conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 50 and 56. The study will be conducted in accordance with the Principles of Good Clinical Practice.

Lander Enterprises, LLC is responsible for the ongoing safety evaluation of the investigational products and will promptly notify participating Investigators and regulatory authorities of findings that could adversely affect the safety of subjects, impact the conduct of the study, or alter the IRB's approval to continue the study. Lander Enterprises, LLC will promptly report all adverse reactions related to the test articles that are both serious and unexpected to the appropriate regulatory authorities and to all Investigators and IRBs currently involved in studies of this test article.

13.3 Subject Information, Consent and Assent

The clinical investigation, including the consent form and assent form, will be reviewed by an IRB in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Informed consent will be obtained from the parent or legal guardian of each subject prior to participation in any study procedures as required by the Food and Drug Administration (FDA) GCP guidelines. Information will be given in both oral and written form and subjects' parents/legal guardian must be given ample opportunity to inquire about details of the study prior to signing and dating the consent form. Assent will be obtained from all children and consent from a parent or legal guardian. An exact copy of the signed consent and assent forms will be given to the parent/legal guardian of the subject and the original will be maintained with the subject's records.

13.4 Authorization to Disclose Protected Health Information

Subjects will be informed of the following information: The purpose of the protected health information (PHI) being collected, the possibility the PHI may be re-disclosed, the duration of

the authorization, the right to revoke the authorization, and the right to refuse signature and limit access to PHI during and following the conduct of the trial. As applicable, written authorization to disclose PHI will be incorporated into the informed consent process and will be obtained prior to the subject entering the study. Each subject will be provided with a signed copy of the authorization and the original will be retained on file at the study center.

Subject confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participating subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

14 MONITORING

A Sponsor representative may meet with the Investigator and his/her staff prior to the entrance of the first subject to review the procedures to be followed in conducting the study. After the enrollment of the first subject, the Investigator will permit the Sponsor to monitor the progress of the trial on site periodically. The Investigator will make available the source documents as well as the subjects' records and signed consent forms.

15 AMENDMENTS/MODIFICATION OF THIS PROTOCOL

No amendment to the protocol will be permitted without approval from the study Sponsor, Investigator, and IRB. Such changes will be documented in writing. Approval by the IRB must be obtained prior to initiation of the amendment.

16 SCHEDULE OF ACTIVITIES

Procedures:	Visit 1 Screening/ Washout (7-14 days prior to Baseline)	Visit 2 Baseline (7-14 days from Screening)	Visit 3 Day 15 ± 2 days	Visit 4 Day 30 ± 2 days
Informed Consent/Assent	X			
Confirm continuing informed consent/assent		X	X	X
Medical/Dental History	X			
Record Concomitant Medications	X	X	X	X
Review Inclusion and Exclusion Criteria	X	X		
Update Medical/Dental History		X	X	X
Confirm Continuing Inclusion/Exclusion		X	X	X
Query Subjects and record Adverse Events		X	X	X
Clinical Exams:				
Intraoral Exam	X	X	X	X
MGI		X	X	X
Gingival Recession, Gingival Abrasion		X	X	X
Pre-brushing LSPI		X	X	X
Post-brushing LSPI				X
Randomization		X		
Dispense washout toothpaste and toothbrush	X			
Washout Products and Diary Review/Return		X		
Supervised use of toothpaste & assigned toothbrush		X		
Dispense toothpaste & assigned toothbrush		X	X	X
Schedule appointment for next visit	X	X	X	
Test Article and Diary Review/Return			X	X
Study Conclusion and Exit				X

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5.1.2 Case Report Forms

CASE REPORT FORMS

Protocol No.
AB-GBP-2023-02

Screening Number			

Sponsor Study No.	Screening Number	VISIT 1 SCREENING (DD/MMM/YYYY)
AB-GBP-2023-02		2023

SUBJECT DEMOGRAPHICS

Gender	☐	Male	☐	Female

☐	American Indian or Alaskan Native	☐	Native Hawaiian or other Pacific Islander
☐	Black or African American	☐	Asian
☐	White	☐	Other, please specify:

Ethnicity	☐ Hispanic or Latino
	☐ Non-Hispanic or Latino

Age	

Sponsor Study No.	Screening ABP-202				VISIT 1 SCREENING (DD/MMM/YYYY)								
AB-GBP-2023-02										2	0	2	3

ORAL EXAM

LOCATION	Normal	Abnormal	Describe Abnormality
Mucosa (including lips)	☐	☐	
Gingival Mucosa	☐	☐	
Hard Palate	☐	☐	
Soft Palate	☐	☐	
Mucogingival Folds	☐	☐	
Tongue	☐	☐	
Sublingual Area	☐	☐	
Submandibular Area	☐	☐	
Salivary Glands	☐	☐	
Tonsilar Area	☐	☐	
Pharyngeal Area	☐	☐	

Teeth	☐	☐	

Examiner Signature: _____

Sponsor Study No.	Screening Number	VISIT 2 - Baseline (DD/MMM/YYYY)
AB-GBP-2023-02		2 0 2 3

ORAL EXAM

LOCATION	Normal	Abnormal	If Abnormal, Check ☒ if AE	Describe Abnormality
Mucosa (including lips)	☐	☐	☐	
Gingival Mucosa	☐	☐	☐	
Hard Palate	☐	☐	☐	
Soft Palate	☐	☐	☐	
Mucogingival Folds	☐	☐	☐	
Tongue	☐	☐	☐	
Sublingual Area	☐	☐	☐	
Submandibular Area	☐	☐	☐	
Salivary Glands	☐	☐	☐	
Tonsillar Area	☐	☐	☐	
Pharyngeal Area	☐	☐	☐	

Teeth	☐	☐	☐	

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2023**

Modified Gingival Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Modified Gingival Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2023**

Gingival Recession

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Gingival Recession

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2023**

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 Baseline DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Maxilla

Tooth	2		3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																								

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	15		14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																								

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 2 BASELINE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Mandible

Tooth	31		30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																									

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	18		19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																									

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Examiner Signature: _____

Sponsor Study No.	Screening Number				VISIT 2 Baseline (DD/MMM/YYYY)								
AB-GBP-2023-02										2	0	2	3

Subject meets eligibility entry criteria

☐ Yes ☐ No

Randomization Number

Sponsor Study No.	Screening Number	VISIT 3 - Day 15 +/- 2 (DD/MMM/YYYY)
AB-GBP-2023-02		2 0 2 3

ORAL EXAM

LOCATION	Normal	Abnormal	If Abnormal, Check ☒ if AE	Describe Abnormality
Mucosa (including lips)	☐	☐	☐	
Gingival Mucosa	☐	☐	☐	
Hard Palate	☐	☐	☐	
Soft Palate	☐	☐	☐	
Mucogingival Folds	☐	☐	☐	
Tongue	☐	☐	☐	
Sublingual Area	☐	☐	☐	
Submandibular Area	☐	☐	☐	
Salivary Glands	☐	☐	☐	
Tonsillar Area	☐	☐	☐	
Pharyngeal Area	☐	☐	☐	

Teeth	☐	☐	☐	

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Modified Gingival Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Modified Gingival Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Recession

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Gingival Recession

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Maxilla

Tooth	2		3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																								

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	15		14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																								

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 3 Day 15 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Mandible

Tooth	31		30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																								

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	18		19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																								

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Examiner Signature: _____

Sponsor Study No.	Screening Number	VISIT 4 - Day 30 +/- 2 Days PRE (DD/MMM/YYYY)
AB-GBP-2023-02		2 0 2 3

ORAL EXAM

LOCATION	Normal	Abnormal	If Abnormal, Check ☒ if AE	Describe Abnormality
Mucosa (including lips)	☐	☐	☐	
Gingival Mucosa	☐	☐	☐	
Hard Palate	☐	☐	☐	
Soft Palate	☐	☐	☐	
Mucogingival Folds	☐	☐	☐	
Tongue	☐	☐	☐	
Sublingual Area	☐	☐	☐	
Submandibular Area	☐	☐	☐	
Salivary Glands	☐	☐	☐	
Tonsillar Area	☐	☐	☐	
Pharyngeal Area	☐	☐	☐	

Teeth	☐	☐	☐	

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Modified Gingival Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Modified Gingival Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Recession

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Gingival Recession

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days PRE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days PRE DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Maxilla

Tooth	2		3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																								

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	15		14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																								

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Gingival Abrasion

Mandible

Tooth	31		30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																																									

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Facial																														

Tooth	18		19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																																									

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A	P	G	A
Lingual																														

Examiner Signature: _____

Sponsor Study No.	Screening Number				VISIT4 - Day 30 +/- 2 Days POST (DD/MMM/YYYY)								
AB-GBP-2023-02										2	0	2	3

ORAL EXAM

LOCATION	Normal	Abnormal	If Abnormal, Check ☒ if AE	Describe Abnormality
Mucosa (including lips)	☐	☐	☐	
Gingival Mucosa	☐	☐	☐	
Hard Palate	☐	☐	☐	
Soft Palate	☐	☐	☐	
Mucogingival Folds	☐	☐	☐	
Tongue	☐	☐	☐	
Sublingual Area	☐	☐	☐	
Submandibular Area	☐	☐	☐	
Salivary Glands	☐	☐	☐	
Tonsillar Area	☐	☐	☐	
Pharyngeal Area	☐	☐	☐	

Teeth	☐	☐	☐	

Examiner Signature: _____

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days POST DATE (*dd/mmm/yyyy*)
Pink Paradise	**AB-GBP-2023-02**		**2 0 2 3**

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Maxilla

Tooth	2			3			4			5			6			7			8			9			10			11			12			13			14			15		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	A			B			C			D			E			F			G			H			I			J		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	15			14			13			12			11			10			9			8			7			6			5			4			3			2		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	J			I			H			G			F			E			D			C			B			A		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Site Study ID	Sponsor Study Number	Screening Number	VISIT 4 - Day 30 +/- 2 Days POST DATE (*dd/mmm/yyyy*)
Pink Paradise	AB-GBP-2023-02		2 0 2 3

Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index

Mandible

Tooth	31			30			29			28			27			26			25			24			23			22			21			20			19			18		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																																										

Tooth	T			S			R			Q			P			O			N			M			L			K		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Facial																														

Tooth	18			19			20			21			22			23			24			25			26			27			28			29			30			31		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																																										

Tooth	K			L			M			N			O			P			Q			R			S			T		
Site	D	G	M	D	G	M	D	G	M	D	G	M	D	G	M	M	G	D	M	G	D	M	G	D	M	G	D	M	G	D
Lingual																														

Area	Total	Sites	Mean
Max.			
Mand.			
Total			

Examiner Signature: _____

Sponsor Study No.	Screening Number			
AB-GBP-2023-02				

SUBJECT SUMMARY

1. Did subject experience an Adverse Event? **Yes** ☐ **No** ☐

2. Did the Subject complete the study as planned? **Yes** ☐ **No** ☐

If 'No', indicate ONE reason:

Withdrawal of consent ☐

Deviation from protocol (including non-compliance) ☐

Lost to follow-up ☐

Adverse Event ☐

Other (give details)_____ ☐

_____

Date:			-				-	2	0	2	3

Investigator Signature ***dd/mmm/yyyy***

Adverse Event Form

Complete this form only if subject experienced any Adverse Events during this study

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Unrelated 2 = Possible 3 = Probable 4 = Definite	*1 = None* *2 = Rx Therapy* *3 = Discontinued Study* 4 = Other (specify)	*1= Resolved w/o sequelae* *2 = Resolved w/sequelae* *3 = Not recovered/resolved* 4 = Death	1 = Yes 2 = No (If yes, complete SAE form)

Adverse Event	Start Date (dd/mmm/yyyy)	Stop Date *(dd/mmm/yyyy)*	Severity	Relationship to Study Treatment	Action Taken	Outcome of AE	Serious Adverse Event?
1.							
2.							
3.							
4.							
5.							

Signature of PI: _____Date: _____

Serious Adverse Event

1. **SAE Onset Date:** _____/_____/_____ ***(dd/mmm/yyyy)***
2. **SAE Stop Date:** ____/_____/_____***(dd/mmm/yyyy)***
3. **Was this an unexpected adverse event?** **Yes** ☐ **No** ☐
4. **Brief description of participant(s) with no personal identifiers:**

   Sex: F ☐ **M** ☐ **Date of Birth:** _____/_____/_____ ***(dd/mmm/yyyy)***
5. **Brief description of the nature of the serious adverse event (attach description if more space needed):**

   _____

   _____

   _____
6. **Category of the serious adverse event:**

   ☐ death – date ____/_____/_____ *(dd/mmm/yyyy)*

   ☐ congenital anomaly / birth defect

   ☐ life-threatening

   ☐ required intervention to prevent permanent impairment

   ☐ hospitalization-initial or prolonged

   ☐ disability / incapacity

   ☐ other:_____
7. **<u>Relationship of event to study test material</u>:**

   ☐ Unrelated (clearly not related to the intervention)

   ☐ Possible (may be related to intervention)

   ☐ Definite (clearly related to intervention)

8. Was study test material/participation discontinued due to event? ☐ **Yes** ☐ **No**

9. What medications or other steps were taken to treat serious adverse event?

_____

_____

_____

_____

10. List any relevant tests, laboratory data, history, including preexisting medical conditions

_____

_____

_____

_____

11. Type of report:

☐ Initial

☐ Follow-up

☐ Final

Signature
of Principal Investigator: _____Date: _____/_____/_____
(dd/mmm/yyyy)

5.1.3 Ethics Committees and Subject Information

U.S. Investigational Review Board, Inc.
6400 SW 72 Court
Miami, FL 33143
Phone: 786-473-3095
Chairperson: Rosa M. Fraga
Email: rmvf1550@aol.com

U.S. Investigational Review Board, Inc.

TO: Jeffery L. Milleman, DDS, MPA, Principal Investigator
Salus Research, Inc. (SRI)

FROM: Rosa M. Fraga, Chairperson

SUBJECT: Approval of Final Clinical Protocol dated May 4, 2023; Washout Diary; Manual Toothbrush Instructions; Treatment Diary; AutoBrush Toothbrush Instructions; Research Subject Information and Consent Form (ADULT) dated May 9, 2023; Research Subject Information and Consent Form (CHILD) dated May 9, 2023; Research Subject Information and Assent Form dated May 9, 2023; Safety Statement dated May 7, 2023 and the Investigators

IRB NUMBER: U.S.IRB2023SRI/04

PROTOCOL NUMBER: AB-GBP-2023-02

DATE OF MEETING: May 9, 2023

PROTOCOL TITLE: CLINICAL SAFETY AND EFFICACY OF AUTOBRUSH® 360° U-SHAPED SONIC TOOTHBRUSH ON PLAQUE AND GINGIVITIS IN A 30-DAY MODEL

The U.S. Investigational Review Board, Inc. is a review committee structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (21 CFR Parts 50 and 56) and is in compliance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRB/IEC and operates in accordance with GCP guidelines and applicable laws and regulations.

At the meeting date indicated above, the Committee reviewed and unanimously approved all documents indicated for the above captioned research study. The Committee recommended that minor changes be made to Research Subject Information and Consent Form (ADULT); Research Subject Information and Consent Form (CHILD); and the Research Subject Information and Assent Form. These changes have been incorporated into the approved forms dated the day of this meeting and have been stamped U.S.IRB "APPROVED" with the date of this meeting and contains all regulatory required consent elements. All materials given to subjects are also stamped U.S.IRB "APPROVED" with the date of this meeting.

This research study has been approved for **one year valid to May 8, 2024**. At the end of this time, you are required to provide this IRB Committee a written status report of this research and obtain approval for the continued research. In the event that you complete the research within this time period, please notify this Committee, in writing, of your completion of this research study. Changes to the protocol or use of non-approved advertisement cannot be initiated without this IRB review and approval. Written notice to this IRB is required in the event of any serious adverse reactions, significant deviations from the protocol or any problems in the research within 5 days. Please provide this reporting to the address noted below so that appropriate follow-up will be initiated.

Rosa M. Fraga, Chairperson

U.S.IRB MAY - 9 2023 "APPROVED"

"Pink Paradise" Washout Diary
(Sponsor Code AB-GBP-2023-02)

Subject No: _____

Use the assigned toothbrush and toothpaste, twice daily for two timed minutes.

Record the date and the exact time of each brushing on the appropriate line as demonstrated in the example.

**Prior to your next visit, please don't eat or drink within 30 minutes of your exams

**Prior to your next visit, please brush within 12 to 16 hours of your exams

Bring ALL study materials to each appointment.

NEVER throw away any dental study materials. DO NOT use any other oral care products during the study.

B = Brush

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Example B 8:00 am B 8:00 pm	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____
2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____
2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____	2023 B _____ B _____

If you have any questions regarding the study, please call
Salus Research at **260-755-1099**

"Pink Paradise" Washout Diary
(Sponsor Code AB-GBP-2023-02)

Subject No: _____

Instructions: Please list any **new** prescription or over-the-counter medications taken. If medicine has a unit dosage (*i.e.* mg, ml, tsp, etc.), include in the "Dosage" column as shown in the examples below.

Name of Medication	Start Date	End Date	Dosage &/or # Taken	Reason for Taking Medication
Tylenol	*2/11/23*	*2/12/23*	*500 mg 2 tab daily*	*headache*

Manual Toothbrush Instructions (5-8 year olds)

UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:

1) Wet your toothbrush and dispense a smear of toothpaste onto the brush head.
2) Brush in your usual manner with your assigned toothbrush for two minutes
3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
4) Rinse brush head after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale

Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

Thank you!

Manual Toothbrush Instructions (9-65 year olds)

INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 and < 18 years (UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):

1) Wet your toothbrush and dispense a full ribbon of toothpaste onto the brush head.
2) Brush in your usual manner with your assigned toothbrush for two minutes
3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
4) Rinse brush head after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale

Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

Thank you!

"Pink Paradise" Treatment Diary
(Sponsor Code AB-GBP-2023-02)

Subject No: _____

Use the assigned toothbrush and toothpaste, twice daily according to your product instruction sheet.

Record the date and the exact time of each brushing on the appropriate line as demonstrated in the example.

**Prior to your next visit, please don't eat or drink within 30 minutes of your exams

**Prior to your next visit, please brush within 12 to 16 hours of your exams

Bring ALL study materials to each appointment.

NEVER throw away any dental study materials. DO NOT use any other oral care products during the study.

B = Brush

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Example B 8:00 am B 8:00 pm	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____
2023 B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____
2023 B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____	**2023** B _____ B _____

If you have any questions regarding the study, please call
Salus Research at **260-755-1099**

"Pink Paradise" Treatment Diary
(Sponsor Code AB-GBP-2023-02)

Subject No: _____

Instructions: Please list any **new** prescription or over-the-counter medications taken. If medicine has a unit dosage (*i.e.* mg, ml, tsp, etc.), include in the "Dosage" column as shown in the examples below.

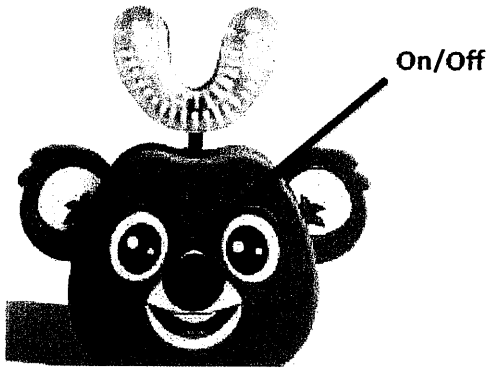
Name of Medication	Start Date	End Date	Dosage &/or # Taken	Reason for Taking Medication
Tylenol	*2/11/23*	*2/12/23*	*500 mg 2 tab daily*	*headache*

AutoBrush 360° Sonic Toothbrush Instructions (5-8 year olds)

INSTRUCTIONS FOR USE for Ages 5 – 8 years old.
UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:

1) Follow package instructions for charging the AutoBrush base device.
2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base.
3) Wet your toothbrush and dispense a smear of paste onto each side of the brush head.
4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base).
5) Hold the base and use biting circular motions while alternating directions for the full 30 seconds.
6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
7) Remove the brush head from the base, rinse and air dry after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale



Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

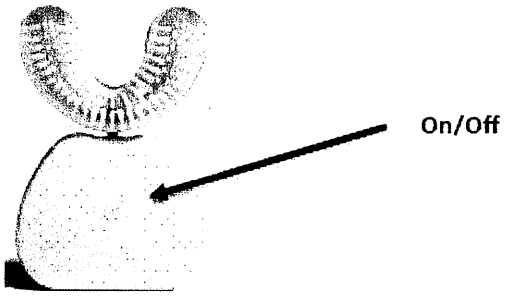
Thank you!

AutoBrush 360° Sonic Toothbrush Instructions (9-65 year olds)

INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 <18 years
(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):

1) Follow package instructions for charging the AutoBrush base device.
2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base.
3) Wet your toothbrush and dispense a ribbon of toothpaste onto each side of the brush head.
4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base).
5) Hold the base and use biting circular motions while alternating directions for the full 30 seconds.
6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
7) Remove the brush head from the base, rinse and air dry after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale



Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

Thank you!

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title: **Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model**

Protocol No.: AB-GBP-2023-02

Sponsor: Lander Enterprises, LLC
1919 Pacific Hwy. PH01
San Diego, CA 92101

Site: Salus Research, Inc. (SRI)
Building #4
1220 Medical Park Drive
Fort Wayne, Indiana 46825
USA

Investigators: Kimberly R. Milleman, RDH, PhD
Jeffery L. Milleman, DDS, MPA
Building #4
1220 Medical Park Drive
Fort Wayne, Indiana 46825
USA

Subject Number_____

INVESTIGATORS STATEMENT

You are being asked to volunteer for a dental research study. Before agreeing to participate in this research study, it is important that you read this form. This form, called a consent form, describes the purpose, procedures, benefits, financial payment, risks and discomforts of this research study. It also describes the alternative procedures that are available to you and your right to withdraw from this research study at any time. No promises or guarantees can be made as to the results of this research study. Please ask as many questions as you need to so that you can decide whether you want your child to be in this research study. This consent form may contain words that you do not understand. Please ask the research study doctor or the research study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or to discuss with family or friends before making your decision.

PURPOSE OF THIS RESEARCH STUDY

The objective of this 30-day, randomized, two group, parallel, examiner-blind clinical research study is to assess the safety and efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

STUDY POPULATION

You have been identified as an individual who may qualify to participate in this research study.

Approximately 80 healthy volunteers (both children and adults) are planned to be eligible and enroll in this research study. Your participation in this research study will last approximately 6 weeks.

EXPERIMENTAL ASPECTS

All products used in this study are marketed Class 1 medical devices and are considered safe when used as directed by the study procedures and are not experimental or investigational in nature. The study procedures are in compliance with how the product is intended to be used by the manufacturers. This research study will be conducted in 4 visits. The first visit will screen subjects to qualify for enrollment, including gingivitis levels. Qualified subjects will be provided with washout products (marketed fluoride toothpaste and toothbrush) to use until the next scheduled visit (approximately 1 to 2 weeks) At the second visit, you will be randomized to one of two toothbrush products and instructed on proper study procedures by study staff for the assigned regimen. At each study visit, subjects will have dental exams and a product safety exam. Additionally, plaque removal after a single, supervised toothbrushing in the research clinic will be assessed at visit 4. All dental exams and procedures to be performed in this research study are standard techniques; however, they are being used in an experimental setting to determine the gingivitis changes and the dental plaque reductions following approximately 30 days of use and after a single toothbrushing at the research site at visit 4.

SPECIFIC PROCEDURES TO BE USED

If you agree to participate in this research study, the following procedures will take place:

Visit 1

Research study staff will perform a screening examination to determine whether you will qualify to enter this research study, then they will:

- Collect demographic information (age, gender, etc.,).
- Ask you to complete a medical questionnaire and interview you about any medical and dental history, current oral conditions, and current medications.
- Examine tissues in your mouth to check for abnormalities, *e.g.,* evidence of gingival abrasion, irritations, lacerations, or ulcerations.
- Complete a dental charting to record the presence of dental restorations such as crowns, veneers, alloys, and composites.
- Assess the level of gingival inflammation (color and swelling of your gums).

If you meet all these screening requirements, the investigators will enroll you in this research study and will provide you a toothbrush and toothpaste to use during the washout period until Visit 2. You will be responsible to attend Visit 2 and follow the specific instructions given by the research study staff.

Visit 2

Research study staff will ask you to abstain from toothbrushing 12 to 16 hours prior to this visit and not to eat or drink 30 minutes (except small sips of water) prior to this appointment. During Visit 2 the research study staff will:

- Update the medical/dental history for any changes in health or new medicines.
- Ask and record if any problems were encountered during the washout period.
- Examine tissues in your mouth to check for abnormalities, for example, evidence of gingival abrasion, irritations, cuts, or sores.
- Assess the level of gingival inflammation (color and swelling of the gums).
- Measure the amount of gingival recession (receding gums) using a calibrated probe.

- Record the amount of plaque on your teeth using a blue food dye that will temporarily discolor the teeth and gums
- Check and record any gum abrasions.

If you meet all the Visit 2 requirements and you are willing to follow the at-home daily study procedures described below, the study staff will enroll you in this research study and will provide you with further instruction. You will be responsible for attending a Day 15 and Day 30 examination. If you qualify to continue in this research study based on the baseline exam at Visit 2, the research study staff will:

- Randomly assign you (by chance, like flipping a coin) to one of two toothbrush groups.
- Issue your research study products for the 30-day plaque and gingivitis study.
- Distribute and provide instructions to use your assigned study toothbrushes. In addition, you will receive a tube of Crest Cavity Protection toothpaste and a study treatment diary.
- Verbally provide instructions about this research study's requirements, including a review of the study toothbrush usage instructions and diary completion instructions.
- Supervise the first use of the assigned study toothbrush to be sure that you understand the usage instructions.
- Confirm that the assigned study toothbrush will be used at home twice daily and to record each usage in the provided diary for the next 30 days.
- Remind you not to use other toothbrushes, toothpaste, interdental cleaning devices, floss or mouthwashes, chewing gum, breath film, whitening products, or other oral care cleaning aids for the duration of this research study.
- Remind you to abstain from toothbrushing 12 to 16 hours prior to Visit 3 and not to eat or drink 30 minutes prior to this research visit. Small sips of water are allowed.
- Schedule your next examination (Visit 3) after 14 days of home use.

The research study dental examiners will not know which study toothbrush that you are assigned to use. However, this information is available to the research study dentist in an emergency. The study staff will advise you not to discuss the assigned study treatment regimen with the examiners or other subjects for the duration of this research study.

Visits 3 & 4

You will return to the study site for your Visit 3 (14 days after Visit 2) and Visit 4 (14 days after Visit 3). You will need to bring the assigned study products to these research visits. In addition, you will be asked to abstain from toothbrushing 12 to 16 hours before each of these appointments and not to eat or drink 30 minutes prior to this research visit, except small sips of water are permitted. During Visits 3 and 4, the research study staff will:

- Inventory and collect all your assigned research study materials (that is, toothbrush, usage instructions, toothpaste, diary).
- Interview you to determine whether the usage instructions, the assigned study toothbrush and diary were used correctly.
- Update the medical/dental history for any changes in health or new medicines.
- Ask and record if any problems were encountered during the washout period or between Visits 3 and 4.
- Examine tissues in your mouth to check for abnormalities, for example, evidence of gingival abrasion, irritations, cuts, or sores.
- Assess the level of gingival inflammation (color and swelling of the gums).
- Measure the amount of gingival recession using a calibrated probe.

- Record the amount of plaque on your teeth using a blue food dye that will temporarily discolor the teeth and gums will be used to assist the examiner.
- Check and record any gum abrasions.
- At Visit 4 you will perform a supervised product use and then have a post-product plaque exam completed.
- After Visit 4, you will be thanked, paid a gratuity and dismissed from the research study.

SUBJECT RESPONSIBILITIES

You must be available to attend each research study visit. Lastly, you must brush as instructed and return all research products at each visit.

During this research study, you will not be allowed to have your teeth cleaned or whitened at a dental office. You must refrain from brushing your teeth for approximately 12 to 16 hours and will not have eaten or drank for at least 30 minutes prior to each research study visit, except small sips of water are permitted.

LENGTH OF PARTICIPATION

If you qualify and are enrolled after the screening exam (Visit 1), you will come back to the clinic 7 to 14 days later. The total length of the study will be approximately 6 weeks. All exams will take place at the Salus Research, Inc. (SRI) dental clinic. Approximately 70 volunteers will complete the research study.

RISKS TO THE SUBJECT

The risk of permanent harm or injury, or disability as a result of participation in this research study is minimal. The dental exams are similar to those used as part of routine oral health care. Participation in this research study is not expected to cause any oral conditions different from those normally experienced in routine dental care. No known side effects or risks are associated with the use of this research study toothbrushes or toothpaste. All products used in this study are class 1 medical devices and are considered safe when used as directed by the study procedures. There is a chance that use of the research study products may involve risks that are currently unknown. You will be asked to report any discomfort or irritation that they experience while using their research study products and for up to 5 days after the last use of this research study product.

Precautions:

- All products given as part of this research study are for the participant use only.

BENEFITS TO THE SUBJECT

There is no guarantee that you will receive any medical or dental benefits from participating in this research study.

COSTS

There will be no costs to participate in this research study.

PAYMENT FOR PARTICIPATION

You will be paid a **$125 gift card** if all research study visits are completed. A **$25 gift card** will be paid for each completed research visit and a bonus of **$25 gift card** will be paid at Visit 4.

ALTERNATIVE TO PARTICIPATION

The alternative is not to participate in this research study. You do not have to take part in this research study to receive treatment for removing dental plaque.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to their health information. These include the right to know who will be able to get the information and why they may be able to get it. The research study doctor must get your authorization (permission) to use or give out any health information that might identify you. Please notify the research study staff if you would like the research study investigator to notify your family dentist about participation in this research study.

WHAT INFORMATION MAY BE USED AND GIVEN TO OTHERS?

If you choose to participate in this research study, the study doctor will get personal information about you. This may include information that might identify you. The research study doctor may also get information about your health including:

- Dental and research records
- Records about the research study related phone calls
- Records about your child's research study visits
- Records of research study exams
- Records of research study products

WHO MAY USE AND GIVE OUT INFORMATION ABOUT YOU?

Information about your health may be used and given to others by the research study doctor and staff. They might see the research information during and after the research study.

WHO MIGHT GET THIS INFORMATION?

Information concerning you that is obtained in connection with this research study will be kept confidential by SRI, except that this information may be given to the sponsor of this research. The records will be coded to protect everyone's identity. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. A representative of the sponsor company may observe the research study procedures at one or more of your study visits.

Information about your child and their health which might identify them may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Government agencies in other countries
- U.S. Investigational Review Board Services, Inc. (U.S. IRB, Inc.®)

WHY WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?

Information about you and your health that might identify you may be given to members of the research study team to enable them to carry out the research study. People from the sponsor and its consultants may be visiting the research site. They will follow how the research study is done, and they will be reviewing information for this purpose. The sponsor will analyze and evaluate the results of the research study and may see protected health information. No information that could be used to identify you will be transferred to the sponsor.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies. The results of this research may be published in

scientific journals or presented at medical meetings, but your identity will not be disclosed. The information may be reviewed by U.S. IRB, Inc., a group of people who perform independent review of research as required by regulations for protecting the rights and safety of research participants.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?
By signing this consent form, you are giving permission to use and give out health information listed above for the purposes described above. If you refuse to give permission, you will not be able to participate in this research study.

MAY I REVIEW OR COPY THE INFORMATION OBTAINED FROM ME OR CREATED ABOUT ME?
You have the right to review and copy your health information. However, if you decide to participate in this research study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose this health information at any time. You do this by sending written notice to the research study doctor. If you withdraw permission, you will not be able to continue being in this research study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

IS MY HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO OTHERS?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that this information will be released to others without your permission. No information that could be used to as an identifier will be transferred to the sponsor.

CONFIDENTIALITY OF THIS RESEARCH STUDY AND PRODUCT
While you are participating in this research study, all information produced, the research study product used, and details of this research study remain property of SRI and the sponsoring company. The information and any materials or items given about or during this research study, such as information regarding this research study toothbrushes and toothpastes or the type of research study being performed, should be considered the confidential business information of the research study sponsor. You are, of course, free to discuss with your family and friends while considering whether to participate in this research study or at any time when discussing your present or future healthcare. This research study product has been provided specifically for you and you must not allow any other person to inspect or try this research study product. At the end of this research study, you will be requested to return all remaining research study product for accountability purposes.

COMPENSATION FOR INJURY
In the event of injury resulting from participation in this research study, immediate treatment is available at SRI. If you participate in this research study, free medical care or payment for injuries or complications will not be offered. However, the sponsor will pay for medical costs not

covered by your own insurance or other program if it has been determined that you are suitable for this research study, if they have followed instructions for this research study, and the condition came about because of direct participation in this research study. If diagnostic work-ups show that the condition giving rise to the costs was not related to this research study, then no medical care or payment for this care will be made. The sponsor will pay for medical expenses for the diagnostic work-ups. When possible, the sponsor will review and approve expenses for the diagnostic work-ups in advance. The sponsor will not pay or provide any other type of benefit for any adverse experience that happens while participating in this research study. Questions about this should be directed to Dr. Jeffery L. Milleman at 260-755-1099 (clinic) or 260-413-7777 (24 hours).

VOLUNTARY PARTICIPATION/WITHDRAWAL

Participation in this research study is voluntary. You may decide not to participate without penalty and without affecting future dental care. If you do agree to participate, you can withdraw from this research study at any time without penalty or loss of benefits, but will be paid for only the visits completed. You will be asked to tell the research study doctor your reason for withdrawal. Your participation in this research study may be stopped at any time by the study doctor or the sponsor without your consent. Your participation might be terminated by the study team if significant deviation from the study regimen or instructions is noted. Your participation might also be ended if their health or safety is affected in the opinion of the study doctor or the sponsor.

NEW FINDINGS

You will be told about new findings relating to the research study toothbrushes that might affect your decision to participate in this research study.

QUESTIONS

If you have any questions about this research study, or if you feel you may have experienced a possible side effect, reaction to this research study product, or a research-related injury, contact the study investigators:

Jeffery L. Milleman, DDS, MPA
Kimberly R. Milleman, RDH, PhD
Salus Research, Inc (SRI)
Building 4
1220 Medical Park Drive
Fort Wayne, IN 46825
Telephone: 260-755-1099 (clinic) or 260-413-7777 (24 hours).

If there are concerns about your rights as a research subject, you may contact:

Rosa M. Fraga, Chairperson
U.S. Investigational Review Board, Inc. (U.S. IRB, Inc.®)
8050 SW 72 Avenue, #2105
Miami, Florida 33143
Telephone: 1-786-473-3095
E-mail: rmvf1550@aol.com

U.S.IRB
MAY - 9 2023
"APPROVED"

U.S. IRB, Inc.® is a group of people who perform independent review of research for protecting the rights and safety of research participants.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree for your child to participate in this research study, you will be given a signed and dated copy of this consent form to keep.

CONSENT

I have read the information in this consent form. All my questions about this research study in it have been answered. I freely consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of my legal rights which they otherwise would have as a subject in a research study.

_____

Subject's Signature Date

_____

Subject's Name (Please print)

_____

Signature of Person Conducting Informed Consent Discussion Date Time

For further information regarding your rights as a volunteer, contact Rosa M. Fraga, Chairperson of the U.S. Investigational Review Board, Inc. (U.S.IRB, Inc.) at 1-786-473-3095 or rmvf1550@aol.com.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title: **Clinical Safety and Efficacy of AutoBrush® 360°U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model**

Protocol No.: AB-GBP-2023-02

Sponsor: Lander Enterprises, LLC
1919 Pacific Hwy. PH01
San Diego, CA 92101

Site: Salus Research, Inc. (SRI)
Building #4
1220 Medical Park Drive
Fort Wayne, Indiana 46825
USA

Investigators: Kimberly R. Milleman, RDH, PhD
Jeffery L. Milleman, DDS, MPA
Building #4
1220 Medical Park Drive
Fort Wayne, Indiana 46825
USA

Subject Number_____

INVESTIGATORS STATEMENT

Your child is being asked to volunteer for a dental research study. Before agreeing to participate in this research study, it is important that you read this form. This form, called a consent form, describes the purpose, procedures, benefits, financial payment, risks and discomforts of this research study. It also describes the alternative procedures that are available to your child to withdraw from this research study at any time. No promises or guarantees can be made as to the results of this research study. Please ask as many questions as you need to so that you can decide whether you want your child to be in this research study. This consent form may contain words that you do not understand. Please ask the research study doctor or the research study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or to discuss with family or friends before making your decision.

PURPOSE OF THIS RESEARCH STUDY

The objective of this 30-day, randomized, two group, parallel, examiner-blind clinical research study is to assess the safety and efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on plaque and gingivitis, compared to a manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

STUDY POPULATION

Your child has been identified as an individual who may qualify to participate in this research

study. Approximately 80 healthy volunteers (both children and adults) are planned to be eligible and enrolled in this research study. Your child's participation in this research study will last approximately 6 weeks.

EXPERIMENTAL ASPECTS

All products used in this study are marketed Class 1 medical devices and are considered safe when used as directed by the study procedures and are not experimental or investigational in nature. The study procedures are in compliance with how the product is intended to be used by the manufacturers. This research study will be conducted in 4 visits. The first visit will screen subjects to qualify for enrollment, including gingivitis levels. Qualified subjects will be provided with washout products to (marketed fluoride toothpaste and toothbrush) use until the next scheduled visit (approximately 1 to 2 weeks later). At the second visit, your child will be randomized to one of two toothbrush products and instructed on proper study procedures by study staff for the assigned regimen. At each study visit, subjects will have dental exams and a product safety exam. Additionally, plaque removal after a single, supervised toothbrushing in the research clinic will be assessed at visit 4. All dental exams and procedures to be performed in this research study are standard techniques; however, they are being used in an experimental setting to determine the gingivitis changes and the dental plaque reductions following approximately 30 days of use and after a single toothbrushing at the research site at visit 4.

SPECIFIC PROCEDURES TO BE USED

If you agree to allow your child to participate, the following procedures will take place:

Visit 1

Research study staff will perform a screening examination to determine whether your child will qualify to enter this research study, then they will:

- Collect demographic information (age, gender, etc.,).
- Ask you to complete a medical questionnaire for your child and interview you about any medical and dental history, current oral conditions, and current medications.
- Examine tissues in your child's mouth to check for abnormalities, *e.g.,* evidence of gingival abrasion, irritations, lacerations, or ulcerations.
- Complete a dental charting to record the presence of dental restorations such as crowns, veneers, alloys, and composites.
- Assess the level of gingival inflammation (color and swelling of your gums).

If your child meets all these screening requirements, the investigators will enroll your child in this research study and will provide them with a toothbrush and toothpaste to use during the washout period until Visit 2. Your child will be responsible to attend Visit 2 and following the specific instructions given by the research study staff.

Visit 2

Research study staff will ask your child to abstain from toothbrushing 12 to 16 hours prior to this visit and not to eat or drink 30 minutes (except small sips of water) prior to this appointment. During Visit 2 the research study staff will:

- Update the medical/dental history for any changes in health or new medicines.
- Ask and record if any problems were encountered during the washout period.
- Examine tissues in your child's mouth to check for abnormalities, for example, evidence of gingival abrasion, irritations, cuts, or sores.
- Assess the level of gingival inflammation (color and swelling of the gums).

- Measure the amount of gingival recession (receding gums) using a calibrated probe.
- Record the amount of plaque on your child's teeth using a blue food dye that will temporarily discolor the teeth and gums.
- Check and record any gum abrasions.

If your child meets all the Visit 2 requirements and they are willing to follow the at-home daily study procedures described below, the study staff will enroll them in this research study and will provide them with further instructions. They will be responsible for attending both a Day 15 and Day 30 examination visit. If they qualify to continue in this research study based on the baseline exam at Visit 2, the research study staff will:

- Randomly assign your child (by chance, like flipping a coin) to one of two toothbrush groups.
- Issue their research study products for the 30-day plaque and gingivitis study.
- Distribute and provide instructions to use their assigned study toothbrushes. In addition, your child will receive a tube of Crest Cavity Protection toothpaste and a study treatment diary.
- Verbally provide instructions about this research study's requirements, including a review of the study toothbrush usage instructions and diary completion instructions.
- Supervise the first use of the assigned study toothbrush to be sure that your child understands the usage instructions.
- Confirm that the assigned study toothbrush will be used at home twice daily and to record each usage in the provided diary for the next 30 days.
- Remind your child not to use other toothbrushes, toothpaste, interdental cleaning devices, floss or mouthwashes, chewing gum, breath film, whitening products, or other oral care cleaning aids for the duration of this research study.
- Remind your child to abstain from toothbrushing 12 to 16 hours prior to Visit 3 and not to eat or drink 30 minutes prior to this research visit. Small sips of water are allowed.
- Schedule your child's next examination (Visit 3) after 2 weeks of home use.

The research study dental examiners will not know which study toothbrush that your child is assigned to use. However, this information is available to the research study dentist in an emergency. The study staff will advise your child not to discuss the assigned study treatment regimen with the examiners or other subjects for the duration of this research study.

Visits 3 & 4

Your child will return to the study site for your Visit 3 (14 days after Visit 2) and Visit 4 (14 day after Visit 3). Your child will need to bring the assigned study products to these research visits. In addition, your child will be asked to abstain from toothbrushing 12 to 16 hours before each of these appointments and not to eat or drink 30 minutes prior to this research visit, except small sips of water are permitted. During Visits 3 and 4, the research study staff will:

- Inventory and collect all their assigned research study materials (that is, toothbrush, usage instructions, toothpaste, diary).
- Interview your child to determine whether the usage instructions, the assigned study toothbrush and diary were used correctly.
- Update the medical/dental history for any changes in health or new medicines.
- Ask and record if any problems were encountered during the washout period or between Visits 3 and 4.
- Examine tissues in your child's mouth to check for abnormalities, for example, evidence of gingival abrasion, irritations, cuts, or sores.
- Assess the level of gingival inflammation (color and swelling of the gums).

- Measure the amount of gingival recession using a calibrated probe.
- Record the amount of plaque on your child's teeth using a blue food dye that will temporarily discolor the teeth and gums will be used to assist the examiner.
- Check and record any gum abrasions.
- At Visit 4 your child will perform a supervised product use and then have a post-product plaque exam completed.
- At Visit 4, your child will be thanked, paid a gratuity and dismissed from the research study.

SUBJECT RESPONSIBILITIES

Your child must be available to attend each research study visit. Lastly, your child must brush as instructed and return all research products at each visit.

During this research study, your child will not be allowed to have their teeth cleaned or whitened at a dental office. Your child must refrain from brushing their teeth for approximately 12 to 16 hours and will not have eaten or drank for at least 30 minutes prior to each research study visit, except small sips of water are permitted.

LENGTH OF PARTICIPATION

If your child qualifies and is enrolled after the screening exam (Visit 1), they will come back to the clinic approximately 7 to 14 days later. The total length of the study will be approximately 6 weeks. All exams will take place at the Salus Research, Inc. (SRI) dental clinic. Approximately 70 volunteers will complete the research study.

RISKS TO THE SUBJECT

The risk of permanent harm or injury, or disability as a result of participation in this research study is minimal. The dental exams are similar to those used as part of routine oral health care. Participation in this research study is not expected to cause any oral conditions different from those normally experienced in routine dental care. No known side effects or risks are associated with the use of this research study toothbrushes or toothpaste. All products used in this study are class 1 medical devices and are considered safe when used as directed by the study procedures. There is a chance that use of the research study products may involve risks that are currently unknown. Your child will be asked to report any discomfort or irritation that they experience while using their research study products and for up to 5 days after the last use of this research study product.

Precautions:

- All products given as part of this research study are for the participant use only.

BENEFITS TO THE SUBJECT

There is no guarantee that your child will receive any medical or dental benefits from participating in this research study.

COSTS

There will be no costs to participate in this research study.

PAYMENT FOR PARTICIPATION

Your child will be paid a **$125 gift card** if all research study visits are completed. A **$25 gift card** will be paid for each completed research visit and a bonus of **$25 gift card** will be paid at Visit 4.

ALTERNATIVE TO PARTICIPATION

The alternative is not to participate in this research study. Your child does not have to take part in this research study to receive treatment for removing dental plaque.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give your child certain rights related to their health information. These include the right to know who will be able to get the information and why they may be able to get it. The research study doctor must get your authorization (permission) to use or give out any health information that might identify your child. Please notify the research study staff if you would like the research study investigator to notify your family dentist about participation in this research study.

WHAT INFORMATION MAY BE USED AND GIVEN TO OTHERS?

If you choose to allow your child to be in this research study, the study doctor will get personal information about your child. This may include information that might identify them. The research study doctor may also get information about your child's health including:

- Dental and research records
- Records about the research study related phone calls
- Records about your child's research study visits
- Records of research study exams
- Records of research study products

WHO MAY USE AND GIVE OUT INFORMATION ABOUT YOU?

Information about your child's health may be used and given to others by the research study doctor and staff. They might see the research information during and after the research study.

WHO MIGHT GET THIS INFORMATION?

Information concerning your child that is obtained in connection with this research study will be kept confidential by SRI, except that this information may be given to the sponsor of this research. The records will be coded to protect everyone's identity. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. A representative of the sponsor company may observe the research study procedures at one or more of their study visits.

Information about your child and their health which might identify them may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Government agencies in other countries
- U.S. Investigational Review Board Services, Inc. (U.S. IRB, Inc.®)

WHY WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?

Information about your child and their health that might identify your child may be given to members of the research study team to enable them to carry out the research study. People from the sponsor and its consultants may be visiting the research site. They will follow how the research study is done, and they will be reviewing information for this purpose. The sponsor will analyze and evaluate the results of the research study and may see protected health information. No information that could be used to identify your child will be transferred to the sponsor.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies. The results of this research may be published in scientific journals or presented at medical meetings, but your child's identity will not be disclosed. The information may be reviewed by U.S. IRB, Inc., a group of people who perform independent review of research as required by regulations for protecting the rights and safety of research participants.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?
By signing this consent form, you are giving permission to use and give out health information listed above for the purposes described above. If you refuse to give permission, your child will not be able to participate in this research study.

MAY I REVIEW OR COPY THE INFORMATION OBTAINED FROM ME OR CREATED ABOUT ME?
You have the right to review and copy your child's health information. However, if you decide to participate in this research study and sign this permission form, you will not be allowed to look at or copy your child's information until after the research is completed.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose this health information at any time. You do this by sending written notice to the research study doctor. If you withdraw permission, your child will not be able to continue being in this research study.

When you withdraw your permission, no new health information which might identify your child will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

IS MY HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO OTHERS?
If you give permission to give your child's identifiable health information to a person or business, the information may no longer be protected. There is a risk that this information will be released to others without your permission. No information that could be used to as an identifier will be transferred to the sponsor.

CONFIDENTIALITY OF THIS RESEARCH STUDY AND PRODUCT
While your child is participating in this research study, all information produced, the research study product used, and details of this research study remain property of SRI and the sponsoring company. The information and any materials or items given about or during this research study, such as information regarding this research study toothbrushes and toothpastes or the type of research study being performed, should be considered the confidential business information of the research study sponsor. You are, of course, free to discuss with your family and friends while considering whether to participate in this research study or at any time when discussing their present or future healthcare. This research study product has been provided specifically for your child and you must not allow any other person to inspect or try this research study product. At the end of this research study, you and your child will be requested to return all remaining research study product for accountability purposes.

COMPENSATION FOR INJURY

In the event of injury resulting from participation in this research study, immediate treatment is available at SRI. If your child participates in this research study, free medical care or payment for injuries or complications will not be offered. However, the sponsor will pay for medical costs not covered by your own insurance or other program if it has been determined that your child is suitable for this research study, if they have followed instructions for this research study, and the condition came about because of direct participation in this research study. If diagnostic work-ups show that the condition giving rise to the costs was not related to this research study, then no medical care or payment for this care will be made. The sponsor will pay for medical expenses for the diagnostic work-ups. When possible, the sponsor will review and approve expenses for the diagnostic work-ups in advance. The sponsor will not pay or provide any other type of benefit for any adverse experience that happens while participating in this research study. Questions about this should be directed to Dr. Jeffery L. Milleman at 260-755-1099 (clinic) or 260-413-7777 (24 hours).

VOLUNTARY PARTICIPATION/WITHDRAWAL

Participation in this research study is voluntary. Your child may decide not to participate without penalty and without affecting future dental care. If your child does agree to participate, they can withdraw from this research study at any time without penalty or loss of benefits, but will be paid for only the visits completed. They will be asked to tell the research study doctor their reason for withdrawal. Their participation in this research study may be stopped at any time by the study doctor or the sponsor without their consent. Your child's participation might be terminated by the study team if significant deviation from the study regimen or instructions is noted. Your child's participation might also be ended if their health or safety is affected in the opinion of the study doctor or the sponsor.

NEW FINDINGS

You will be told about new findings relating to the research study toothbrushes that might affect your child's decision to participate in this research study.

QUESTIONS

If you have any questions about this research study, or if you feel your child may have experienced a possible side effect, reaction to this research study product, or a research-related injury, contact the study investigators:

Jeffery L. Milleman, DDS, MPA
Kimberly R. Milleman, RDH, PhD
Salus Research, Inc (SRI)
Building 4
1220 Medical Park Drive
Fort Wayne, IN 46825
Telephone: 260-755-1099 (clinic) or 260-413-7777 (24 hours).

If there are concerns about your rights as a research subject, you may contact:

Rosa M. Fraga, Chairperson
U.S. Investigational Review Board, Inc. (U.S. IRB, Inc.®)
8050 SW 72 Avenue, #2105
Miami, Florida 33143
Telephone: 1-786-473-3095
E-mail: rmvf1550@aol.com

U.S. IRB, Inc.® is a group of people who perform independent review of research for protecting the rights and safety of research participants.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree for your child to participate in this research study, you will be given a signed and dated copy of this consent form to keep.

CONSENT

I have read the information in this consent form. All my questions about this research study and my child's participation in it have been answered. I freely consent for my child to participate in this research study.

I authorize the use and disclosure of my child's health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of my child's legal rights which they otherwise would have as a subject in a research study.

_____ _____

Parent or Legal Guardian Signature Date

_____

Child's Name (Please print)

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

For further information regarding your child's rights as a volunteer, contact Rosa M. Fraga, Chairperson of the U.S. Investigational Review Board, Inc.® (U.S.IRB, Inc.®) at 1-786-473-3095 or rmvfl1550@aol.com.

Parent/Guardian Initials _____
IRB #: U.S.IRB2023SRI/04-CHILD
VERSION: May 9, 2023
VALID TO: May 8, 2024

RESEARCH SUBJECT INFORMATION AND ASSENT FORM

TITLE:	Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model
PROTOCOL NO.:	AB-GBP-2023-02
INVESTIGATORS:	Kimberly R. Milleman, RDH, PhD Jeffery L. Milleman, DDS, MPA Salus Research, Inc. Building #4 1220 Medical Park Drive Fort Wayne, Indiana 46825 United States 260-755-1099
STUDY SITE:	Salus Research, Inc. (SRI) Building #4 1220 Medical Park Drive Fort Wayne, Indiana 46825 United States
Study-Related Phone Number(s):	Jeffery L. Milleman, DDS, MPA 260-413-7777 (24 hours)

SUBJECT NUMBER_____

ASSENT FORM FOR MINOR STUDY SUBJECTS

You are being asked to be in a research study. A research study is a way to get new information about things, in this case, two marketed toothbrushes (a power and manual) with a fluoride toothpaste. You have been chosen because this is a research study for people (ages 5 to 65 years old) who have at least 12 natural and healthy teeth. There will be at least 20 children (ages 5 to 12) and adolescents (ages 13 to 17) taking part in this research study.

By being in this research study, we will tell you what will happen at each visit. You and your parent or legal guardian can choose whether you will take part, we will ask you and your parent or legal guardian some questions about your health and our dental examiner will have a look in your mouth to see how your mouth looks before, during and after using the study toothbrush with toothpaste. This form you are reading is called an assent form. It gives you the information you need to know about this research study.

Subject Initials _____
IRB #: U.S.IRB2023SRI/04-CHILD ASSENT
VERSION: May 9, 2023
VALID TO: May 8, 2024

After we tell you about it, we will ask if you would like to be in this study or not. Take as long as you need to decide if you want to say YES or NO. Whatever you decide is OK. Your parents have also been told about this research study, and you can ask them to help you understand.

If you decide that you want to be a part of this research study, you will be given a new tube of toothpaste and a soft manual toothbrush to use for the first week or two. During the second visit to the research clinic, you will be randomly assigned (like the flip of a coin) to 1 of the 2 toothbrush groups and given a new tube of toothpaste to use for the next 30 days. If you are given the manual toothbrush, you will brush your teeth for 2 minutes. With the power brush, you will brush your teeth for 30 seconds.

There are some things about this research study that you should know. We are not aware of any problems with the use of the study toothbrushes and toothpaste. There is a small chance that problems may happen from using the study products that are not known. If you feel any discomfort, you must tell your parent or legal guardian who will then call Salus Research, Inc.

This research study will last about 6 weeks and you will need to have 4 appointments (called visits). Today is the first one. The visits will be at the Salus Research Inc. dental research clinic. Each visit will take less than 60 minutes of your time. At each research study visit, you will:

- Allow the study staff to look at your teeth and the inside of your mouth with a dental light.
- Allow the dental examiner to grade the amount of gum swelling (inflammation) in your mouth.
- Rinse your mouth with a blue dye solution that will make it easy to see the dental plaque (sticky film) on your teeth. The blue dye will discolor your teeth and gums.
- Allow the dental examiners to grade the plaque deposits on your teeth and abrasions on your gums. Abrasions are small scratches or scrapes on your gums that can be caused by a toothbrush.
- Allow the study staff to ask questions about any sore spots or discomfort you may have noticed.
- Brush your teeth using the study toothbrush and toothpaste that is given to you.

You will be given **a $125 gift card** for helping with this study.

Did anyone else check that the study is OK to do?

This research study has been checked by a group of people who make sure that the research is fair and safe.

Is there anything that I won't be able to do during the study?

- You cannot take part in any other research like this before or during this research study.
- You cannot eat or drink for 30 minutes, except for small sips of water, before each study visit.

You can visit your dentist for emergencies.

Will it hurt when the dentist looks at my mouth?

No, the dental examiner will use a special blue food dye and a puff of air to measure the dental plaque on your teeth.

What if something goes wrong?

- Should something happen to you during this research study, your parent/legal guardian has been told what to do.
- When we are finished with this research study, we will write a report about what was learned. This report will not include your name or that you were in this research study.
- You do not have to be in this research study if you do not want to be. You can say no, and no one will be angry with you. If you decide to stop after we begin, that's okay too.

AGREEMENT TO BE IN THE STUDY

This assent form contains important information to help you decide if you want to be in this research study. If you have any questions that are not answered in this assent form, ask one of the study staff.

When you sign this assent form you agree that:

- you have had a chance to ask questions.
- you understand English.
- you want to be in this research study.
- you agree to use only the toothbrush that we give to you.
- you will brush your teeth 12 to 16 hours before each research study visit.
- You will NOT eat or drink for 30 minutes before each research study visit, except for small sips of water.

ASSENT (REQUIRED FOR SUBJECTS LESS THAN 18 YEARS OF AGE)

I have read the information in this assent form (or it has been read to me). My parent (s) or my legal guardian (if I have one) and this research study doctor and/or staff have explained this research study to me and have answered my questions. I agree to be in this research study.

Printed Name or Signature of Subject for Assent	Date	Age (years)

I confirm that I have explained this research study to the extent that is compatible with the subject's understanding, and that the subject has agreed to participate in this research study.

Signature of Person Conducting Assent Discussion	Date

For further information regarding your rights as a volunteer, contact Rosa M. Fraga, Chairperson of the U.S. Investigational Review Board, Inc.® (U.S.IRB, Inc.®) at 1-786-473-3095 or rmvf1550@aol.com.

Subject Initials _____
IRB #: U.S.IRB2023SRI/04-CHILD ASSENT
VERSION: May 9, 2023
VALID TO: May 8, 2024

U.S.
Investigational Review Board, Inc.

TO: Jeffery L. Milleman, DDS, MPA, Principal Investigator
Salus Research, Inc. (SRI)

FROM: Rosa M. Fraga, Chairperson

SUBJECT: Approval of Final Clinical Protocol Amendment 1 dated May 22, 2023; Revised AutoBrush 360° Sonic Toothbrush Instructions (5-8 years old) & Revised AutoBrush 360° Sonic Toothbrush Instructions (9-65 years old)

IRB NUMBER: U.S.IRB2023SRI/04

PROTOCOL NUMBER: AB-GBP-2023-02

DATE OF MEETING: May 23, 2023

PROTOCOL TITLE: CLINICAL SAFETY AND EFFICACY OF AUTOBRUSH® 360° U-SHAPED SONIC TOOTHBRUSH ON PLAQUE AND GINGIVITIS IN A 30-DAY MODEL

The U.S. Investigational Review Board, Inc. is a review committee structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (21 CFR Parts 50 and 56) and is in compliance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRB/IEC and operates in accordance with GCP guidelines and applicable laws and regulations.

This research study has been approved for **one year valid to May 8, 2024**. At the end of this time, you are required to provide this IRB Committee a written status report of this research and obtain approval for the continued research. In the event that you complete the research within this time period, please notify this Committee, in writing, of your completion of this research study. Changes to the protocol or use of non-approved advertisement cannot be initiated without this IRB review and approval. Written notice to this IRB is required in the event of any serious adverse reactions, significant deviations from the protocol or any problems in the research within 5 days. Please provide this reporting to the address noted below so that appropriate follow-up will be initiated.

Final Clinical Protocol Amendment 1 dated May 19, 2023; Revised AutoBrush 360° Sonic Toothbrush Instructions (5-8 years old) & Revised AutoBrush 360° Sonic Toothbrush Instructions (9-65 years old) were reviewed and approval is hereby granted with no changes requested to the informed consent form.

Rosa M. Fraga, Chairperson

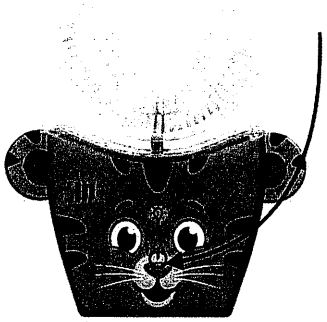
U.S.IRB
MAY 23 2023
"APPROVED"

AutoBrush 360° Sonic Toothbrush Instructions (5-8 years old)

INSTRUCTIONS FOR USE for Ages 5 – 8 years old.
UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:

1) Follow package instructions for charging the AutoBrush base device.
2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base.
3) Wet your toothbrush and dispense a smear of paste onto each side of the brush head.
4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base).
   *** **DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON**
5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds.
6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
7) Remove the brush head from the base, rinse and air dry after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale



DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON!!

Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

Thank you!

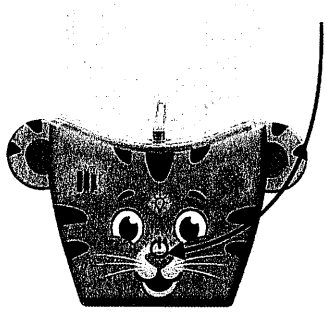
U.S.IRB
MAY 23 2023
"APPROVED"

AutoBrush 360° Sonic Toothbrush Instructions (9-65 years old)

INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 <18 years
(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):

1) Follow package instructions for charging the AutoBrush base device.
2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base.
3) Wet your toothbrush and dispense a ribbon of toothpaste onto each side of the brush head.
4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base).
   *** **DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON**
5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds.
6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
7) Remove the brush head from the base, rinse and air dry after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale



DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON!!

Please record your brushing on the provided diary card.

If you have any questions regarding this study, please call Salus Research at 260-755-1099.

Thank you!

U.S.IRB
MAY 23 2023
"APPROVED"

U.S.
Investigational Review Board, Inc.

July 18, 2023

Jeffery L. Milleman, DDS, MPA
Salus Research, Inc. (SRI)
1220 Medical Park Drive, Building 4
Fort Wayne, IN 46825

IRB NUMBER:	**U.S.IRB2023SRI/04**
PROTOCOL NUMBER:	**AB-GBP-2023-02**
DATE OF APPROVAL:	**May 9, 2023**
PROTOCOL TITLE:	**CLINICAL SAFETY AND EFFICACY OF AUTOBRUSH® 360° U-SHAPED SONIC TOOTHBRUSH ON PLAQUE AND GINGIVITIS IN A 30-DAY MODEL**

Dear Dr. Milleman:

We are in receipt of the Study Closure Report signed by you on July 17, 2023, relating to the above captioned research study, indicating that the study was closed on July 14, 2023.

The Committee reviewed the Study Closure Report and unanimously accepted the research study as closed.

Very truly yours,

ROSA M. FRAGA
Chairperson

Salus Research
main 260.755.1099
fax 260.755.1128
www.SalusResearch.us
1220 Medical Park Dr., Building 4 • Fort Wayne, IN 46825 USA

STUDY CLOSURE REPORT

IRB Name: U.S. Investigational Review Board, Inc.

IRB Study Number: U.S.IRB2023SRI/04

IRB Approval Date: 5/23/2023

Investigative Site: Salus Research, Inc.

Investigator Name: Dr. Jeffery L. Milleman

Investigator Phone: 260-755-1099

Sponsor Name: Lander Enterprises, LLC

Protocol Number: AB-GBP-2023-02

Protocol Title: CLINICAL SAFETY AND EFFICACY OF AUTOBRUSH® 360° U-SHAPED SONIC TOOTHBRUSH ON PLAQUE AND GINGIVITIS IN A 30-DAY MODEL

Complete this closure form when all subjects have finished their final visits and follow-up, and when the sponsor or its representative has indicated that the study is closed at this site.

Date Study Closed: 14-Jul-23

Final Subject Enrollment Information:

Total subjects who signed the consent form:		79
Screening failures	2	
Began study drug, device, or procedures:	77	
Withdrew from study:	2	
Total subjects who completed the study:		75

Were there any Serious Adverse Events (SAE) or other unanticipated problems at this site that were not previously reported to the IRB?

[X] No [ ] Yes (If Yes, attach the information)

Comments about the study: The study was completed according to the protocol without any significant problems.

Investigator Signature (or Designee) — *Date* 17 JUL 2023

5.1.4 Investigators and Study Personnel

Principle Investigator:	Jeffrey L. Milleman, DDS, MPA Salus Research 1220 Medical Park Drive, Building #4 Fort Wayne, IN 46825 Tel: (260) 755-1099 milleman@salusresearch.us
Sub Investigator/Clinical Examiner:	Kimberly R. Milleman, BSDH, MS, PhD Salus Research, Inc. kmilleman@salusresearch.us
Others (study coordinator):	Abigale L. Yoder, BS Salus Research Phone: (260) 755-1099 Fax: (260) 755-1128 yoder@salusresearch.us
Sponsor:	Chris Lander Lander Enterprises, LLC dba AutoBrush® 5700 Biscayne Blvd, Apt 822 Miami, Florida 33137
Monitor:	Sylvia L. Santos, RDH, MS SLS Clinical Research Consulting, LLC Phone: 201-572-9223 sersantos@verizon.net
Statistician	Howard M. Proskin, Ph.D. Howard M. Proskin & Associates, Inc. 35 Sleepy Hollow Ln. Rochester, NY 14618 hproskin@hmproskin.com

1-Page Curricula Vitae and Licenses for Salus Research Study Team are attached.

5.1.5 Sponsor and Investigator Signatures

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Principal Investigator:

Signed: _____ Date: _____

Jeffery L. Milleman, DDS, MPA
Salus Research, Inc.
1220 Medical Park Drive, Building #4
Fort Wayne, Indiana 46825
(260) 755-1099

Sponsor Representative:

Signed:  Date: 10/20/2023

Chris Lander
Lander Enterprises, LLC dba AutoBrush®
5700 Biscayne Blvd Apt 822
Miami, Florida 33137

5.1.6 List of Study Products

Manual toothbrush: ADA reference manual soft-bristled toothbrush

Sonic toothbrush: AutoBrush® 360° U-shaped Sonic Toothbrush

5.1.7 Randomization Scheme and Codes

Randomization for Lander AB-GBP-2023-02

Block #	Randomization #	Treatment Assignment	Subject Number	Date Assigned	Staff Initials
Low-01	L001	Control	1014	13 Jun 2023	KSW
Low-01	L002	Control	1015	13 Jun 2023	KSW
Low-01	L003	Test	1016	13 Jun 2023	KSW
Low-01	L004	Test	1025	13 Jun 2023	KSW
Low-02	L005	Test	1054	13 Jun 2023	KSW
Low-02	L006	Control	1076	13 Jun 2023	KSW
Low-02	L007	Test	1051	13 Jun 2023	KSW
Low-02	L008	Control	1010	14 Jun 2023	KSW
Low-03	L009	Control	1030	14 Jun 2023	KSW
Low-03	L010	Control	1031	14 Jun 2023	KSW
Low-03	L011	Test	1078	14 Jun 2023	KSW
Low-03	L012	Test	1045	15 Jun 2023	KSW
Low-04	L013	Test	1047	15 Jun 2023	KSW
Low-04	L014	Test	1048	15 Jun 2023	KSW
Low-04	L015	Control	1046	15 Jun 2023	KSW
Low-04	L016	Control	1065	15 Jun 2023	KSW
Low-05	L017	Control	1066	15 Jun 2023	KSW
Low-05	L018	Test	1060	15 Jun 2023	KSW
Low-05	L019	Test	1059	15 Jun 2023	KSW
Low-05	L020	Control	1058	15 Jun 2023	KSW
Low-06	L021	Control	1069	15 Jun 2023	KSW
Low-06	L022	Test	1068	15 Jun 2023	KSW
Low-06	L023	Test	1071	15 Jun 2023	KSW
Low-06	L024	Control	1039	15 Jun 2023	KSW
Low-07	L025	Control			
Low-07	L026	Test			
Low-07	L027	Control			
Low-07	L028	Test			
Low-08	L029	Test			
Low-08	L030	Control			
Low-08	L031	Test			
Low-08	L032	Control			
Low-09	L033	Control			
Low-09	L034	Test			
Low-09	L035	Test			
Low-09	L036	Control			
Low-10	L037	Test			
Low-10	L038	Control			
Low-10	L039	Test			

Randomization for Lander AB-GBP-2023-02

Block #	Randomization #	Treatment Assignment	Subject Number	Date Assigned	Staff Initials
High-01	H001	Test	1057	13 Jun 2023	KSW
High-01	H002	Test	1001	13 Jun 2023	KSW
High-01	H003	Control	1003	13 Jun 2023	KSW
High-01	H004	Control	1005	13 Jun 2023	KSW
High-02	H005	Control	1052	13 Jun 2023	KSW
High-02	H006	Test	1007	13 Jun 2023	KSW
High-02	H007	Test	1017	13 Jun 2023	KSW
High-02	H008	Control	1019	13 Jun 2023	KSW
High-03	H009	Test	1020	13 Jun 2023	KSW
High-03	H010	Control	1018	13 Jun 2023	KSW
High-03	H011	Control KSW 13 Jun 2023	~~1014~~ 1026	13 Jun 2023	KSW
High-03	H012	Test	1024	13 Jun 2023	KSW
High-04	H013	Test	1021	13 Jun 2023	KSW
High-04	H014	Test	1055	13 Jun 2023	KSW
High-04	H015	Control	1035	13 Jun 2023	KSW
High-04	H016	Control	1011	13 Jun 2023	KSW
High-05	H017	Control	1006	13 Jun 2023	KSW
High-05	H018	Test	1029	13 Jun 2023	KSW
High-05	H019	Test	1077	13 Jun 2023	KSW
High-05	H020	Control	1037	13 Jun 2023	KSW
High-06	H021	Control	1050	13 Jun 2023	KSW
High-06	H022	Test	1075	13 Jun 2023	KSW
High-06	H023	Control	1002	14 Jun 2023	KSW
High-06	H024	Test	1044	14 Jun 2023	KSW
High-07	H025	Test	1043	14 Jun 2023	KSW
High-07	H026	Control	1008	14 Jun 2023	KSW
High-07	H027	Control	1004	14 Jun 2023	KSW
High-07	H028	Test	1012	14 Jun 2023	KSW
High-08	H029	Test	1032	14 Jun 2023	KSW
High-08	H030	Control	1022	14 Jun 2023	KSW
High-08	H031	Test	1013	14 Jun 2023	KSW
High-08	H032	Control	1027	14 Jun 2023	KSW
High-09	H033	Test	1033	14 Jun 2023	KSW
High-09	H034	Control	1034	14 Jun 2023	KSW
High-09	H035	Control	1028	14 Jun 2023	KSW
High-09	H036	Test	1074	15 Jun 2023	KSW
High-10	H037	Test	1049	15 Jun 2023	KSW
High-10	H038	Control	1042	15 Jun 2023	KSW
High-10	H039	Test	1053	15 Jun 2023	KSW
High-10	H040	Control	1064	15 Jun 2023	KSW

		Control	1062	15 Jun 2023	KSW
h-11	H044	Control	1023	15 Jun 2023	KSW
h-12	H045	Test	1036	15 Jun 2023	KSW
h-12	H046	Control	1061	15 Jun 2023	KSW
gh-12	H047	Control	1056	15 Jun 2023	KSW
gh-12	H048	Test	1073	15 Jun 2023	KSW
gh-13	H049	Test	1072	15 Jun 2023	KSW
gh-13	H050	Test	1070	15 Jun 2023	KSW
gh-13	H051	Control KSW 15 Jun 2023	~~1040~~ 1038	15 Jun 2023	KSW
igh-13	H052	Control	1040	15 Jun 2023	KSW
ligh-14	H053	Test	1079	15 Jun 2023	KSW
ligh-14	H054	Control			
ligh-14	H055	Control			
ligh-14	H056	Test			
High-15	H057	Test			
High-15	H058	Test			
High-15	H059	Control			
High-15	H060	Control			
High-16	H061	Control			
High-16	H062	Test			
High-16	H063	Test			
High-16	H064	Control			
High-17	H065	Test			
High-17	H066	Test			
High-17	H067	Control			
High-17	H068	Control			
High-18	H069	Control			
High-18	H070	Test			
High-18	H071	Control			
High-18	H072	Test			
High-19	H073	Test			
High-19	H074	Test			
High-19	H075	Control			
High-19	H076	Control			
High-20	H077	Test			
High-20	H078	Control			
High-20	H079	Test			
High-20	H080	Control			

5.1.8 Publications Referenced in the Report

Please refer to the reference list in Section 3.5 of this report.

5.2 Statistical Narrative Report

Protocol No. AB-GBP-2023-02

Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Final Statistical Report

05 October 2023

Report Prepared by:

Howard M. Proskin, Ph.D.

Howard M. Proskin & Associates, Inc.
35 Sleepy Hollow Ln.
Rochester, NY 14618

Objective:

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial was to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. The extent of gingival abrasion and recession was evaluated.

Study Design:

This single-center, randomized, controlled, and double-blind study was conducted according parallel-groups design. Following a screening examination at which subject eligibility was determined and informed consent and assent was obtained, enrolled subjects reported to the study site for three subsequent visits: Baseline, Day 15, and Day 30. At the Baseline visit, subjects were randomized to one of the two study toothbrushes, and were instructed to use their assigned toothbrush twice daily over the course of the study according to instructions provided.

At Baseline and at each follow-up study visit, whole mouth oral examinations were performed according to the Modified Gingival Index (MGI); the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI); gingival abrasion; and gingival recession. An oral soft and hard tissue (OSHT) examination was also performed at each visit. At the Day 30 visit, subjects brushed their teeth with the assigned product while in the dental clinic, and were reexamined for LSPI and OSHT following brushing (to enable an assessment of pre- to post-brushing changes). OSHT was also performed at the Screening visit. Information regarding Adverse Events was obtained at Baseline and at all follow-up study visits. Additional details concerning the conduct of the study are provided in the study protocol.

Study Populations:

The Safety Population consisted of all eligible subjects who were randomized into the study and performed at least one use of the study product. The Per-protocol (PP) population included subjects who completed all study visits without any major protocol violations.

Study Endpoints:

Safety endpoints included:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

Efficacy Endpoints were as follows:

Primary Efficacy variables:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.

Secondary Efficacy Variables:

- MGI at Day 15:
  - Whole mouth mean change.
  - Gumline (marginal).
  - Proximal (marginal).
  - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
  - Pre- and Post- brushing Whole mouth.
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
  - Gumline.
  - Proximal.
  - Distal score of the last posterior tooth in each quadrant.
- LSPI scores at Day 30
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Statistical Analyses:

All analyses for safety were performed on the Safety population. Analyses for efficacy were performed on the PP population. All hypothesis tests performed for treatment comparisons were two-sided, and employed a 0.05 level of significance.

Changes from Methodology described in the protocol are presented in the Appendix below.

Safety Review:

All findings regarding OSHT observations, gingival recession, and gingival abrasion were presented in listings.

For gingival recession, for each study treatment, cross tabulations of pre versus post visit scores were prepared for each pair of study visits (Baseline vs. Day 15, Baseline vs. Day 30, and Day 15 vs. Day 30) that illustrate the number of measured sites that exhibited each score transition. Each of these cross tabulations also presented, for those sites which presented each score at the earlier visit, the percentage that transitioned to each of the scores seen at the later visit. Additionally, a table was prepared that presented, for each study visit, a summary of the subject-wise mean recession scores for each treatment, and the number and percentage of subjects in each treatment group that presented at least one measured site with recession of 1mm or higher; and that presented at least one measured site with recession of 2mm or higher.

For gingival abrasion, cross tabulations were prepared as described above for the gingival recession scores. These cross tabulations were prepared separately for transitions of abrasion scores; and also for transitions of assigned abrasion category scores (as described above). In the latter, those sites that presented abrasion scores of 0 (*i.e.*, no abrasion) were assigned a category score of zero. Two additional summary tables were prepared for the gingival abrasion data:

1. A summary indicating, for each treatment and study visit,
    a. A categorical distribution of subjects according to:
        i. the number of measured sites that presented any abrasion (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
        ii. the number of measured sites that presented Category 1 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
        iii. the number of measured sites that presented Category 2 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
    b. The number and percentage of subjects with at least 1 site:
        i. Presenting an abrasion lesion of 1mm or higher
        ii. Presenting an abrasion lesion of 2mm or higher
        iii. Presenting an abrasion lesion of 3mm or higher.
2. Summaries of the subject-wise mean abrasion scores by treatment group and visit that included:
    a. A summary of the scores at the visit, and for post-baseline visits, a summary of the changes from baseline at the visit;
    b. For each post-baseline visit, based on an analysis of covariance (ANCOVA) model that employed the treatment group as a fixed effect, and that included the corresponding baseline value as a covariate,
        i. An estimate of the change from baseline that included the Least-squares mean (LS mean) and its standard error; a 95% confidence interval for the LS mean; and the p-value for the comparison of the LS mean change versus zero.
        ii. The results of a comparison of the Test treatment versus the Control with respect to the changes from baseline, including the difference between the LS means for the treatments, and its standard error; a 95% confidence interval for the difference; and p-value from the between-treatment comparison.

Demographic and Baseline Characteristics:
Demographic variables (age, gender, race, and ethnicity) and Baseline characteristics (mean MGI and LSPI) were summarized by treatment group and overall. Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.

Efficacy:
For each efficacy variable, a summary of the subject-wise mean scores by treatment group and visit was provided, presenting the same content as described above for the analysis of subject-wise mean gingival abrasion scores.

Data listings were provided for all efficacy variables.

RESULTS

A total of 77 subjects were randomized to a study treatment, of whom 75 participated in post-Baseline (follow-up) study visits. All results are provided in the sets of tables and listings that accompany this report. Except for the disposition table (Table 1), all tables are based on the PP population.

Demographics (Table 2):

Subjects ranged in age from 5 to 64. Although the mean age was slightly larger in the Control group, this difference was not statistically significant. Both treatment groups were roughly 40% male, and consisted predominately of White subjects. Fewer than 4% of the subjects in the study were Hispanic/Latino. The whole mouth MGI was slightly higher for the Control group (TBP; statistically sig.) Mean LSPI at baseline was comparable in the groups.

SAFETY

GINGIVAL RECESSION: (Tables 5.1-23T – 5.2)

At Baseline, the percentage of subjects who presented any gingival recession was 48.6% in the Test group and 57.9% in the Control group. Site-wise score cross-tabulations indicated that that every measured site presented the same recession score at all study visits. Thus, there was no apparent impact on gingival recession associated with either study toothbrush.

GINGIVAL ABRASION: (Tables 6.1-23T – 6.4)

Site-wise score transitions: For both study toothbrushes, among sites presenting no abrasion at the earlier visit, over 97% presented no abrasion at the later visit. Among sites presenting any positive level of abrasion at the earlier visit, most tended to present reduced levels of abrasion at the later visit.

Site-wise transitions of Category scores: The results for Category score transitions parallel those for score transitions as described above.

Categorical summary: At Baseline, the percentage of subjects presenting any level of gingival abrasion was 94.6% in the Test group, and 84.2% for the Control group. For subsequent study visits, the percentage presenting any level of gingival abrasion tended to be numerically higher in the Control group.

Analysis of Subject-wise mean abrasion scores: For both treatment groups statistically significant reductions from baseline were presented at Day 15 and Day 30; with significantly greater reductions in the Test group versus the Control at both visits.

EFFICACY

MGI: (Tables 3.1 – 3.4):

Test: For all subsets, significant reductions from baseline were presented at Day 15 and Day 30; with significantly greater reductions than for Control at both visits.

Control: for all subsets, small reductions from baseline were presented at both follow-up visits, which in most instances were not statistically significant.

LSPI: (Tables 4.1 – 4.4):

Test: For all subsets, significant reductions from baseline were presented at Day 15 and Day 30 pre-brushing; and significant reductions from pre-brushing at Day 30 post-brushing. Significantly greater reductions than for Control were presented in all instances.

Control: for all subsets, small non-statistically significant reductions from baseline were presented at Day 15 and Day 30 pre-brushing; and statistically significant (except for the most-distal subset) reductions from pre-brushing were presented at day 30 post-brushing.

APPENDIX: Changes in Statistical Methodology from that described in the study protocol.

The following methods represent changes from the statistical methodologies that had been described in the study protocol.

Study Parameter: Demographics
Statistical Methodology Employed: Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.
Statistical Methodology Described in the Study Protocol: Categorical demographic and baseline data will be evaluated using Fisher's Exactness Test and continuous demographic and baseline data will be evaluated using ANOVA.
Rationale for the change: ANOVA is the same as a t-test when comparing two groups. Chi-squared tests are the method typically used by the statistician for demographics tables, and are appropriate for the task.

Study Parameter: Gingival Recession
Statistical Methodology Employed: Cross-tabulations of site-wise score transitions between pairs of visits.
Statistical Methodology Described in the Study Protocol: No summary of site-wise scores was mentioned in the study protocol.
Rationale for the change: Cross-tabulations were added in order to present a clear picture of changes in site-wise recession findings over the course of the study.

Study Parameter: Gingival Recession
Statistical Methodology Employed: Analysis of subject-wise mean recession scores employing an ANCOVA model.
Statistical Methodology Described in the Study Protocol: Mean change in gingival recession at Day 15 and Day 30 is mentioned as a study endpoint, but the analysis methodology is not explicitly described.
Rationale for the change: The description of the ANCOVA methodology in this report represents more of a clarification, as opposed to a change.

Study Parameter: Gingival Recession
Statistical Methodology Employed: For each treatment group at each study visit, the number and percentage of subjects in each treatment group that presented at least one measured site with recession of 1mm or higher; and that presented at least one measured site with recession of 2mm or higher.
Statistical Methodology Described in the Study Protocol: (Not presented)
Rationale for the change: It is felt that the addition of this summary adds to the understanding of the possible impact of the study treatments on gingival recession.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Cross-tabulations of site-wise score transitions between pairs of visits; cross-tabulations of site-wise abrasion Category transitions between pairs of visits
Statistical Methodology Described in the Study Protocol: No summary of site-wise scores or categories was mentioned in the study protocol.
Rationale for the change: These cross-tabulations were added in order to present a clear picture of changes in site-wise gingival abrasion findings over the course of the study.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: (none)
Statistical Methodology Described in the Study Protocol: Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
Rationale for the change: This protocol-proposed analysis was replaced by the cross-tabulations described above. It is felt that the cross-tabulations provided a clearer picture of the possible changes in gingival abrasion that could occur within each treatment group over the course of the study.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Categorical distributions of subjects according to numbers of sites with specific abrasion findings by treatment and visit.
Statistical Methodology Described in the Study Protocol: (No corresponding analysis was mentioned in the study protocol.)
Rationale for the change: It is felt that this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Analysis of subject-wise mean abrasion scores employing an ANCOVA model.
Statistical Methodology Described in the Study Protocol: (No corresponding analysis on subject-wise mean abrasion scores was mentioned in the study protocol.)
Rationale for the change: It is felt that this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.

Study Parameter: Efficacy parameters
Statistical Methodology Employed: Analysis of subject-wise mean abrasion scores employing an ANCOVA model. Dunnett's test was not employed.
Statistical Methodology Described in the Study Protocol: Methodology described in the protocol included mention of Dunnett's test.
Rationale for the change: Since there are only two study treatments, there is not need to employ Dunnett's test for this study.

Study Parameter: Adverse Events
Statistical Methodology Employed: (No analyses were performed)
Statistical Methodology Described in the Study Protocol: The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity.
Rationale for the change: No adverse event data was provided for statistical analysis.

5.3 Subject Data Listings

5.3.1 Randomization

Listing 1
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1001	H002	Test
1002	H023	Control
1003	H003	Control
1004	H027	Control
1005	H004	Control
1006	H017	Control
1007	H006	Test
1008	H026	Control
1010	L008	Control
1011	H016	Control
1012	H028	Test
1013	H031	Test
1014	L001	Control
1015	L002	Control
1016	L003	Test
1017	H007	Test
1018	H010	Control
1019	H008	Control
1020	H009	Test
1021	H013	Test
1022	H030	Control
1023	H044	Control
1024	H012	Test
1025	L004	Test
1026	H011	Control
1027	H032	Control

Listing 1 (Cont'd)
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1028	H035	Control
1029	H018	Test
1030	L009	Control
1031	L010	Control
1032	H029	Test
1033	H033	Test
1034	H034	Control
1035	H015	Control
1036	H045	Test
1037	H020	Control
1038	H051	Control
1039	L024	Control
1040	H052	Control
1042	H038	Control
1043	H025	Test
1044	H024	Test
1045	L012	Test
1046	L015	Control
1047	L013	Test
1048	L014	Test
1049	H037	Test
1050	H021	Control
1051	L007	Test
1052	H005	Control
1053	H039	Test
1054	L005	Test

Listing 1 (Cont'd)
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1055	H014	Test
1056	H047	Control
1057	H001	Test
1058	L020	Control
1059	L019	Test
1060	L018	Test
1061	H046	Control
1062	H043	Control
1063	H041	Test
1064	H040	Control
1065	L016	Control
1066	L017	Control
1067	H042	Test
1068	L022	Test
1069	L021	Control
1070	H050	Test
1071	L023	Test
1072	H049	Test
1073	H048	Test
1074	H036	Test
1075	H022	Test
1076	L006	Control
1077	H019	Test
1078	L011	Test
1079	H053	Test

5.3.2 Subject Disposition (All Randomized Subjects)

Listing 2
Subject Disposition
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1001	05/31/2023	No	Yes	07/12/2023		
1007	05/31/2023	No	Yes	07/13/2023		
1012	05/31/2023	No	Yes	07/14/2023		
1013	05/31/2023	No	Yes	07/14/2023		
1016	05/31/2023	No	Yes	07/13/2023		
1017	05/31/2023	No	Yes	07/12/2023		
1020	05/31/2023	No	Yes	07/12/2023		
1021	05/31/2023	No	Yes	07/12/2023		
1024	05/31/2023	No	Yes	07/11/2023		
1025	05/31/2023	No	Yes	07/11/2023		
1029	05/31/2023	No	Yes	07/12/2023		
1032	05/31/2023	No	Yes	07/13/2023		
1033	05/31/2023	No	Yes	07/13/2023		
1036	05/31/2023	No	Yes	07/12/2023		
1043	06/01/2023	No	Yes	07/12/2023		
1044	06/01/2023	No	Yes	07/13/2023		
1045	06/01/2023	No	Yes	07/13/2023		
1047	06/01/2023	No	Yes	07/13/2023		
1048	06/01/2023	No	Yes	07/13/2023		
1049	06/01/2023	No	Yes	07/13/2023		
1051	06/01/2023	No	Yes	07/12/2023		
1053	06/01/2023	No	Yes	07/12/2023		

Listing 2 (Cont'd)
Subject Disposition
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1054	06/01/2023	No	Yes	07/12/2023		
1055	06/01/2023	No	Yes	07/12/2023		
1057	06/01/2023	No	Yes	07/12/2023		
1059	06/01/2023	No	Yes	07/12/2023		
1060	06/01/2023	No	Yes	07/12/2023		
1063	06/01/2023	No	No	06/28/2023	Subject withdrew from study	Baseline Visit
1067	06/01/2023	No	Yes	07/12/2023		
1068	06/01/2023	No	Yes	07/14/2023		
1070	06/01/2023	No	Yes	07/14/2023		
1071	06/01/2023	No	Yes	07/12/2023		
1072	06/01/2023	No	Yes	07/12/2023		
1073	06/01/2023	No	Yes	07/14/2023		
1074	06/01/2023	No	No	06/30/2023	Subject withdrew from study	Baseline Visit
1075	06/01/2023	No	Yes	07/12/2023		
1077	06/01/2023	No	Yes	07/13/2023		
1078	06/01/2023	No	Yes	07/13/2023		
1079	06/01/2023	No	Yes	07/12/2023		

Listing 2 (Cont'd)
Subject Disposition
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1002	05/31/2023	No	Yes	07/12/2023		
1003	05/31/2023	No	Yes	07/12/2023		
1004	05/31/2023	No	Yes	07/14/2023		
1005	05/31/2023	No	Yes	07/12/2023		
1006	05/31/2023	No	Yes	07/13/2023		
1008	05/31/2023	No	Yes	07/12/2023		
1010	05/31/2023	No	Yes	07/14/2023		
1011	05/31/2023	No	Yes	07/12/2023		
1014	05/31/2023	No	Yes	07/13/2023		
1015	05/31/2023	No	Yes	07/13/2023		
1018	05/31/2023	No	Yes	07/13/2023		
1019	05/31/2023	No	Yes	07/12/2023		
1022	05/31/2023	No	Yes	07/13/2023		
1023	05/31/2023	No	Yes	07/13/2023		
1026	05/31/2023	No	Yes	07/11/2023		
1027	05/31/2023	No	Yes	07/12/2023		
1028	05/31/2023	No	Yes	07/13/2023		
1030	05/31/2023	No	Yes	07/13/2023		
1031	05/31/2023	Yes	Yes	07/13/2023		
1034	05/31/2023	No	Yes	07/12/2023		
1035	05/31/2023	No	Yes	07/12/2023		
1037	05/31/2023	No	Yes	07/12/2023		

Listing 2 (Cont'd)
Subject Disposition
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1038	06/01/2023	No	Yes	07/13/2023		
1039	06/01/2023	No	Yes	07/13/2023		
1040	06/01/2023	No	Yes	07/13/2023		
1042	06/01/2023	No	Yes	07/13/2023		
1046	06/01/2023	No	Yes	07/13/2023		
1050	06/01/2023	No	Yes	07/12/2023		
1052	06/01/2023	No	Yes	07/13/2023		
1056	06/01/2023	No	Yes	07/12/2023		
1058	06/01/2023	No	Yes	07/12/2023		
1061	06/01/2023	No	Yes	07/12/2023		
1062	06/01/2023	No	Yes	07/13/2023		
1064	06/01/2023	No	Yes	07/12/2023		
1065	06/01/2023	No	Yes	07/12/2023		
1066	06/01/2023	No	Yes	07/12/2023		
1069	06/01/2023	No	Yes	07/14/2023		
1076	06/01/2023	No	Yes	07/13/2023		

5.3.3 Protocol Deviations

There were no protocol deviations in this study.

5.3.4 Demographic Data

Listing 3
Subject Demographic Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1001	35	Female	White	Non-Hispanic/Non-Latino
1007	53	Female	White	Non-Hispanic/Non-Latino
1012	47	Female	White	Non-Hispanic/Non-Latino
1013	47	Female	White	Non-Hispanic/Non-Latino
1016	7	Male	White	Non-Hispanic/Non-Latino
1017	37	Female	White	Non-Hispanic/Non-Latino
1020	17	Male	White	Hispanic/Latino
1021	36	Male	White	Non-Hispanic/Non-Latino
1024	13	Male	White	Non-Hispanic/Non-Latino
1025	11	Female	White	Non-Hispanic/Non-Latino
1029	45	Male	White	Non-Hispanic/Non-Latino
1032	39	Male	White	Non-Hispanic/Non-Latino
1033	27	Male	White	Non-Hispanic/Non-Latino
1036	55	Female	White	Non-Hispanic/Non-Latino
1043	33	Female	White	Non-Hispanic/Non-Latino
1044	51	Female	White	Non-Hispanic/Non-Latino
1045	8	Female	White	Non-Hispanic/Non-Latino
1047	6	Female	White	Non-Hispanic/Non-Latino
1048	9	Male	White	Non-Hispanic/Non-Latino
1049	41	Female	White	Non-Hispanic/Non-Latino
1051	5	Male	White	Non-Hispanic/Non-Latino
1053	41	Female	White	Non-Hispanic/Non-Latino

Listing 3 (Cont'd)
Subject Demographic Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1054	11	Male	Other	Non-Hispanic/Non-Latino
1055	44	Female	Other	Non-Hispanic/Non-Latino
1057	28	Female	Black or African American	Non-Hispanic/Non-Latino
1059	12	Male	White	Non-Hispanic/Non-Latino
1060	7	Female	White	Non-Hispanic/Non-Latino
1063	14	Female	White	Non-Hispanic/Non-Latino
1067	13	Male	White	Non-Hispanic/Non-Latino
1068	12	Female	White	Non-Hispanic/Non-Latino
1070	15	Female	White	Non-Hispanic/Non-Latino
1071	9	Male	White	Non-Hispanic/Non-Latino
1072	13	Male	White	Non-Hispanic/Non-Latino
1073	50	Female	White	Non-Hispanic/Non-Latino
1074	52	Female	White	Non-Hispanic/Non-Latino
1075	23	Female	White	Non-Hispanic/Non-Latino
1077	40	Female	White	Non-Hispanic/Non-Latino
1078	10	Female	White	Non-Hispanic/Non-Latino
1079	52	Female	White	Non-Hispanic/Non-Latino

Listing 3 (Cont'd)
Subject Demographic Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1002	46	Male	White	Non-Hispanic/Non-Latino
1003	58	Female	White	Non-Hispanic/Non-Latino
1004	34	Female	White	Non-Hispanic/Non-Latino
1005	47	Female	White	Non-Hispanic/Non-Latino
1006	24	Female	White	Non-Hispanic/Non-Latino
1008	37	Female	White	Non-Hispanic/Non-Latino
1010	7	Female	White	Non-Hispanic/Non-Latino
1011	64	Female	White	Non-Hispanic/Non-Latino
1014	11	Male	White	Non-Hispanic/Non-Latino
1015	8	Male	White	Non-Hispanic/Non-Latino
1018	32	Female	White	Non-Hispanic/Non-Latino
1019	15	Male	White	Hispanic/Latino
1022	17	Male	White	Non-Hispanic/Non-Latino
1023	17	Female	White	Non-Hispanic/Non-Latino
1026	35	Male	White	Non-Hispanic/Non-Latino
1027	36	Female	American Indian /Alaskan Native	Non-Hispanic/Non-Latino
1028	40	Female	White	Non-Hispanic/Non-Latino
1030	11	Male	White	Non-Hispanic/Non-Latino
1031	9	Male	White	Non-Hispanic/Non-Latino
1034	57	Male	White	Non-Hispanic/Non-Latino
1035	57	Male	American Indian /Alaskan Native	Hispanic/Latino
1037	52	Male	White	Non-Hispanic/Non-Latino

Listing 3 (Cont'd)
Subject Demographic Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1038	41	Male	White	Non-Hispanic/Non-Latino
1039	7	Female	White	Non-Hispanic/Non-Latino
1040	39	Female	White	Non-Hispanic/Non-Latino
1042	53	Female	White	Non-Hispanic/Non-Latino
1046	12	Female	White	Non-Hispanic/Non-Latino
1050	36	Female	White	Non-Hispanic/Non-Latino
1052	51	Female	White	Non-Hispanic/Non-Latino
1056	41	Male	White	Non-Hispanic/Non-Latino
1058	10	Male	White	Non-Hispanic/Non-Latino
1061	37	Female	White	Non-Hispanic/Non-Latino
1062	44	Female	White	Non-Hispanic/Non-Latino
1064	41	Female	White	Non-Hispanic/Non-Latino
1065	8	Male	White	Non-Hispanic/Non-Latino
1066	8	Male	White	Non-Hispanic/Non-Latino
1069	11	Female	White	Non-Hispanic/Non-Latino
1076	12	Female	White	Non-Hispanic/Non-Latino

5.3.5 Individual Efficacy Response Data

Listing 4.1

Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.63	1.99	2.02
1007	1.94	1.76	2.29
1012	2.45	2.23	1.79
1013	2.12	1.76	1.06
1016	2.51	1.80	1.42
1017	2.06	1.71	1.53
1020	2.63	2.10	1.74
1021	2.85	2.35	1.48
1024	3.00	2.24	1.78
1025	2.75	1.87	1.71
1029	2.90	2.17	1.69
1032	2.79	2.21	1.83
1033	2.67	1.96	2.04
1036	1.81	1.45	0.93
1043	1.99	1.61	1.05
1044	2.50	1.79	1.75
1045	2.85	2.17	2.15
1047	2.50	1.93	1.31
1048	2.58	1.83	1.30
1049	2.51	1.79	1.18
1051	1.95	1.73	0.71
1053	2.38	1.67	1.29

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 4.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1054	2.42	1.76	1.45
1055	2.32	1.47	1.13
1057	2.02	1.72	1.44
1059	2.74	1.74	1.37
1060	2.70	1.87	1.24
1063	2.51	.	.
1067	3.00	1.78	1.70
1068	2.37	1.92	1.24
1070	2.61	2.01	1.76
1071	2.39	1.88	1.09
1072	2.17	1.73	1.56
1073	2.40	2.17	1.68
1074	2.70	.	.
1075	2.08	1.66	1.11
1077	2.43	1.89	1.52
1078	2.78	1.77	1.09
1079	2.62	2.21	2.15

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 4.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1002	2.20	2.05	2.18
1003	2.54	2.87	2.79
1004	2.65	2.33	2.70
1005	2.90	2.48	2.90
1006	2.88	2.67	2.70
1008	2.64	2.54	2.57
1010	2.36	2.11	2.20
1011	3.00	2.97	3.00
1014	2.66	3.00	2.75
1015	2.81	2.27	2.31
1018	2.18	2.29	2.49
1019	2.86	2.48	2.68
1022	2.94	2.93	2.95
1023	2.80	2.68	2.65
1026	2.83	2.86	2.89
1027	2.77	2.56	2.74
1028	2.52	2.62	2.46
1030	2.83	2.59	2.77
1031	2.76	2.45	2.47
1034	2.48	2.42	2.53
1035	2.73	2.57	2.86
1037	2.60	2.58	2.58

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 4.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1038	2.59	2.26	2.32
1039	2.38	2.38	1.80
1040	2.26	2.05	2.55
1042	2.36	2.40	2.40
1046	2.77	2.62	2.49
1050	2.35	1.92	2.27
1052	1.89	2.20	2.02
1056	2.51	2.09	2.30
1058	2.43	2.50	2.39
1061	2.22	2.32	2.36
1062	3.00	3.00	3.00
1064	2.52	2.48	2.53
1065	2.90	2.82	2.59
1066	3.00	2.91	2.75
1069	2.49	2.53	2.08
1076	2.47	2.58	2.67

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 4.2

Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.21	1.63	1.55
1007	1.52	1.43	2.02
1012	2.21	2.00	1.36
1013	1.88	1.50	0.50
1016	2.28	1.57	1.15
1017	1.63	1.34	1.07
1020	2.43	1.79	1.39
1021	2.64	2.05	1.04
1024	3.00	1.98	1.38
1025	2.66	1.52	1.32
1029	2.76	1.80	1.31
1032	2.63	1.98	1.38
1033	2.31	1.50	1.59
1036	1.63	1.11	0.56
1043	1.66	1.07	0.48
1044	2.11	1.21	1.26
1045	2.73	1.96	1.73
1047	2.38	1.55	0.90
1048	2.29	1.50	0.83
1049	2.14	1.41	0.66
1051	1.75	1.43	0.25
1053	2.09	1.33	0.89

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 4.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1054	2.18	1.45	1.00
1055	1.96	1.12	0.66
1057	1.78	1.36	1.02
1059	2.44	1.35	0.90
1060	2.56	1.58	0.81
1063	2.20	.	.
1067	3.00	1.39	1.23
1068	2.04	1.48	0.88
1070	2.38	1.68	1.27
1071	2.21	1.63	0.75
1072	2.02	1.36	1.14
1073	2.19	1.79	1.19
1074	2.48	.	.
1075	1.95	1.32	0.71
1077	2.09	1.52	1.09
1078	2.55	1.52	0.61
1079	2.33	2.02	1.81

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 4.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1002	1.91	1.89	1.82
1003	2.34	2.75	2.55
1004	2.32	2.16	2.30
1005	2.72	2.22	2.74
1006	2.70	2.34	2.38
1008	2.39	2.11	2.24
1010	2.20	1.93	1.91
1011	3.00	2.90	3.00
1014	2.54	3.00	2.52
1015	2.60	2.21	2.13
1018	1.59	1.93	2.02
1019	2.67	2.26	2.37
1022	2.85	2.83	2.88
1023	2.61	2.45	2.29
1026	2.68	2.80	2.70
1027	2.52	2.23	2.42
1028	2.10	2.37	2.10
1030	2.61	2.35	2.52
1031	2.57	2.27	2.23
1034	2.27	2.07	2.16
1035	2.54	2.44	2.76
1037	2.33	2.23	2.23

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 4.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1038	2.39	2.04	1.96
1039	2.15	2.13	1.35
1040	1.93	1.82	2.27
1042	2.04	2.15	2.15
1046	2.54	2.38	2.20
1050	2.08	1.48	1.94
1052	1.43	2.00	1.68
1056	2.21	1.88	2.02
1058	2.27	2.27	2.16
1061	1.75	1.98	1.98
1062	3.00	3.00	3.00
1064	2.29	2.13	2.20
1065	2.78	2.50	2.25
1066	3.00	2.79	2.53
1069	2.27	2.38	1.77
1076	2.24	2.44	2.41

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 4.3

Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.83	2.18	2.25
1007	2.15	1.92	2.43
1012	2.57	2.34	2.01
1013	2.24	1.89	1.33
1016	2.63	1.91	1.55
1017	2.28	1.89	1.76
1020	2.73	2.25	1.92
1021	2.95	2.50	1.70
1024	3.00	2.38	1.98
1025	2.80	2.05	1.91
1029	2.97	2.36	1.87
1032	2.88	2.33	2.06
1033	2.85	2.19	2.27
1036	1.91	1.62	1.11
1043	2.15	1.88	1.34
1044	2.70	2.08	1.99
1045	2.91	2.28	2.36
1047	2.56	2.11	1.51
1048	2.73	1.99	1.53
1049	2.69	1.97	1.44
1051	2.05	1.89	0.94
1053	2.53	1.84	1.49

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 4.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1054	2.53	1.91	1.67
1055	2.50	1.64	1.37
1057	2.14	1.90	1.65
1059	2.90	1.93	1.60
1060	2.77	2.01	1.46
1063	2.67	.	.
1067	3.00	1.97	1.94
1068	2.53	2.14	1.43
1070	2.73	2.18	2.00
1071	2.48	2.00	1.26
1072	2.25	1.92	1.77
1073	2.51	2.35	1.93
1074	2.81	.	.
1075	2.15	1.83	1.31
1077	2.59	2.07	1.74
1078	2.90	1.90	1.33
1079	2.77	2.30	2.32

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 4.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1002	2.35	2.13	2.36
1003	2.64	2.93	2.90
1004	2.82	2.42	2.89
1005	2.99	2.61	2.98
1006	2.96	2.83	2.87
1008	2.77	2.76	2.74
1010	2.43	2.20	2.34
1011	3.00	3.00	3.00
1014	2.72	3.00	2.86
1015	2.91	2.30	2.41
1018	2.47	2.47	2.73
1019	2.95	2.58	2.83
1022	2.98	2.98	2.98
1023	2.90	2.79	2.83
1026	2.90	2.90	2.99
1027	2.89	2.73	2.89
1028	2.73	2.74	2.64
1030	2.93	2.72	2.89
1031	2.85	2.55	2.59
1034	2.58	2.59	2.72
1035	2.83	2.63	2.91
1037	2.73	2.75	2.76

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 4.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1038	2.69	2.37	2.49
1039	2.50	2.51	2.02
1040	2.43	2.16	2.69
1042	2.52	2.52	2.53
1046	2.89	2.74	2.64
1050	2.49	2.14	2.43
1052	2.13	2.30	2.19
1056	2.66	2.20	2.44
1058	2.51	2.61	2.50
1061	2.46	2.48	2.54
1062	3.00	3.00	3.00
1064	2.63	2.65	2.70
1065	2.96	2.98	2.76
1066	3.00	2.97	2.85
1069	2.60	2.60	2.24
1076	2.58	2.65	2.81

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 4.4

Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.13	1.50	1.50
1007	1.63	1.38	2.00
1012	2.25	2.00	1.38
1013	2.13	1.63	0.63
1016	2.25	1.25	1.00
1017	1.88	1.75	1.38
1020	2.25	1.75	1.38
1021	2.75	2.25	1.25
1024	3.00	2.00	1.00
1025	2.75	1.88	1.38
1029	2.88	1.88	1.38
1032	2.50	1.88	1.13
1033	2.25	1.75	1.75
1036	1.88	1.38	0.88
1043	1.63	1.13	0.50
1044	2.50	1.50	1.75
1045	2.63	2.13	1.63
1047	2.38	1.88	1.13
1048	2.25	1.63	0.88
1049	2.38	1.63	0.88
1051	2.00	1.63	0.38
1053	2.25	1.88	1.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 4.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1054	2.13	1.38	0.88
1055	2.00	1.00	0.63
1057	2.25	1.50	1.38
1059	2.50	1.38	1.00
1060	2.75	1.88	0.75
1063	2.38	.	.
1067	3.00	1.63	1.13
1068	2.13	1.88	0.88
1070	2.25	1.50	1.25
1071	2.00	1.75	0.38
1072	2.00	1.25	1.00
1073	2.13	1.75	1.13
1074	2.38	.	.
1075	2.13	1.63	0.63
1077	2.38	1.63	1.38
1078	2.50	1.50	0.50
1079	2.25	2.13	1.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 4.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1002	2.13	2.13	2.25
1003	2.25	2.75	2.63
1004	2.50	2.13	2.25
1005	2.88	2.38	2.88
1006	2.75	2.38	2.38
1008	2.75	2.75	2.50
1010	2.25	1.88	1.75
1011	3.00	3.00	3.00
1014	2.38	3.00	2.63
1015	2.63	2.00	2.13
1018	1.88	2.13	2.00
1019	2.63	2.13	2.25
1022	2.75	2.75	2.75
1023	2.63	2.63	2.38
1026	2.75	2.88	3.00
1027	2.38	2.50	2.63
1028	2.25	2.63	2.13
1030	2.50	2.50	2.50
1031	2.38	2.13	2.13
1034	2.63	2.38	2.50
1035	2.63	2.38	2.38
1037	2.50	2.75	2.63

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 4.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1038	2.63	2.13	1.88
1039	2.25	2.13	1.50
1040	2.00	1.75	2.13
1042	2.13	2.38	2.25
1046	2.38	2.63	2.50
1050	2.25	2.00	2.13
1052	1.25	2.00	1.88
1056	2.38	1.88	2.00
1058	2.50	2.50	2.50
1061	2.13	2.00	2.13
1062	3.00	3.00	3.00
1064	2.38	2.13	2.25
1065	3.00	2.75	2.50
1066	3.00	3.00	3.00
1069	2.25	2.50	1.63
1076	2.38	2.50	2.63

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.1

Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	2.91	2.04	1.98	1.56
1007	2.67	2.17	2.32	1.47
1012	2.61	2.75	2.75	2.29
1013	2.38	2.30	2.38	1.78
1016	2.55	1.80	2.27	1.46
1017	2.97	2.14	2.39	1.80
1020	2.86	2.59	2.81	2.29
1021	2.52	2.26	2.23	1.73
1024	3.38	2.74	2.36	1.71
1025	3.99	2.71	2.19	1.62
1029	2.83	2.15	2.41	1.73
1032	2.95	2.46	2.26	1.51
1033	2.95	2.13	1.95	1.36
1036	2.65	1.77	2.17	1.58
1043	2.41	1.97	1.95	1.30
1044	2.88	2.31	2.31	1.65
1045	4.01	2.45	2.62	1.42
1047	3.51	2.13	2.10	1.38
1048	3.44	2.03	1.74	0.76
1049	2.76	1.79	2.04	1.48
1051	2.78	1.99	1.79	1.21
1053	2.50	1.38	1.30	1.27

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 5.1 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1054	3.37	2.05	1.79	1.13
1055	2.53	1.99	1.92	1.24
1057	3.48	2.60	2.72	2.30
1059	3.05	1.72	1.80	1.40
1060	3.18	1.41	1.47	0.73
1063	3.12	.	.	.
1067	3.86	2.43	2.54	1.67
1068	3.76	2.26	2.19	1.70
1070	3.61	2.95	2.55	1.61
1071	3.84	2.33	2.00	1.35
1072	3.29	1.71	1.99	1.40
1073	3.30	2.68	2.56	2.29
1074	2.40	.	.	.
1075	2.86	2.26	2.05	1.67
1077	2.50	2.35	2.23	1.44
1078	2.92	2.27	2.14	1.40
1079	2.97	2.28	2.25	1.79

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 5.1 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1002	2.62	2.79	2.86	2.62
1003	2.86	2.98	3.04	2.74
1004	2.65	2.63	2.53	2.45
1005	3.14	3.12	3.01	2.64
1006	2.94	2.89	2.95	2.86
1008	2.51	2.77	2.85	2.57
1010	3.33	3.20	3.92	2.99
1011	2.85	2.85	2.73	2.47
1014	3.27	3.56	3.49	3.17
1015	3.51	3.40	3.65	3.46
1018	2.35	2.45	2.58	2.35
1019	2.55	3.04	3.22	2.83
1022	3.18	3.13	3.05	2.72
1023	3.28	3.27	3.13	2.84
1026	3.24	3.83	3.54	2.93
1027	2.90	3.03	2.99	2.85
1028	2.61	2.97	2.86	2.62
1030	2.89	3.39	3.08	2.86
1031	3.54	3.66	3.54	3.07
1034	2.72	2.55	2.59	2.58
1035	3.65	3.09	3.04	2.71
1037	2.78	2.90	2.76	2.49

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 5.1 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1038	2.65	2.49	2.51	2.33
1039	3.19	2.87	2.95	2.95
1040	2.53	2.54	2.60	2.39
1042	2.56	2.57	2.55	2.19
1046	2.81	3.08	2.77	2.51
1050	3.19	2.52	3.38	2.92
1052	2.35	2.40	2.49	2.46
1056	2.74	2.45	2.39	2.35
1058	3.18	3.11	3.12	2.94
1061	2.60	2.43	2.56	2.21
1062	3.69	3.35	3.33	3.12
1064	3.18	3.25	3.19	3.01
1065	3.09	3.01	3.31	2.85
1066	3.35	3.21	3.37	2.73
1069	3.90	3.77	3.26	2.97
1076	3.27	3.04	3.20	2.89

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

Listing 5.2

Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	2.36	0.98	0.86	0.25
1007	1.91	1.23	1.57	0.04
1012	2.09	1.98	2.07	1.20
1013	1.73	1.10	1.46	0.19
1016	2.28	1.48	2.13	0.54
1017	2.48	0.86	1.48	0.32
1020	2.32	2.11	2.52	1.13
1021	1.84	1.23	1.30	0.29
1024	3.25	2.45	1.43	0.54
1025	4.00	2.70	1.98	0.66
1029	2.63	1.30	1.69	0.11
1032	2.75	2.14	1.88	0.21
1033	2.72	1.26	1.15	0.17
1036	2.43	1.11	1.44	0.39
1043	1.96	0.73	1.02	0.00
1044	2.53	1.55	1.53	0.18
1045	4.00	2.19	2.50	0.38
1047	3.40	1.83	1.83	0.48
1048	3.40	1.52	1.58	0.23
1049	2.41	0.59	1.05	0.09
1051	2.70	1.68	1.35	0.20
1053	2.35	0.50	0.35	0.26

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 5.2 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1054	3.23	1.36	1.09	0.05
1055	1.86	0.86	0.92	0.12
1057	3.28	1.96	2.66	1.68
1059	2.90	0.85	1.04	0.31
1060	3.10	0.77	0.92	0.29
1063	2.98	.	.	.
1067	3.77	1.88	1.84	0.71
1068	3.71	1.69	1.69	0.48
1070	3.48	2.59	2.13	0.45
1071	3.73	1.58	1.52	0.63
1072	3.17	1.07	1.86	0.83
1073	3.04	1.92	1.69	0.88
1074	1.88	.	.	.
1075	2.61	1.38	0.95	0.18
1077	1.87	1.76	1.35	0.30
1078	2.70	1.89	1.80	0.30
1079	2.73	1.35	1.04	0.25

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 5.2 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1002	2.23	2.32	2.52	2.13
1003	2.43	2.70	2.84	2.30
1004	2.54	2.54	2.25	2.21
1005	2.78	2.78	2.78	2.24
1006	2.70	2.64	2.79	2.70
1008	1.52	2.22	2.41	1.98
1010	3.17	3.02	3.87	2.63
1011	2.58	2.52	2.52	1.96
1014	3.20	3.41	3.28	2.83
1015	3.42	3.35	3.60	3.31
1018	1.63	2.04	2.20	1.71
1019	2.09	2.83	3.11	2.46
1022	3.10	2.94	2.90	2.38
1023	3.04	3.09	2.89	2.57
1026	2.73	3.70	3.30	2.41
1027	2.58	2.75	2.71	2.33
1028	2.21	2.71	2.48	2.13
1030	2.80	3.30	2.93	2.70
1031	3.48	3.61	3.48	2.91
1034	2.30	2.05	2.23	2.11
1035	3.54	2.90	2.80	2.18
1037	2.42	2.54	2.40	1.83

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 5.2 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1038	2.54	2.18	2.38	1.88
1039	3.06	2.88	2.85	2.85
1040	2.04	2.07	2.27	1.70
1042	2.25	2.29	2.25	1.63
1046	2.68	2.96	2.60	2.10
1050	2.83	1.96	3.17	2.48
1052	1.89	2.18	2.30	2.09
1056	2.63	2.23	2.33	2.08
1058	3.14	2.98	3.05	2.86
1061	2.30	2.02	2.32	1.54
1062	3.46	3.08	3.10	2.84
1064	2.95	3.00	2.95	2.61
1065	2.95	2.90	3.15	2.65
1066	3.29	3.15	3.35	2.47
1069	3.79	3.56	3.10	2.77
1076	3.19	2.87	3.07	2.61

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

Listing 5.3

Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.19	2.56	2.54	2.21
1007	3.05	2.63	2.70	2.19
1012	2.87	3.13	3.09	2.83
1013	2.71	2.90	2.83	2.58
1016	2.68	1.96	2.34	1.92
1017	3.21	2.78	2.85	2.54
1020	3.13	2.83	2.96	2.88
1021	2.86	2.77	2.70	2.45
1024	3.44	2.89	2.82	2.30
1025	3.98	2.71	2.30	2.10
1029	2.93	2.57	2.77	2.54
1032	3.04	2.62	2.46	2.15
1033	3.06	2.56	2.35	1.95
1036	2.76	2.10	2.54	2.18
1043	2.63	2.59	2.41	1.96
1044	3.05	2.68	2.70	2.38
1045	4.02	2.58	2.68	1.95
1047	3.56	2.29	2.24	1.83
1048	3.46	2.28	1.81	1.03
1049	2.94	2.38	2.54	2.17
1051	2.81	2.15	2.01	1.71
1053	2.57	1.81	1.78	1.78

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 5.3 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1054	3.44	2.40	2.14	1.67
1055	2.87	2.56	2.42	1.80
1057	3.58	2.92	2.75	2.61
1059	3.13	2.15	2.18	1.94
1060	3.22	1.73	1.75	0.95
1063	3.19	.	.	.
1067	3.91	2.71	2.88	2.14
1068	3.79	2.55	2.45	2.31
1070	3.68	3.13	2.76	2.20
1071	3.90	2.71	2.24	1.72
1072	3.36	2.02	2.06	1.68
1073	3.43	3.06	3.00	3.00
1074	2.66	.	.	.
1075	2.98	2.71	2.61	2.41
1077	2.81	2.65	2.67	2.02
1078	3.03	2.45	2.31	1.95
1079	3.10	2.75	2.86	2.57

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 5.3 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1002	2.81	3.03	3.03	2.87
1003	3.08	3.13	3.14	2.96
1004	2.71	2.68	2.67	2.56
1005	3.33	3.29	3.13	2.84
1006	3.06	3.02	3.04	2.95
1008	3.01	3.04	3.07	2.86
1010	3.41	3.28	3.95	3.17
1011	2.98	3.02	2.83	2.73
1014	3.30	3.63	3.60	3.35
1015	3.55	3.43	3.67	3.53
1018	2.71	2.65	2.77	2.67
1019	2.78	3.15	3.28	3.01
1022	3.22	3.22	3.13	2.88
1023	3.40	3.36	3.25	2.97
1026	3.50	3.89	3.66	3.19
1027	3.06	3.17	3.13	3.11
1028	2.81	3.10	3.05	2.87
1030	2.93	3.43	3.15	2.95
1031	3.57	3.68	3.57	3.15
1034	2.93	2.81	2.77	2.81
1035	3.71	3.19	3.16	2.98
1037	2.96	3.08	2.94	2.82

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 5.3 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1038	2.71	2.65	2.58	2.56
1039	3.25	2.86	3.00	3.00
1040	2.78	2.77	2.77	2.73
1042	2.71	2.71	2.70	2.48
1046	2.87	3.14	2.85	2.72
1050	3.37	2.80	3.48	3.13
1052	2.58	2.51	2.59	2.64
1056	2.79	2.56	2.42	2.49
1058	3.20	3.18	3.16	2.98
1061	2.75	2.64	2.68	2.55
1062	3.80	3.49	3.45	3.26
1064	3.30	3.38	3.31	3.21
1065	3.16	3.06	3.39	2.95
1066	3.38	3.24	3.38	2.85
1069	3.95	3.88	3.33	3.07
1076	3.31	3.12	3.26	3.03

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 5.4

Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.00	2.13	1.75	0.63
1007	3.38	2.00	2.50	0.00
1012	3.13	3.50	3.63	2.88
1013	3.38	3.00	2.88	1.50
1016	2.75	1.50	2.75	1.38
1017	3.00	1.88	2.63	1.13
1020	3.75	2.50	2.88	2.38
1021	3.00	2.38	2.13	0.25
1024	3.38	2.63	2.75	2.25
1025	3.38	2.50	2.38	2.00
1029	2.75	1.50	2.13	0.75
1032	3.25	2.63	2.63	0.75
1033	2.75	2.13	1.50	0.25
1036	3.00	1.88	1.00	0.00
1043	3.13	1.88	2.00	0.38
1044	2.88	2.13	2.75	0.75
1045	3.38	2.63	2.75	0.38
1047	3.13	1.63	1.63	1.00
1048	3.38	1.75	1.75	0.00
1049	3.50	1.63	1.75	0.00
1051	3.13	2.38	2.13	0.75
1053	3.38	1.13	2.13	1.63

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.4 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1054	3.13	1.88	0.75	0.38
1055	3.38	1.00	1.88	0.38
1057	3.25	2.50	2.25	1.88
1059	3.13	1.75	1.50	0.38
1060	3.88	2.38	2.75	1.00
1063	3.50	.	.	.
1067	3.50	2.50	3.00	1.25
1068	3.50	2.13	2.63	1.38
1070	3.50	3.00	3.00	1.13
1071	4.38	2.75	2.50	0.38
1072	3.38	1.00	0.75	0.38
1073	3.38	2.38	3.00	3.00
1074	3.75	.	.	.
1075	3.25	2.75	2.63	1.00
1077	3.38	2.88	2.88	0.50
1078	3.25	2.50	2.25	0.88
1079	3.25	2.50	3.00	0.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.4 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1002	3.25	3.50	3.00	3.00
1003	3.25	3.50	3.50	3.25
1004	3.50	3.13	3.38	3.25
1005	3.75	3.63	3.25	3.13
1006	2.75	2.75	3.00	2.88
1008	2.88	3.00	2.75	2.63
1010	4.00	3.50	4.13	4.00
1011	2.88	2.88	2.88	3.00
1014	3.50	3.50	3.38	3.50
1015	3.25	3.13	3.25	3.38
1018	2.88	2.88	3.25	3.00
1019	3.13	3.38	3.75	3.50
1022	3.13	2.88	2.88	2.75
1023	3.38	3.13	3.25	3.13
1026	3.00	3.38	2.88	2.63
1027	3.25	3.38	3.38	3.25
1028	3.13	3.63	3.75	3.63
1030	3.13	3.13	2.88	3.25
1031	3.13	3.25	3.38	3.38
1034	3.13	2.75	2.75	2.88
1035	3.25	3.25	3.00	3.25
1037	3.25	3.13	3.13	3.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.4 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1038	2.75	2.75	2.75	2.75
1039	3.50	2.88	3.13	3.00
1040	3.38	3.38	3.25	2.88
1042	2.50	2.63	2.75	2.38
1046	3.38	2.88	3.13	3.00
1050	3.13	2.75	3.38	3.25
1052	3.00	2.63	2.88	3.00
1056	3.13	3.13	2.75	2.75
1058	2.88	2.63	2.88	2.75
1061	3.25	2.75	3.25	2.88
1062	4.00	3.75	4.00	4.00
1064	3.63	3.50	3.63	3.38
1065	3.50	3.38	3.38	3.13
1066	3.50	3.25	2.75	2.63
1069	4.13	4.13	3.88	3.63
1076	3.38	3.25	3.25	2.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

5.3.6 Individual Safety Data

Listing 6
Gingival Recession Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1001	168	0.071	156	12	0	168	0.071	156	12	0	168	0.071	156	12	0
1007	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1012	168	0.012	166	2	0	168	0.012	166	2	0	168	0.012	166	2	0
1013	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1016	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1017	168	0.131	148	18	2	168	0.131	148	18	2	168	0.131	148	18	2
1020	168	0.024	164	4	0	168	0.024	164	4	0	168	0.024	164	4	0
1021	168	0.024	164	4	0	168	0.024	164	4	0	168	0.024	164	4	0
1024	168	0.012	166	2	0	168	0.012	166	2	0	168	0.012	166	2	0
1025	150	0.000	150	0	0	150	0.000	150	0	0	150	0.000	150	0	0
1029	162	0.235	128	30	4	162	0.235	128	30	4	162	0.235	128	30	4
1032	168	0.179	138	30	0	168	0.179	138	30	0	168	0.179	138	30	0
1033	162	0.148	141	18	3	162	0.148	141	18	3	162	0.148	141	18	3
1036	162	0.049	154	8	0	162	0.049	154	8	0	162	0.049	154	8	0
1043	168	0.006	167	1	0	168	0.006	167	1	0	168	0.006	167	1	0
1044	114	0.211	92	20	2	114	0.211	92	20	2	114	0.211	92	20	2
1045	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1047	120	0.000	120	0	0	120	0.000	120	0	0	120	0.000	120	0	0
1048	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1049	168	0.060	158	10	0	168	0.060	158	10	0	168	0.060	158	10	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 6 (Cont'd)
Gingival Recession Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1051	120	0.000	120	0	0	120	0.000	120	0	0	120	0.000	120	0	0
1053	162	0.000	162	0	0	162	0.000	162	0	0	162	0.000	162	0	0
1054	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1055	150	0.000	150	0	0	150	0.000	150	0	0	150	0.000	150	0	0
1057	150	0.007	149	1	0	150	0.007	149	1	0	150	0.007	149	1	0
1059	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1060	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1063	168	0.000	168	0	0		(No visit)					(No visit)			
1067	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1068	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1070	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1071	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1072	126	0.000	126	0	0	126	0.000	126	0	0	126	0.000	126	0	0
1073	144	0.347	103	32	9	144	0.347	103	32	9	144	0.347	103	32	9
1074	168	0.054	159	9	0		(No visit)					(No visit)			
1075	168	0.012	166	2	0	168	0.012	166	2	0	168	0.012	166	2	0
1077	162	0.025	158	4	0	162	0.025	158	4	0	162	0.025	158	4	0
1078	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1079	156	0.147	135	19	2	156	0.147	135	19	2	156	0.147	135	19	2

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 6 (Cont'd)
Gingival Recession Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1002	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1003	168	0.024	165	2	1	168	0.024	165	2	1	168	0.024	165	2	1
1004	168	0.030	163	5	0	168	0.030	163	5	0	168	0.030	163	5	0
1005	138	0.174	118	16	4	138	0.174	118	16	4	138	0.174	118	16	4
1006	168	0.024	164	4	0	168	0.024	164	4	0	168	0.024	164	4	0
1008	138	0.058	130	8	0	138	0.058	130	8	0	138	0.058	130	8	0
1010	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1011	144	0.125	127	16	1	144	0.125	127	16	1	144	0.125	127	16	1
1014	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1015	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1018	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1019	162	0.006	161	1	0	162	0.006	161	1	0	162	0.006	161	1	0
1022	156	0.000	156	0	0	156	0.000	156	0	0	156	0.000	156	0	0
1023	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1026	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1027	156	0.045	149	7	0	156	0.045	149	7	0	156	0.045	149	7	0
1028	156	0.045	149	7	0	156	0.045	149	7	0	156	0.045	149	7	0
1030	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1031	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1034	132	0.227	107	20	5	132	0.227	107	20	5	132	0.227	107	20	5

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 6 (Cont'd)
Gingival Recession Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1035	150	0.147	132	14	4	150	0.147	132	14	4	150	0.147	132	14	4
1037	144	0.160	124	17	3	144	0.160	124	17	3	144	0.160	124	17	3
1038	168	0.054	159	9	0	168	0.054	159	9	0	168	0.054	159	9	0
1039	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1040	168	0.036	162	6	0	168	0.036	162	6	0	168	0.036	162	6	0
1042	144	0.243	119	15	10	144	0.243	119	15	10	144	0.243	119	15	10
1046	150	0.000	150	0	0	150	0.000	150	0	0	150	0.000	150	0	0
1050	156	0.026	152	4	0	156	0.026	152	4	0	156	0.026	152	4	0
1052	168	0.089	153	15	0	168	0.089	153	15	0	168	0.089	153	15	0
1056	144	0.083	133	10	1	144	0.083	133	10	1	144	0.083	133	10	1
1058	129	0.000	129	0	0	129	0.000	129	0	0	129	0.000	129	0	0
1061	168	0.113	151	15	2	168	0.113	151	15	2	168	0.113	151	15	2
1062	150	0.013	148	2	0	150	0.013	148	2	0	150	0.013	148	2	0
1064	168	0.018	165	3	0	168	0.018	165	3	0	168	0.018	165	3	0
1065	120	0.000	120	0	0	120	0.000	120	0	0	120	0.000	120	0	0
1066	102	0.000	102	0	0	102	0.000	102	0	0	102	0.000	102	0	0
1069	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1076	162	0.031	157	5	0	162	0.031	157	5	0	162	0.031	157	5	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 7

Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1001	164	0.079	8	1	164	0.024	4	0	164	0.000	0	0
1007	164	0.055	2	2	164	0.000	0	0	164	0.012	1	0
1012	164	0.030	1	1	164	0.006	1	0	164	0.000	0	0
1013	144	0.035	4	0	144	0.028	4	0	144	0.000	0	0
1016	144	0.014	1	0	144	0.056	5	0	144	0.014	1	0
1017	164	0.079	5	2	164	0.006	1	0	164	0.000	0	0
1020	164	0.152	5	5	164	0.012	2	0	164	0.000	0	0
1021	164	0.006	1	0	164	0.030	1	1	164	0.012	1	0
1024	164	0.067	4	1	164	0.000	0	0	164	0.024	2	0
1025	152	0.033	3	0	152	0.000	0	0	152	0.007	1	0
1029	160	0.000	0	0	160	0.056	6	0	160	0.025	3	0
1032	164	0.055	3	1	164	0.012	2	0	164	0.018	2	0
1033	160	0.050	3	1	160	0.000	0	0	160	0.000	0	0
1036	160	0.094	4	2	160	0.019	3	0	160	0.013	2	0
1043	164	0.012	1	0	164	0.024	3	0	164	0.012	1	0
1044	116	0.026	2	0	116	0.009	1	0	116	0.017	2	0
1045	148	0.034	2	1	148	0.007	1	0	148	0.000	0	0
1047	120	0.075	2	2	120	0.000	0	0	120	0.000	0	0
1048	148	0.074	2	3	148	0.007	1	0	148	0.027	3	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 7 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1049	164	0.061	4	1	164	0.000	0	0	164	0.006	1	0
1051	120	0.017	2	0	120	0.008	1	0	120	0.000	0	0
1053	160	0.019	2	0	160	0.050	4	1	160	0.025	3	0
1054	140	0.064	1	2	140	0.029	3	0	140	0.021	2	0
1055	148	0.081	6	1	148	0.027	3	0	148	0.000	0	0
1057	150	0.073	5	1	150	0.000	0	0	150	0.007	1	0
1059	148	0.014	2	0	148	0.027	4	0	148	0.020	2	0
1060	148	0.054	1	2	148	0.007	1	0	148	0.007	1	0
1063	164	0.061	4	1		(No visit)				(No visit)		
1067	164	0.000	0	0	164	0.000	0	0	164	0.000	0	0
1068	148	0.027	3	0	148	0.027	3	0	148	0.000	0	0
1070	164	0.091	7	1	164	0.006	1	0	164	0.000	0	0
1071	148	0.041	4	0	148	0.027	3	0	148	0.014	1	0
1072	136	0.051	4	0	136	0.015	2	0	136	0.000	0	0
1073	140	0.043	4	0	140	0.014	1	0	140	0.000	0	0
1074	164	0.024	0	1		(No visit)				(No visit)		
1075	164	0.073	2	2	164	0.012	2	0	164	0.006	1	0
1077	160	0.100	4	3	160	0.025	4	0	160	0.019	2	0
1078	140	0.086	3	2	140	0.000	0	0	140	0.000	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 7 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1079	152	0.013	2	0	152	0.013	1	0	152	0.013	1	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 7 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1002	164	0.000	0	0	164	0.006	1	0	164	0.024	2	0
1003	164	0.110	4	3	164	0.085	5	2	164	0.030	2	1
1004	164	0.098	5	2	164	0.030	1	1	164	0.012	1	0
1005	140	0.057	4	0	140	0.029	2	0	140	0.043	4	0
1006	164	0.037	2	1	164	0.000	0	0	164	0.024	3	0
1008	140	0.043	3	0	140	0.043	2	1	140	0.036	1	1
1010	144	0.000	0	0	144	0.007	1	0	144	0.014	1	0
1011	144	0.014	1	0	144	0.063	2	2	144	0.000	0	0
1014	144	0.035	1	1	144	0.042	5	0	144	0.000	0	0
1015	148	0.095	1	4	148	0.027	2	0	148	0.027	2	0
1018	164	0.012	1	0	164	0.006	1	0	164	0.012	2	0
1019	160	0.125	3	5	160	0.094	4	2	160	0.038	3	0
1022	156	0.019	2	0	156	0.096	3	3	156	0.032	3	0
1023	164	0.024	2	0	164	0.061	5	1	164	0.018	3	0
1026	138	0.072	4	2	138	0.036	0	1	138	0.022	2	0
1027	156	0.071	4	1	156	0.026	4	0	156	0.000	0	0
1028	156	0.000	0	0	156	0.038	4	0	156	0.000	0	0
1030	144	0.056	2	1	144	0.014	2	0	144	0.042	3	0
1031	140	0.043	3	0	140	0.057	5	0	140	0.014	1	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 7 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1034	138	0.232	10	5	138	0.138	6	2	138	0.109	7	1
1035	152	0.020	2	0	152	0.039	4	0	152	0.039	3	0
1037	140	0.071	2	2	140	0.014	2	0	140	0.007	1	0
1038	164	0.317	7	10	164	0.134	10	2	164	0.061	5	1
1039	148	0.122	9	1	148	0.034	4	0	148	0.020	2	0
1040	164	0.152	5	4	164	0.024	3	0	164	0.030	1	1
1042	148	0.047	3	1	148	0.020	2	0	148	0.034	3	0
1046	152	0.079	7	0	152	0.039	4	0	152	0.026	3	0
1050	156	0.103	4	3	156	0.019	3	0	156	0.032	2	1
1052	164	0.073	5	1	164	0.012	2	0	164	0.000	0	0
1056	140	0.029	2	0	140	0.021	2	0	140	0.014	2	0
1058	140	0.043	2	1	140	0.029	4	0	140	0.036	1	1
1061	164	0.000	0	0	164	0.049	4	1	164	0.000	0	0
1062	152	0.007	1	0	152	0.125	6	3	152	0.007	1	0
1064	164	0.110	8	2	164	0.012	2	0	164	0.030	1	1
1065	132	0.114	5	2	132	0.121	7	2	132	0.000	0	0
1066	114	0.000	0	0	114	0.070	4	0	114	0.000	0	0
1069	148	0.000	0	0	148	0.000	0	0	148	0.000	0	0
1076	160	0.088	6	2	160	0.056	6	0	160	0.000	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 8
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1001	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1007	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1012	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1013	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1016	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1017	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1020	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1021	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1024	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1025	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1029	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1032	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1033	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1036	Screening Visit	(none)	(none)	Incisal Edge Fracture on #8 and #9
	Baseline Visit	(none)	(none)	Incisal Edge Fracture on #8 and #9
	Day 15 Visit	(none)	(none)	Incisal Edge Fracture on #8 and #9
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	Incisal Edge Fracture on #8 and #9
	Day 30 Visit - POST-BRUSHING	(none)	(none)	Incisal Edge Fracture on #8 and #9

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1043	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1044	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1045	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1047	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1048	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1049	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1051	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1053	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1054	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1055	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1057	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1059	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1060	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1063	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1067	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1068	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1070	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1071	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1072	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1073	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1074	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)
1075	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1077	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1078	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1079	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1002	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1003	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1004	Screening Visit	(none)	(none)	Incisal Edge Fracture tooth #8
	Baseline Visit	(none)	(none)	Incisal Edge Fracture tooth #8
	Day 15 Visit	(none)	(none)	Incisal Edge Fracture tooth #8
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	Incisal Edge Fracture tooth #8
	Day 30 Visit - POST-BRUSHING	(none)	(none)	Incisal Edge Fracture tooth #8
1005	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1006	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1008	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1010	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1011	Screening Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #10
	Baseline Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #10
	Day 15 Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #10
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	Incisal Edge Fracture #10
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	Incisal Edge Fracture #10

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1014	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1015	Screening Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #9
	Baseline Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #9
	Day 15 Visit	(none)	Coating Generalized Moderate	Incisal Edge Fracture #9
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	Incisal Edge Fracture #9
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	Incisal Edge Fracture #9

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1018	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1019	Screening Visit	(none)	(none)	Incisal Edge Fracture on #23, #24
	Baseline Visit	(none)	(none)	Incisal Edge Fracture on #23, #24
	Day 15 Visit	(none)	(none)	Incisal Edge Fracture on #23, #24
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	Incisal Edge Fracture on #23, #24
	Day 30 Visit - POST-BRUSHING	(none)	(none)	Incisal Edge Fracture on #23, #24

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1022	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1023	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1026	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1027	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1028	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1030	Screening Visit	Angular cheilitis on Right Side	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1031	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	Aphthous ulcer right labial mucosa 4mm*	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1034	Screening Visit	(none)	Coating Generalized Moderate	Mesial Lingual Cusp Fracture on #30
	Baseline Visit	(none)	Coating Generalized Moderate	Mesial Lingual Cusp Fracture on #30
	Day 15 Visit	(none)	Coating Generalized Moderate	Mesial Lingual Cusp Fracture on #30
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	Mesial Lingual Cusp Fracture on #30
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	Mesial Lingual Cusp Fracture on #30

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1035	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1037	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1038	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1039	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1040	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)
1042	Screening Visit	(none)	Coating Generalized Mild	Insical Edge Fracture on #9
	Baseline Visit	(none)	Coating Generalized Mild	Insical Edge Fracture on #9
	Day 15 Visit	(none)	Coating Generalized Mild	Insical Edge Fracture on #9
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	Insical Edge Fracture on #9
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	Insical Edge Fracture on #9

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1046	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1050	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1052	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1056	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1058	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1061	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1062	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1064	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1065	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1066	Screening Visit	(none)	(none)	Incisal Edge Fracture #10
	Baseline Visit	(none)	(none)	Incisal Edge Fracture #10
	Day 15 Visit	(none)	(none)	Incisal Edge Fracture #10
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	Incisal Edge Fracture #10
	Day 30 Visit - POST-BRUSHING	(none)	(none)	Incisal Edge Fracture #10

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 8 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1069	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1076	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

5.3.7 Adverse Event Listings (Each Subject)

Only one subject experienced an adverse during this study.

Subj ID	Tx	Adverse Event	Start Date	Stop Date	Severity	Relationship to Study Treatment	Action Taken	Outcome of AE	Serious
					1=Mild 2=Moderate 3=Severe	1=Unrelated 2=Possible 3=Probable 4=Definite	1=None 2=Rx Therapy 3=Discontinued Study 4=Other	1=Resolved w/o sequelae 2=Resolved w/sequelae 3=Ongoing 4=Not recovered/ Not resolved 5=Death	1=Yes 2=No
1031	MTB	Aphthous ulcer right labial mucosa 4mm	30JUN2023	13JUL2023	2	1	1	1	2

AE, adverse event; MTB, manual toothbrush; Rx, medical prescription; Tx, treatment group