Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area

Prepared for:

L'Oreal USA

Luke Kruger

Thomas J. Stephens & Associates, Inc.

Stephens Study Number: C17-D122

Sponsor Study Number: PBL-17-033

1801 North Glenville Drive Suite 200 Richardson, Texas 75081-1906
T 972.392.1529 **F** 972.392.2347 **w** www.stephens-associates.com

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PURPOSE

Skin aging is affected by both intrinsic and extrinsic factors. Intrinsic aging is a continuous process that normally begins in the mid-twenties. Extrinsic aging is caused by environmental exposure, primarily UV light. Within normal skin (wrinkle-free), the dermis is composed of abundant type I and type VII collagen, as well as elastin, which provide tissue strength, resiliency, and recoil. The aging process results in a drastic loss of collagen and elastin over time. This results in skin laxity and fragility as well as visible signs associated with aging, such as fine lines/wrinkles at crow's feet and under eye, skin roughness around the eye, and lack of firmness around the eye.

Clarisonic has developed an antiaging system consisting of a sonic eye massage applicator. This device consists of a handle and a polymer attachment with Aluminum tips.

- The handle that provides the oscillating motor motion is an existing OTC Clarisonic skin care device that is currently released for sale [key functional parameters of the handle (approximate values): Frequency-75Hz, Duty Cycle-10.9%, Loaded amplitude-average 4.5 degrees (peak to peak)]
- The attachment/applicator operates at oscillating frequency and amplitude similar to existing OTC Clarisonic face brushes. The applicator material is 6063-T6 Aluminum, which is hard anodized and Teflon impregnated.

Figure 1: Image of the Sonic Eye Massage Applicator

This single-center clinical trial was conducted for L'Oreal USA to assess the efficacy of the Sponsor's sonic eye massage applicator when used with Clarisonic Profile handle to apply a placebo eye cream by women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, and around the eye area rough skin texture and lack of firmness, including those with self-perceived sensitive skin.

The trial was conducted in 2 separate periods; a 4-week phase-in period where subjects applied a placebo eye cream manually by hand and an 8-week evaluation period where subjects applied the same placebo eye cream using a sonic eye massage applicator attached to a Clarisonic Profile handle.

The clinical study would determine whether the sonic eye massage applicator, when used with the Clarisonic Profile handle to apply a placebo eye cream for 8 weeks during the treatment period, provided enhanced efficacy when compared to baseline in women who have had used the placebo eye cream twice per day (morning and evening) for 4 weeks during the phase-in period.

GENERAL INFORMATION

Stephens Study Number:	C17-D122
Sponsor Study Number:	PBL-17-033
Test:	Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area
Test Materials:	Eye Cream Fla# 818724 1 Sonic Massage Applicator 5000797 Clarisonic Profile Handle
Investigator:	Lily Jiang, PhD
Sub-Investigator/Study Physician:	Peter D. Hino, MD, FAAD
Sub-Investigator:	Summer Acevedo, PhD
Compliance and Clinical Writing Manager:	Adra Blaine
Testing and Administrative Facility:	Thomas J. Stephens & Associates, Inc. Texas Research Center 1801 North Glenville Drive, Suite 200 Richardson, Texas 75081
Sponsor:	L'Oreal USA US Claims Evaluations 30 Terminal Avenue Clark, New Jersey 07066
Sponsor Representative:	Luke Kruger
Testing Start Date:	Phase-in Period: 25 Sep 2017 Evaluation Period: 23 Oct 2017
Testing End Date:	Phase-in Period: 21 Nov 2017 Evaluation Period: 16 Jan 2018

SUMMARY

This single-center clinical trial was conducted for L'Oreal USA to assess the efficacy of the Sponsor's sonic eye massage applicator when used with Clarisonic Profile handle to apply a placebo eye cream by women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, and around the eye area rough skin texture and lack of firmness, including those with self-perceived sensitive skin.

The trial was conducted in 2 separate periods; a 4-week phase-in period where subjects applied a placebo eye cream (Eye Cream Fla# 818724 1) manually by hand and an 8-week evaluation period where subjects applied the same placebo eye cream using an applicator (Sonic Massage Applicator 5000797) attached to a Clarisonic Profile Handle.

A total of 68 subjects completed the 4-week phase-in period and 56 subjects completed the 8-week evaluation period.

Phase-in period consisted of visit 1 (screening), visit 2 (post-screening week 2), and visit 3 (post-screening week 4). Evaluation period consisted of visit 3 (baseline and post-application), visit 4 (week 4), and visit 5 (week 8).

Visit 3 for both periods occurred on the same day when each subject's eligibility was verified which included change in clinical grading scores for efficacy parameters between visits 2 and 3 of no more than 0.5. At visit 3, those who did not qualify for the evaluation period were dismissed from the study and those who met eligibility requirements were enrolled into the 8-week evaluation period of the study.

Subjects participated in the following procedure at each phase-in and evaluation (if qualified) period time point (unless indicated otherwise):

- Clinical Grading of Efficacy Parameters
  Subjects were clinically graded for fine lines and wrinkles on the crow's feet area, fine lines and wrinkles on the under-eye area, skin texture/smoothness (visual) on the eye area, and firmness (palpation) on the eye area. Note that fine lines and wrinkles were evaluated separately on each specified location.

- VISIA-CR Imaging Procedures
  At post-screening week 4/evaluation period baseline and weeks 4 and 8, a total of 15 full-face digital images were taken of each subject's face (left, right, and center views) using the VISIA CR photo-station (Canfield Imaging Systems, Fairfield, New Jersey) with a Canon Mark II digital SLR camera (Canon Incorporated, Tokyo, Japan) under the following lighting conditions: standard 1 (visible [bright]), standard 2 (visible), standard 3 (raking light for crow's feet area), cross-polarized, and parallel polarized. Note that 3 images were taken for each lighting condition.

Overall Conclusions

Overall results of the phase-in period of this single-center clinical trial indicates that use of the Sponsor's placebo eye cream (Eye Cream Fla# 818724 1) by manual hand application twice per day for 4 weeks by women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, and around the eye area rough skin texture and lack of firmness, including those with self-perceived sensitive skin, produced minimal improvements, if any, in mean score for fine lines on the crow's feet and under-eye area, wrinkles on the crow's feet area, and skin texture/smoothness (visual) and firmness (palpation) on the eye area. There were no improvements for wrinkles on the under-eye area after 4 weeks of use. By the 4-week phase-in period completion, subject's eye had acclimated to the use of the placebo eye cream twice per day, to serve as the baseline for the evaluation period where subjects would apply the same placebo eye cream using an applicator (Sonic Massage Applicator 5000797) attached to a Clarisonic Profile Handle on the face twice per day for 8 weeks.

SUMMARY (continued)

Overall Conclusions (continued)
Overall results of the evaluation period of this single-center clinical trial indicates that the Sponsor's Sonic Massage Applicator 5000797 when used with the Clarisonic Profile Handle to apply a placebo eye cream (Eye Cream Fla# 818724 1) was effective in improving all evaluated visual photoaging parameters when used twice per day for 8 weeks in women, including those with self-perceived sensitive skin, who have used the same placebo eye cream twice per day for 4 weeks by manual hand application during the phase-in period.

Results of the clinical grading of efficacy parameters during the evaluation period indicate that use of Sonic Massage Applicator 5000797 attached to Clarisonic Profile Handle to apply Eye Cream Fla# 818724 1 produced a statistically significant improvement in scores for fine lines and wrinkles on the crow's feet area, fine lines and wrinkles on the under-eye area, skin texture/smoothness (visual) on the eye area, and firmness (palpation) on the eye area at post-application and weeks 4 and 8 when compared with baseline. Note that the scores at baseline were recorded when subject's eye had acclimated to the use of the same eye cream twice per day for 4 weeks by manual hand application.

STORAGE, HANDLING, AND DOCUMENTATION OF TEST MATERIALS

The receipt of study materials by Thomas J. Stephens & Associates, Inc. was documented in a study material log, which serves as a permanent record of the receipt, storage, return, and disposition of all study materials. All study materials are kept in a locked product-storage room accessible to designated staff members only. At the Sponsor's request, used Eye Cream Fla# 818724 1 will be destroyed and all devices (Sonic Massage Applicator 5000797 and Clarisonic Profile Handle) and unused Eye Cream Fla# 818724 1 will be returned to the Sponsor according to Stephens' Standard Operating Procedures (SOPs).

TEST MATERIAL DESCRIPTIONS

Table 1 presents the test material descriptions. Each test material was labeled with the assigned test material identification number (TMIN) and product identification (ID).

Table 1: Test Material Descriptions

TMIN	Product ID	Physical Properties	Frequency
0304-17C	Eye Cream Fla# 818724 1	White, cloudy cream	Twice per day
0447-17C	Sonic Massage Applicator 5000797[a]	Purple head with a white base, opaque solid	Twice per day
0352-17C	Clarisonic Profile Handle[a]	White, opaque solid	Twice per day

[a] Used during the evaluation period.

INFORMED CONSENT

Written informed consent conforming to Title 21 Code of Federal Regulations (CFR) 50.25 was obtained from each subject. As part of the informed consent process, the prospective subject was given as much time as needed to read the informed consent form (ICF) and had the opportunity to have any study-related questions answered to their satisfaction prior to signing the ICF. The original signed ICF for each subject participating in the study was retained in the study file and each subject received a copy of the signed ICF. Refer to Appendix V Sample Forms for a copy of the ICF.

INSTITUTIONAL REVIEW BOARD

Prior to subject enrollment for the study, the protocol and ICF for this study were reviewed and approved by IntegReview Institutional Review Board (IRB) on 13 Sep 2017. Additionally, the user instructions were approved prior to implementation on 03 Oct 2017. IntegReview IRB, located in Austin, Texas, is a duly constituted IRB under Title 21 CFR Parts 50 and 56. Refer to Appendix IV IRB Documents.

RECORD OF SPONSOR MONITORING VISITS

The Sponsor was permitted to perform site visits during the course of the study and inspect all case report forms (CRFs) and other documentation directly associated with the study. Sponsor representatives (Katherine Ortblad, Luke Kruger, and Margarita Yatskayer) visited the testing facility on 23 Oct 2017 to monitor the study.

SUBJECT DISPOSITION AND DEMOGRAPHICS

A summary of subject disposition information is included in Table 2. The demographic information for the per-protocol (PP) population is presented in Table 3. For applicable parameters, the number of subjects in each category is listed with the percentage of total subjects in parentheses. Refer to Appendix VI Screening/Enrollment Log.

Table 2: Subject Disposition

	Phase-In Period Subjects	Evaluation Period Subjects
Enrolled subjects	70	59
PP population (completed subjects)	68	56
Discontinued subjects	2	3
Noncompliance	1[a]	2[b]
Subject requested withdrawal	1	1

[a] Subject was unable to attend post-screening week 2 visit.

[b] Subjects did not use the device for multiple weeks.

Table 3: Summary of Demographic Information – PP Population

	Phase-In Period Subjects		Evaluation Period Subjects	
N	68		56	
Age (years)				
Mean	58.6		58.5	
Standard deviation	5.2		5.1	
Minimum	41		41	
Median	60.0		59.0	
Maximum	65		65	
	N	**(%)**	**N**	**(%)**
Sex				
Female	68	(100.0)	56	(100.0)
Ethnicity				
Hispanic or Latino	4	(5.9)	3	(5.4)
Not Hispanic or Latino	64	(94.1)	53	(94.6)
Race				
Asian	4	(5.9)	4	(7.1)
White or Caucasian	64	(94.1)	52	(92.9)
Fitzpatrick skin type				
I	3	(4.4)	2	(3.6)
II	43	(63.2)	33	(58.9)
III	22	(32.4)	21	(37.5)
Sensitive skin	39	(57.4)	34	(60.7)

ADVERSE EVENTS

An adverse event (AE) is defined as any untoward medical occurrence in a clinical investigation where a subject is administered any product or medical device, regardless of causal relationship with the test article. In general, the most common side effects associated with topical products are mild irritation, which may include (but are not limited to) subjective sensations (such as itching, burning, stinging, tingling), scaling/dryness, and redness. Additionally, test materials applied to the eye areas have the potential to cause eye watering/tearing, redness of the eyes, corneal erosions, and foreign body sensation in the eyes.

Symptoms of irritation, including the examples above, may not have been treated as adverse reactions if they were mild in nature, even if the symptoms did not resolve over time. Symptoms that were persistent and moderate to severe in nature, or that involved elevation (eg, edema, papules, vesicles, spreading) were considered AEs. The Investigator or designee had the final authorization to determine if a reaction was considered an AE.

A brief summary of the nonserious AE recorded during the study is presented in Table 4. Refer to Appendix VII Adverse Event Form.

Table 4: Nonserious Adverse Event

Subject	Adverse Event (Location)	Date Started	Date Ended	Severity	Relationship	Outcome
036	Muscle spasms (lower back)	27 Oct 2017	05 Nov 2017	Mild	Unlikely	Resolved
037	Vision blurred (both eyes)	22 Nov 2017	29 Nov 2017	Mild	Unlikely	Resolved
053[a]	Burning sensation (both eyes)	22 Nov 2017	05 Jan 2018	Moderate	Probable	Resolved
	Eye irritation (both eyes)	22 Nov 2017	05 Jan 2018	Moderate	Probable	Resolved

[a] After speaking with the subject further about the symptoms, it was in the opinion of the PI that the subject was using the cream and device too close to her eyes. The subject was reinstructed on how to use the device.

PROTOCOL AMENDMENTS

Any changes or formal clarification to the procedures outlined in the protocol were documented as protocol amendments. Notes to file (for internal purposes) were used to identify study discrepancies, provide clarification, or record slight variations for items that did not require a protocol amendment.

There were no amendments to the protocol.

PROTOCOL DEVIATIONS

Any violations to the protocol that may have significantly affected the completeness, accuracy, and/or reliability of the study data or may have affected subjects' rights, safety, or well-being were documented as deviations. Notes to file (for internal clarification purposes) were used to record items that did not qualify as deviations.

The following protocol deviations were recorded during the study:

- Clinical grading of efficacy parameters was started 2 minutes before the end of acclimation time for subject 018 at the post-screening week 2 visit. Subject did not remove all makeup prior to attending the visit thus was required to remove the residual makeup at the clinic and acclimate for 20 instead of 15 minutes.
- These subjects attended each specified evaluation visit outside of the allowed ± 3 days window (actual number of days after the ± 3 days window is included in parentheses): 020 (+4), 028 (+3), and 055 (+6) at week 4, and 026 (+7) at week 8.

The detailed protocol deviation log was reviewed and signed by the Investigator and forwarded to the Sponsor. Refer to Appendix III Protocol Deviation Log.

PROCEDURES AND METHODS

Prior to the start of the study, prospective subjects were screened over the telephone for eligibility criteria using an IRB-approved script. Women between the ages of 40 and 65 years who are nonsmokers, including those with self-perceived sensitive skin, were scheduled for eligibility screening at the clinic. Prospective subjects were instructed to remove all makeup at least 2 hours prior to visits 1-3.

At visit 1 (screening), prospective subjects completed the informed consent process and signed the ICF. Prospective subjects who signed this initial paperwork were assigned a screening number and acclimated to ambient temperature and humidity conditions for at least 15 minutes prior to participating in evaluation procedures.

Prospective subjects were screened by the Investigator or designee for qualification criteria, including the following:

- Fitzpatrick Type Skin Classification: Types I-III qualified
  The Fitzpatrick Skin Classification is based on the skin's unprotected response to the first 30-45 minutes of sun exposure after a winter season without sun exposure. The categories of skin types are as follows:

Type	Physical Characteristics	Skin Reaction to UV
I	White; very fair; red or blonde hair; blue eyes; freckles	Always burns easily; never tans
II	White; fair; red or blonde hair; blue, hazel, or green eyes	Always burns easily; tans minimally
III	Cream white; fair with any eye or hair color; very common	Burns moderately; tans gradually
IV	Brown; typical Mediterranean white skin	Burns minimally; always tans well
V	Dark brown; mid-eastern skin types, black hair, olive skin	Rarely burns; tans profusely
VI	Black; black hair, black eyes, black skin	Never burns; deeply pigmented

- Facial Skin Conditions
  Clinically determined moderate conditions (score of 4.5-6.5 according to modified Griffiths scale[1] where 0=none and 9=severe) for the following parameters:
  - Fine lines on crow's feet area
  - Wrinkles on crow's feet area
  - Fine lines on under eye area
  - Wrinkles on under eye area
  - Skin roughness around the eye area
  - Firmness around the eye area

Candidate subjects who passed the eligibility screening participated in the following procedure:

- **Clinical Grading of Efficacy Parameters**
  Subjects were clinically graded for the following efficacy parameters at the indicated locations according to the listed numerical definitions (half point scores were used as necessary to more accurately describe the skin condition Note that the clinical graders were not allowed to reference previous scores at post baseline assessments) :

  Fine lines: crow's feet and under-eye area (graded separately for each location)
  0 = No fine lines
  1 = A few indistinct, shallow fine lines observable
  2 = A few distinct, shallow fine lines observable
  3 = Several distinct shallow fine lines observable
  4 = Distinct shallow and few deeper fine lines observable
  5 = Deeper fine lines observable
  6 = Distinct deeper fine lines observable
  7 = Much deeper fine lines observable
  8 = Pronounced fine lines observable
  9 = Significant (severe) fine lines observable

PROCEDURES AND METHODS (continued)

- **Clinical Grading of Efficacy Parameters (continued)**

Wrinkles: crow's feet and under-eye area (graded separately for each location)

0 = No wrinkles
1 = A few indistinct, shallow wrinkles observable
2 = A few distinct, shallow wrinkles observable
3 = Several distinct shallow wrinkles observable
4 = Distinct shallow and few deeper wrinkles observable
5 = Deeper wrinkles observable
6 = Distinct deeper wrinkles observable
7 = Much deeper wrinkles observable
8 = Pronounced wrinkles observable
9 = Significant (severe) wrinkles observable

Skin Texture/Smoothness (visual): eye area

0 = No palpable skin roughness, drag and/or surface bumps/depressions
1 = Barely palpable skin roughness, drag and/or surface bumps/depressions
2 = Slightly palpable skin roughness, drag and/or surface bumps/depressions
3 = Slight to mildly palpable skin roughness, drag and/or surface bumps/depressions
4 = Mildly to moderately palpable skin roughness, drag and/or surface bumps/depressions
5 = Moderately palpable skin roughness, drag and/or surface bumps/depressions
6 = Moderately to pronounced palpable skin roughness, drag and/or surface bumps/depressions
7 = Pronounced palpable skin roughness, drag and/or surface bumps/depressions
8 = Pronounced to significantly palpable skin roughness, drag and/or surface bumps/depressions
9 = Significantly (severe) palpable skin roughness, drag and/or surface bumps/depressions

Firmness (palpation): eye area

0 = A significantly pliant or flexible skin feel
1 = A pronounced to significantly pliant or flexible skin feel
2 = A pronounced pliant or flexible skin feel
3 = A moderate to pronounced pliant or skin flexible feel
4 = A moderate pliant or flexible skin feel
5 = A mild to moderate pliant or flexible skin feel
6 = A mildly pliant or flexible skin feel
7 = A slight to mildly pliant or flexible skin feel
8 = A slight to barely detectable pliant or flexible skin feel
9 = No evidence of pliant or flexible skin feel

Candidate subjects completed an eligibility and health questionnaire. Those who met eligibility requirements were enrolled into the 4-week phase-in period of the study. A sufficient number of subjects were enrolled to have approximately 50% of subjects with self-perceived sensitive skin.

Subjects were provided with a unit of the placebo eye cream (Eye Cream Fla# 818724 1). The following usage instructions were explained by clinic personnel:

Usage Instructions for the Phase-In Period:
Apply eye cream by hand (manually) twice per day (morning and evening/bedtime) to the eye area using your normal technique after cleansing using your regular facial cleanser and cleansing procedure. Avoid getting the cream in your eyes.

Subjects were also provided with a calendar of study visits, written usage/study instructions, and a daily diary to record product application times and comments.

PROCEDURES AND METHODS (continued)

Subjects returned to the clinic for visit 2 (post-screening week 2) and participated in the following procedures:

- Clinic personnel recorded concomitant medications and questioned subjects regarding changes in their health. AEs were recorded if applicable.
- Daily diaries were collected and reviewed for compliance. New diaries were distributed and completed diaries were retained by the clinic.
- Test material units were collected and visually inspected for compliance. Test material units were returned to subjects or new units were distributed as needed.
- Subjects acclimated to ambient temperature and humidity conditions for at least 15 minutes and then participated in clinical grading of efficacy parameters as previously described.

Subjects returned to the clinic for visit 3 (post-screening week 4/evaluation period baseline) and participated in the following procedures:

- Clinic personnel recorded concomitant medications and questioned subjects regarding changes in their health. AEs were recorded if applicable.
- Daily diaries were collected and reviewed for compliance. New diaries were distributed to subjects continuing to evaluation period and completed diaries were retained by the clinic.
- Test material units were collected and visually inspected for compliance. Test material units were returned to subjects or new units were distributed as needed to subjects continuing to evaluation period.
- Subjects acclimated to ambient temperature and humidity conditions for at least 15 minutes and then participated in clinical grading of efficacy parameters as previously described. Applicable rooms were maintained at a temperature of 68°-75°F and the relative humidity ranged from 35%-65%. Refer to Appendix VIII Room Temperature and Humidity Log.
- Qualification for entry into the 8-week evaluation period was reviewed and confirmed as described below:
    - o <u>Facial Skin Conditions</u>
      Clinically determined moderate conditions (score of 4.0-6.5 according to modified Griffiths scale[1] where 0=none and 9=severe) for the following parameters:
        - Fine lines on crow's feet area
        - Wrinkles on crow's feet area
        - Fine lines on under eye area
        - Wrinkles on under eye area
        - Skin roughness around the eye area
        - Firmness around the eye area
    - o Subjects were required to not have had a change of more than 0.5 in any of the clinical grading of efficacy parameter scores between visits 2 and 3.

  Those who did not qualify for the evaluation period were dismissed from the study. Those who met eligibility requirements were enrolled into the 8-week evaluation period of the study and assigned a subject number.

- Subjects had digital images taken as described below:

    - **VISIA-CR Imaging Procedures**
      Clinic personnel ensured subjects had a clean face with no makeup and subjects removed any jewelry from the areas to be photographed. Subjects were provided with a black or gray matte headband to keep hair away from the face. A black or gray matte cloth was draped over the subjects' clothing. Subjects were instructed to adopt neutral, nonsmiling expressions with their eyes gently closed, and were carefully positioned for each photograph.

      A total of 15 full-face digital images were taken of each subject's face (left, right, and center views) using the VISIA CR photo-station (Canfield Imaging Systems, Fairfield, New Jersey) with a Canon Mark II digital SLR camera (Canon Incorporated, Tokyo, Japan) under the following lighting conditions: standard 1 (visible [bright]), standard 2 (visible), standard 3 (raking light for crow's feet area), cross-polarized, and parallel polarized. Note that 3 images were taken for each lighting condition.

PROCEDURES AND METHODS (continued)

- Subjects were provided with a unit of the device (Clarisonic Profile Handle) and applicator (Sonic Massage Applicator 5000797). The following usage instructions were explained by clinic personnel:

  Usage Instructions for the Evaluation Period:

  - Apply the Eye Cream Fla# 818724 1 using the Sonic Massage Applicator (programmed to run on a 4-5 degree amplitude, 75 Hz and for 1 minute) with Clarisonic Profile Handle [Setting 2 (4-5 degrees amplitude, 75 hz)] twice per day (morning and evening/bedtime) to the eye area after cleansing using your regular facial cleanser and cleansing procedure. No instructions on how to cleanse or how long to cleanse will be given.
  - Apply a liberal amount of the Eye Cream Fla# 818724 1 by hand to the treatment zone, then use the sonic massage applicator for 30 seconds on each eye area (right and left eye area - specifically under the eye, onto the crow's feet, and above the brow bone).

  Refer to Appendix V Sample Forms for a copy of the instruction for use/user guide which includes the detailed usage instructions provided to the subjects. Subjects were also instructed to use the test materials as directed at least 2 hours prior to visits 4-5 and to not apply any other topical products (including sunscreen) to the face or eye area until visit completion.

- Subjects performed the first use of the sonic massage applicator to apply the placebo eye cream, in the clinic, under the supervision of clinic personnel. At 15 minutes after test material application, clinical grading of efficacy parameters was repeated.

Subjects returned to the clinic for visit 4 (week 4) and visit 5 (week 8). Subjects participated in the following procedures at each visit (unless otherwise indicated):

- Clinic personnel recorded concomitant medications and questioned subjects regarding changes in their health. AEs were recorded if applicable.
- Daily diaries were collected and reviewed for compliance. New diaries were distributed at week 4 and completed diaries were retained by the clinic.
- Test material units were collected and visually inspected for compliance. Test material units were returned to subjects or new units were distributed as needed at week 4 and retained by the clinic at study completion.
- Subjects acclimated to ambient temperature and humidity conditions for at least 15 minutes and then participated in clinical grading of efficacy parameters as previously described. Applicable rooms were maintained at a temperature of 68°-75°F and the relative humidity ranged from 35%-65%. Refer to Appendix VIII Room Temperature and Humidity Log.
- After acclimation, subjects participated in the following procedures as previously described:
  - Clinical grading of efficacy parameters
  - VISIA-CR imaging

BIOSTATISTICS AND DATA MANAGEMENT

The PP population was the primary population for all statistical analyses testing. The PP population included all subjects who completed the study in general accordance with the protocol. The statistical analyses for all evaluations were conducted separately for the 4-week phase-in period and the 8-week evaluation period.

For clinical grading of efficacy parameters, a descriptive statistical summary is provided, including the number of observations (N), mean, median, standard deviation, minimum, and maximum at all time points.

For the phase-in period, a similar summary table was provided for the difference between the scores at visit 2 (post-screening week 2) and visit 3 (post-screening week 4/evaluation period baseline).

For the evaluation period, mean of the change from baseline (defined as the post-baseline value minus the baseline) was estimated at each applicable post-baseline time point. The null hypothesis that the mean change from baseline is zero was tested using a Wilcoxon signed-rank test.

BIOSTATISTICS AND DATA MANAGEMENT (continued)
The following were calculated and reported for each evaluation parameter at applicable post-baseline time point(s):

$$\text{Percent mean change from baseline} = \frac{(\text{visit mean score} - \text{baseline mean score}) \times 100}{\text{baseline mean score}}$$

$$\text{Percent of subjects improved/worsened} = \frac{(\text{number of subjects improved/worsened from baseline}) \times 100}{\text{total number of subjects}}$$

For clinical grading of efficacy parameters, descriptive statistics for the phase-in period are presented in Table 8 and Table 9, and descriptive statistics and change from baseline statistics for the evaluation period are presented in Table 10 and Table 11.

Calibration grading raw data was sent to the Sponsor directly without any statistical analysis by Stephens.

All statistical tests were 2-sided at significance level alpha=0.05. *P* values are reported to 3 decimal places (0.000). No multiple testing corrections were considered in the study. Statistical analyses were performed using SAS software version 9.4 series (SAS Statistical Institute).

Clinical grading scores were recorded using the Stephens electronic data capture (EDC) system, which is a computerized system designed for the collection of clinical data in electronic format. The 3 major aspects of EDC are a graphical user interface for data entry, a validation component to check for user data, and a reporting tool for analysis of the collected data. The Stephens EDC is compliant with Food and Drug Administration (FDA) regulations, namely the FDA's 21 CFR Part 11 regulation "Electronic Records; Electronic Signatures," which regulates the use of EDC in trials. Content validation procedures were performed to ensure adequate coverage of critical EDC system features.

Images were forwarded to the Sponsor according to Stephens SOPs and any protocol specifications.

Note regarding n-values:

- For the phase-in period: At the final visit (post-screening week 4/evaluation period baseline), subjects C21 and F02 did not meet the facial conditions requirement of having moderate conditions (score of 4.0-6.5) for the following parameters: fine lines and wrinkles on crow's feet and under eye area, skin roughness and firmness around the eye area. Since both subjects would not qualify for the 8-week evaluation period, they were excluded from grading resulting in unavailable data at post-screening week 4/evaluation period baseline.
- For the evaluation period: Subject 056 missed the week 4 visit for the evaluation period resulting in missing data.

QUALITY ASSURANCE
All clinical research studies performed by Thomas J. Stephens & Associates, Inc. are conducted in accordance with federal regulations and Good Clinical Practice guidelines. Stephens independent Quality Assurance Unit monitored the study conduct and audited the study documents, data, and clinical study report. All data and supporting documentation are accurate, complete, and in compliance with the requirements of the protocol and Stephens SOPs.

Data review and analyses were performed by an independent data committee, consisting of selected representatives from clinical services, quality assurance unit, and statistics department of Stephens. When requested, it was the responsibility of the independent data committee to send any interim data to the Sponsor.

MAINTENANCE OF RECORDS

All original records (including the study protocol, source documents, ICFs, screening/enrollment log, and any other records or forms used in this study) and a copy of the final report will be retained on file in the Thomas J. Stephens & Associates, Inc. archives for 2 years from the date of study completion. When the archive time has expired, the study files will either be sent to the Sponsor at the Sponsor's expense or destroyed.

RESULTS AND CONCLUSIONS

Clinical Grading of Efficacy Parameters for the Phase-In Period (Table 8 and Table 9)

The clinical grading of efficacy parameters for the phase-in period showed that there were mild improvements in mean score for fine lines on the crow's feet and under-eye area, wrinkles on the crow's feet area, and skin texture/smoothness (visual) and firmness (palpation) on the eye area after using Eye Cream Fla# 818724 1 by manual hand application for 4 weeks. There were no improvements for wrinkles on the under-eye area after using Eye Cream Fla# 818724 1 by manual hand application for 4 weeks.

Note that the clinical graders were not allowed to reference previous scores at post baseline assessments.

Table 5: Results for Clinical Grading of Efficacy Parameters (Phase-In Period)

Time Point	*N*	*Mean*
Fine lines: crow's feet		
Screening	68	4.84
Post-screening Week 2	68	4.60
Post-screening/Evaluation Baseline	66	4.55
Fine lines: under-eye		
Screening	68	5.13
Post-screening Week 2	68	5.04
Post-screening/Evaluation Baseline	66	4.86
Wrinkles: crow's feet		
Screening	68	5.18
Post-screening Week 2	68	5.16
Post-screening/Evaluation Baseline	66	5.12
Wrinkles: under-eye		
Screening	68	5.27
Post-screening Week 2	68	5.34
Post-screening/Evaluation Baseline	66	5.38
Skin Texture/Smoothness (visual)		
Screening	68	5.35
Post-screening Week 2	68	5.29
Post-screening/Evaluation Baseline	66	5.33
Firmness (palpation)		
Screening	68	5.43
Post-screening Week 2	68	5.39
Post-screening/Evaluation Baseline	66	5.39

RESULTS AND CONCLUSIONS (continued)

The mean difference between the scores at visit 2 (post-screening week 2) and visit 3 (post-screening week 4) showed that the changes were minimal between -0.17 and 0.04.

Table 6: Results for Clinical Grading of Efficacy Parameters Score Differences at Visits 2 and 3 (Phase-In Period)

Time Point	*N*	*Mean*
Fine lines: crow's feet		
Post-screening/Evaluation Baseline	66	-0.07
Fine lines: under-eye		
Post-screening/Evaluation Baseline	66	-0.17
Wrinkles: crow's feet		
Post-screening/Evaluation Baseline	66	-0.05
Wrinkles: under-eye		
Post-screening/Evaluation Baseline	66	0.04
Skin Texture/Smoothness (visual)		
Post-screening/Evaluation Baseline	66	0.04
Firmness (palpation)		
Post-screening/Evaluation Baseline	66	0.00

Clinical Grading of Efficacy Parameters for the Evaluation Period (Table 11)

Use of Sonic Massage Applicator 5000797 attached to Clarisonic Profile Handle to apply Eye Cream Fla# 818724 1 produced a statistically significant decrease (improvement) in clinical grading scores for fine lines and wrinkles on the crow's feet area, fine lines and wrinkles on the under-eye area, skin texture/smoothness (visual) on the eye area, and firmness (palpation) on the eye area at post-application and weeks 4 and 8 when compared with baseline.

Table 7: Results for Clinical Grading of Efficacy Parameters (Treatment Period)

Time Point	*N*	*Mean*	*Mean Change*	*Mean Change, %*	*Signed-Rank Test P-value*[a]
Fine lines: crow's feet					
Post-screening/Evaluation Baseline	56	4.54	-	-	-
Post-App	56	4.21	-0.33	-7.3	**<.001**
Week 4	55	4.19	-0.33	-7.2	**<.001**
Week 8	56	3.88	-0.65	-14.4	**<.001**
Fine lines: under-eye					
Post-screening/Evaluation Baseline	56	4.91	-	-	-
Post-App	56	4.63	-0.29	-5.8	**<.001**
Week 4	55	4.56	-0.35	-7.0	**<.001**
Week 8	56	4.28	-0.63	-12.9	**<.001**

[a] **Bold** indicates statistical significant p-value<0.05. Testing hypothesis is that the mean change from Post-screening/Evaluation Baseline is equal to zero. Decrease indicates improvement from Post-screening/Evaluation Baseline.

Table 7: Results for Clinical Grading of Efficacy Parameters (Treatment Period)

Time Point	*N*	*Mean*	*Mean Change*	*Mean Change, %*	*Signed-Rank Test P-value*[a]
Wrinkles: crow's feet					
Post-screening/Evaluation Baseline	56	5.13	-	-	-
Post-App	56	5.04	-0.08	-1.6	**0.035**
Week 4	55	4.97	-0.15	-2.8	**<.001**
Week 8	56	4.75	-0.38	-7.3	**<.001**
Wrinkles: under-eye					
Post-screening/Evaluation Baseline	56	5.40	-	-	-
Post-App	56	5.28	-0.13	-2.3	**<.001**
Week 4	55	5.16	-0.22	-4.1	**<.001**
Week 8	56	4.91	-0.49	-9.1	**<.001**
Skin Texture/Smoothness (visual)					
Post-screening/Evaluation Baseline	56	5.35	-	-	-
Post-App	56	5.24	-0.11	-2.0	**0.011**
Week 4	55	5.15	-0.19	-3.6	**<.001**
Week 8	56	4.94	-0.41	-7.7	**<.001**
Firmness (palpation)					
Post-screening/Evaluation Baseline	56	5.37	-	-	-
Post-App	56	5.28	-0.09	-1.7	**0.002**
Week 4	55	5.15	-0.21	-3.9	**<.001**
Week 8	56	4.81	-0.55	-10.3	**<.001**

[a] **Bold** indicates statistical significant p-value<0.05. Testing hypothesis is that the mean change from Post-screening/Evaluation Baseline is equal to zero. Decrease indicates improvement from Post-screening/Evaluation Baseline.

RESULTS AND CONCLUSIONS (continued)

Overall Conclusions

Overall results of the phase-in period of this single-center clinical trial indicates that use of the Sponsor's placebo eye cream (Eye Cream Fla# 818724 1) by manual hand application twice per day for 4 weeks by women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, and around the eye area rough skin texture and lack of firmness, including those with self-perceived sensitive skin, produced minimal improvements, if any, in mean score for fine lines on the crow's feet and under-eye area, wrinkles on the crow's feet area, and skin texture/smoothness (visual) and firmness (palpation) on the eye area. There were no improvements for wrinkles on the under-eye area after 4 weeks of use (see Tables 8 and 9). By the 4-week phase-in period completion, subject's eye had acclimated to the use of the placebo eye cream twice per day, to serve as the baseline for the evaluation period where subjects would apply the same placebo eye cream using an applicator (Sonic Massage Applicator 5000797) attached to a Clarisonic Profile Handle on the face twice per day for 8 weeks.

Overall results of the evaluation period of this single-center clinical trial indicates that the Sponsor's Sonic Massage Applicator 5000797 when used with the Clarisonic Profile Handle to apply a placebo eye cream (Eye Cream Fla# 818724 1) was effective in improving all evaluated visual photoaging parameters when used twice per day for 8 weeks in women, including those with self-perceived sensitive skin, who have used the same placebo eye cream twice per day for 4 weeks by manual hand application during the phase-in period.

Results of the clinical grading of efficacy parameters during the evaluation period indicate that use of Sonic Massage Applicator 5000797 attached to Clarisonic Profile Handle to apply Eye Cream Fla# 818724 1 produced a statistically significant improvement in scores for fine lines and wrinkles on the crow's feet area, fine lines and wrinkles on the under-eye area, skin texture/smoothness (visual) on the eye area, and firmness (palpation) on the eye area at post-application and weeks 4 and 8 when compared with baseline. Note that the scores at baseline were recorded when subject's eye had acclimated to the use of the same eye cream twice per day for 4 weeks by manual hand application.

REFERENCES

1. Griffiths CE, Wang TS, Hamilton TA, Voorhees JJ, Ellis CN. A photonumeric scale for the assessment of cutaneous photodamage. *Arch Dermatol*. 1992;128(3):347-351.

REPORT APPROVAL

Report approved by:

THOMAS J. STEPHENS & ASSOCIATES, INC.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:08:37 -05'00'

Lily Jiang, PhD — Date
Investigator

Peter D. Hino, MD
2018.06.15 12:22:40 -05'00'

Peter D. Hino, MD, FAAD — Date
Sub-Investigator/Study Physician

Summer Acevedo, PhD

Digitally signed by Summer Acevedo, PhD
DN: cn=Summer Acevedo, PhD, o=Stephens and Associates, ou, email=sacevedo@stephens-associates.com, c=US
Date: 2018.06.15 14:07:17 -05'00'

Summer Acevedo, PhD — Date
Sub-Investigator

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I. Efficacy Data Results Tables

Table 8: Descriptive Statistics for Clinical Grading of Efficacy Parameters (Phase-In Period)

Time Point	*N*	*Mean*	*Standard Deviation*	*Minimum*	*Median*	*Maximum*
Fine lines: crow's feet						
Screening	68	4.84	0.45	4.50	4.50	6.50
Post-screening Week 2	68	4.60	0.48	4.00	4.50	6.00
Post-screening/Evaluation Baseline	66	4.55	0.47	4.00	4.50	6.50
Fine lines: under-eye						
Screening	68	5.13	0.39	4.50	5.00	6.00
Post-screening Week 2	68	5.04	0.42	4.00	5.00	6.00
Post-screening/Evaluation Baseline	66	4.86	0.47	4.00	5.00	6.00
Wrinkles: crow's feet						
Screening	68	5.18	0.52	4.50	5.00	6.50
Post-screening Week 2	68	5.16	0.54	4.00	5.00	6.50
Post-screening/Evaluation Baseline	66	5.12	0.57	4.00	5.00	6.50
Wrinkles: under-eye						
Screening	68	5.27	0.45	4.50	5.00	6.50
Post-screening Week 2	68	5.34	0.45	4.50	5.50	6.50
Post-screening/Evaluation Baseline	66	5.38	0.44	4.50	5.50	6.50
Skin Texture/Smoothness (visual)						
Screening	68	5.35	0.34	5.00	5.50	6.50
Post-screening Week 2	68	5.29	0.35	5.00	5.00	6.50
Post-screening/Evaluation Baseline	66	5.33	0.33	5.00	5.50	6.50
Firmness (palpation)						
Screening	68	5.43	0.47	4.50	5.50	6.50
Post-screening Week 2	68	5.39	0.47	4.50	5.50	6.50
Post-screening/Evaluation Baseline	66	5.39	0.41	4.50	5.50	6.00

Table 9: Descriptive Statistics for Clinical Grading of Efficacy Parameters Score Differences at Visits 2 and 3 (Phase-In Period)

Time Point	*N*	*Mean*	*Standard Deviation*	*Minimum*	*Median*	*Maximum*
Fine lines: crow's feet						
Post-screening/Evaluation Baseline	66	-0.07	0.36	-0.50	0.00	0.50
Fine lines: under-eye						
Post-screening/Evaluation Baseline	66	-0.17	0.39	-1.00	0.00	1.00
Wrinkles: crow's feet						
Post-screening/Evaluation Baseline	66	-0.05	0.32	-0.50	0.00	0.50
Wrinkles: under-eye						
Post-screening/Evaluation Baseline	66	0.04	0.25	-0.50	0.00	0.50
Skin Texture/Smoothness (visual)						
Post-screening/Evaluation Baseline	66	0.04	0.29	-0.50	0.00	0.50
Firmness (palpation)						
Post-screening/Evaluation Baseline	66	0.00	0.26	-1.00	0.00	0.50

The difference between the post-screening week 2 (visit 2) and post-screening week 4/evaluation baseline (visit 3) is calculated by subtracting visit 3 score from visit 2 score.

Table 10: Descriptive Statistics for Clinical Grading of Efficacy Parameters (Treatment Period)

Time Point	*N*	*Mean*	*Standard Deviation*	*Minimum*	*Median*	*Maximum*
Fine lines: crow's feet						
Post-screening/Evaluation Baseline	56	4.54	0.49	4.00	4.50	6.50
Post-App	56	4.21	0.52	3.00	4.00	5.50
Week 4	55	4.19	0.63	3.00	4.00	6.00
Week 8	56	3.88	0.67	2.00	4.00	5.00
Fine lines: under-eye						
Post-screening/Evaluation Baseline	56	4.91	0.44	4.00	5.00	6.00
Post-App	56	4.63	0.45	3.50	4.50	5.50
Week 4	55	4.56	0.48	3.50	4.50	5.50
Week 8	56	4.28	0.55	3.00	4.00	5.50
Wrinkles: crow's feet						
Post-screening/Evaluation Baseline	56	5.13	0.56	4.00	5.00	6.50
Post-App	56	5.04	0.61	4.00	5.00	6.50
Week 4	55	4.97	0.62	3.50	5.00	6.50
Week 8	56	4.75	0.68	3.00	5.00	6.50
Wrinkles: under-eye						
Post-screening/Evaluation Baseline	56	5.40	0.46	4.50	5.50	6.50
Post-App	56	5.28	0.49	4.50	5.00	6.50
Week 4	55	5.16	0.48	4.50	5.00	6.50
Week 8	56	4.91	0.56	4.00	5.00	6.00
Skin Texture/Smoothness (visual)						
Post-screening/Evaluation Baseline	56	5.35	0.34	5.00	5.50	6.50
Post-App	56	5.24	0.36	4.50	5.00	6.50
Week 4	55	5.15	0.33	4.50	5.00	6.00
Week 8	56	4.94	0.41	4.00	5.00	5.50
Firmness (palpation)						
Post-screening/Evaluation Baseline	56	5.37	0.41	4.50	5.50	6.00
Post-App	56	5.28	0.43	4.50	5.00	6.00
Week 4	55	5.15	0.50	4.00	5.00	6.50
Week 8	56	4.81	0.41	4.00	5.00	5.50

Table 11: Change from Baseline Statistics for Clinical Grading of Efficacy Parameters (Treatment Period)

Time Point	*N*	*Subject Improved, %*	*Subject Worsened, %*	*Mean Change*	*Standard Deviation for Change*	*Mean Change, %*	*Signed-Rank Test P-value*[a]
Fine lines: crow's feet							
Post-App	56	60.7	1.8	-0.33	0.32	-7.3	<.001
Week 4	55	58.2	5.5	-0.33	0.39	-7.2	<.001
Week 8	56	78.6	5.4	-0.65	0.53	-14.4	<.001
Fine lines: under-eye							
Post-App	56	57.1	3.6	-0.29	0.31	-5.8	<.001
Week 4	55	60.0	5.5	-0.35	0.40	-7.0	<.001
Week 8	56	78.6	5.4	-0.63	0.53	-12.9	<.001
Wrinkles: crow's feet							
Post-App	56	21.4	5.4	-0.08	0.25	-1.6	0.035
Week 4	55	32.7	5.5	-0.15	0.30	-2.8	<.001
Week 8	56	58.9	1.8	-0.38	0.38	-7.3	<.001
Wrinkles: under-eye							
Post-App	56	25.0	0.0	-0.13	0.22	-2.3	<.001
Week 4	55	45.5	1.8	-0.22	0.27	-4.1	<.001
Week 8	56	76.8	0.0	-0.49	0.35	-9.1	<.001
Skin Texture/Smoothness (visual)							
Post-App	56	25.0	5.4	-0.11	0.28	-2.0	0.011
Week 4	55	40.0	1.8	-0.19	0.26	-3.6	<.001
Week 8	56	71.4	0.0	-0.41	0.30	-7.7	<.001
Firmness (palpation)							
Post-App	56	17.9	0.0	-0.09	0.19	-1.7	0.002
Week 4	55	43.6	5.5	-0.21	0.33	-3.9	<.001
Week 8	56	83.9	0.0	-0.55	0.34	-10.3	<.001

[a] Calculated from Wilcoxon signed-rank test. Testing hypothesis is that the mean change from Post-screening/ Evaluation Baseline is zero.

II. Raw Data

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
101	A01	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5	5
101	A01	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6.5	6
101	A01	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
101	A01	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	6	6
101	A01	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	6	6
101	A01	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6
102	A02	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
102	A02	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6
102	A02	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
102	A02	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
102	A02	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
102	A02	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6.5	6.5	6
105	A05	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
105	A05	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
105	A05	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5.5
105	A05	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5
105	A05	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
105	A05	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
106	A06	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5
106	A06	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6.5	6.5	6.5
106	A06	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5
106	A06	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
106	A06	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	6	5.5
106	A06	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6.5	6.5	6
107	A07	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
107	A07	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5
107	A07	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4	4.5
107	A07	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	5	5.5
107	A07	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
107	A07	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5.5	5
108	A08	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5
108	A08	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5
108	A08	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5
108	A08	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
108	A08	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
108	A08	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
111	A11	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
111	A11	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5.5
111	A11	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
111	A11	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	4.5	5
111	A11	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
111	A11	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	4.5	5
112	A12	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5	4.5
112	A12	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6
112	A12	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5.5
112	A12	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
112	A12	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
112	A12	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
113	A13	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4
113	A13	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	5
113	A13	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
113	A13	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	5
113	A13	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
113	A13	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
115	A15	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5
115	A15	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5
115	A15	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
115	A15	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	5.5	6
115	A15	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	6
115	A15	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
117	A17	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
117	A17	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	6	6
117	A17	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4
117	A17	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5.5
117	A17	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
117	A17	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	6
118	A18	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
118	A18	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5
118	A18	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4.5
118	A18	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
118	A18	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
118	A18	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
119	A19	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
119	A19	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	5	4.5
119	A19	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5.5
119	A19	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5
119	A19	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
119	A19	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	4.5	5
120	A20	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	4.5
120	A20	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	5
120	A20	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4
120	A20	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
120	A20	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
120	A20	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
202	B02	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	4.5
202	B02	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	5
202	B02	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	5.5	5
202	B02	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
202	B02	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
202	B02	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	5.5	6

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
203	B03	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
203	B03	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5
203	B03	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5
203	B03	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
203	B03	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
203	B03	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
206	B06	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
206	B06	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5.5
206	B06	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5
206	B06	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
206	B06	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
206	B06	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
209	B09	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	5	5
209	B09	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
209	B09	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	6
209	B09	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6.5	6	5.5
209	B09	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
209	B09	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
212	B12	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
212	B12	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	5
212	B12	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
212	B12	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	6	6
212	B12	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	6	5.5
212	B12	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
216	B16	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	5
216	B16	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6
216	B16	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
216	B16	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6
216	B16	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	6	6
216	B16	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
218	B18	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	4.5
218	B18	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	6
218	B18	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5.5
218	B18	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	5.5	5.5
218	B18	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
218	B18	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
219	B19	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
219	B19	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	5
219	B19	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
219	B19	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	6	5.5
219	B19	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
219	B19	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
221	B21	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
221	B21	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5
221	B21	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
221	B21	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6.5	6.5	6.5
221	B21	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	5.5	5.5
221	B21	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
223	B23	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
223	B23	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5
223	B23	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
223	B23	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5
223	B23	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5
223	B23	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
301	C01	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	6	6	5.5
301	C01	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
301	C01	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
301	C01	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
301	C01	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5
301	C01	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5
302	C02	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
302	C02	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5.5
302	C02	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	6	5.5
302	C02	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5.5
302	C02	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
302	C02	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
303	C03	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
303	C03	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
303	C03	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
303	C03	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
303	C03	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5
303	C03	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
305	C05	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
305	C05	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	6	5.5
305	C05	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	4
305	C05	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
305	C05	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
305	C05	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6
309	C09	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
309	C09	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	5
309	C09	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
309	C09	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6.5	6.5
309	C09	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	5.5	6
309	C09	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
310	C10	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5
310	C10	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
310	C10	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	6	5
310	C10	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5.5
310	C10	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
310	C10	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
311	C11	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5	4.5
311	C11	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5
311	C11	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4
311	C11	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
311	C11	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
311	C11	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5
312	C12	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
312	C12	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5
312	C12	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	4
312	C12	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
312	C12	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
312	C12	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
314	C14	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	4.5	4.5
314	C14	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
314	C14	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5.5
314	C14	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	4.5	4.5
314	C14	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
314	C14	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	4.5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
315	C15	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
315	C15	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	5.5	6
315	C15	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	6	5.5
315	C15	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5.5
315	C15	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
315	C15	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
319	C19	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
319	C19	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
319	C19	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5
319	C19	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
319	C19	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
319	C19	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	4.5	4.5
320	C20	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5
320	C20	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4
320	C20	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5
320	C20	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
320	C20	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5
320	C20	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5.5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
321	C21	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	.
321	C21	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	.
321	C21	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	.
321	C21	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	.
321	C21	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	.
321	C21	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	.
401	D01	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
401	D01	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
401	D01	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
401	D01	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	5	5
401	D01	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
401	D01	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	5	5
402	D02	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
402	D02	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5
402	D02	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5
402	D02	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
402	D02	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
402	D02	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
404	D04	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5.5	5
404	D04	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	5.5	5.5
404	D04	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5
404	D04	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
404	D04	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
404	D04	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6.5	6.5	5.5
406	D06	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	4.5
406	D06	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
406	D06	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5.5
406	D06	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
406	D06	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
406	D06	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6
407	D07	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	6	5.5	5
407	D07	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	5
407	D07	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	5.5	5.5
407	D07	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	5	5
407	D07	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
407	D07	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
409	D09	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4
409	D09	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
409	D09	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
409	D09	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	6
409	D09	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
409	D09	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
411	D11	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
411	D11	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	5
411	D11	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	5
411	D11	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5.5
411	D11	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5
411	D11	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	6
412	D12	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5
412	D12	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6
412	D12	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	5
412	D12	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
412	D12	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
412	D12	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
413	D13	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5
413	D13	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
413	D13	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5
413	D13	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
413	D13	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
413	D13	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
418	D18	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
418	D18	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	5	4.5
418	D18	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
418	D18	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6
418	D18	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
418	D18	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	4.5	4.5
420	D20	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	6	5.5	5
420	D20	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	4.5
420	D20	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
420	D20	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
420	D20	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	6	5.5
420	D20	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
423	D23	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
423	D23	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
423	D23	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5.5
423	D23	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
423	D23	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
423	D23	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
424	D24	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	5	5
424	D24	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	5
424	D24	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
424	D24	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
424	D24	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
424	D24	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
425	D25	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
425	D25	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4	4
425	D25	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5
425	D25	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
425	D25	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
425	D25	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
427	D27	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
427	D27	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	4.5
427	D27	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
427	D27	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5
427	D27	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5
427	D27	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5
503	E03	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
503	E03	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5
503	E03	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4.5
503	E03	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
503	E03	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	5
503	E03	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
506	E06	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4
506	E06	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	5.5	5.5
506	E06	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5.5	5
506	E06	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5
506	E06	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
506	E06	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
507	E07	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5
507	E07	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	5
507	E07	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5
507	E07	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	5.5	5.5
507	E07	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5
507	E07	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5
508	E08	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	6.5	6	6.5
508	E08	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6.5	6.5	6.5
508	E08	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5.5
508	E08	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
508	E08	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6.5	6.5	6.5
508	E08	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6
510	E10	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
510	E10	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5.5
510	E10	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
510	E10	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
510	E10	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
510	E10	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
512	E12	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5.5	5
512	E12	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	6
512	E12	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
512	E12	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
512	E12	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5.5
512	E12	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5.5
514	E14	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
514	E14	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	4.5
514	E14	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
514	E14	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6
514	E14	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
514	E14	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
516	E16	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4
516	E16	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
516	E16	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	4.5
516	E16	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5
516	E16	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
516	E16	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
601	F01	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5
601	F01	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
601	F01	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	5.5	5
601	F01	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5.5
601	F01	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
601	F01	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5.5	5.5
602	F02	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	.
602	F02	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	.
602	F02	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	.
602	F02	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	.
602	F02	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	.
602	F02	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	.
605	F05	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5.5
605	F05	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	5.5
605	F05	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5
605	F05	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6.5	6.5
605	F05	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
605	F05	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
606	F06	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4
606	F06	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5
606	F06	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5
606	F06	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
606	F06	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5
606	F06	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5
607	F07	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5
607	F07	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
607	F07	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5
607	F07	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	6	6
607	F07	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5
607	F07	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5
608	F08	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
608	F08	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
608	F08	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5.5
608	F08	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5.5
608	F08	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5
608	F08	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6.5	6	6

Subject No	Screening Number	Treatment	Detail	Parameter	Screening	Post_screening Week2	Post_screening_ EvaluationBaselin
609	F09	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
609	F09	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	5	5
609	F09	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4
609	F09	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5
609	F09	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5
609	F09	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	6	6
613	F13	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5
613	F13	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5
613	F13	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4
613	F13	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5.5	5
613	F13	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	5
613	F13	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
1	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5	4.5
1	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6	6
1	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	4.5
1	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	5.5	6
1	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	6	5.5	5.5
1	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6	5.5
2	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	3.5	3.5
2	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6	5
2	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	4
2	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	5
2	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	4.5
2	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6.5	5.5
3	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5	4
3	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6.5	6.5	6.5	6.5
3	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5	4
3	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5.5	5
3	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
3	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6	5.5
4	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5	5
4	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6	5.5
4	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5	4
4	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	4.5
4	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5	5
4	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
5	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	3.5
5	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	5	4
5	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5	4.5
5	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	4.5
5	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	5	5
5	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5.5	5
6	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3.5
6	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5	5
6	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	4	4
6	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	4.5
6	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	5.5	4.5
6	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
7	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3.5
7	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5	5
7	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4.5	4
7	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5	5
7	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
7	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
8	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5	4.5
8	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
8	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	5
8	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	4.5
8	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
8	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
9	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	3.5	4.5	4.5
9	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5.5
9	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4	4	4	4

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
9	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	5
9	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
9	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5.5	4.5
10	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5	4
10	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
10	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	5	5	4
10	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	5.5	5.5	5.5
10	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	5.5	5.5	5.5
10	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
13	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5	4.5
13	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5	4
13	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	4.5	4.5
13	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	4.5	4.5	4
13	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
13	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
14	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4	4.5	4
14	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6	6
14	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4	4
14	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6	5.5
14	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	5	5.5	5.5
14	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5.5
15	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4.5	4
15	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	5	4.5
15	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5	4
15	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5.5	5.5
15	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5	5
15	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5.5	5.5
16	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3.5
16	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	5.5	5
16	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	3.5
16	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5	4
16	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5	4.5
16	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
17	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4.5	4.5
17	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5	4.5
17	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	6	5	5.5	5
17	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5.5
17	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5
17	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	5
18	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3.5
18	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	5	4.5
18	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4	3
18	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5.5
18	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
18	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	4.5
19	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	5	4	5
19	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	6	5.5
19	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5.5	5.5
19	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
19	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
19	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
20	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	3.5	3.5
20	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5	5
20	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5	4.5
20	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	4.5
20	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
20	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	5
21	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	4	3.5
21	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5	4.5
21	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5	4
21	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6.5	6	6	6
21	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
21	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
22	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	4	3
22	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
22	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4	4
22	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	5
22	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
22	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5	4.5
23	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	4
23	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
23	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5	4
23	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	5.5	5.5	6
23	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
23	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	5
24	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5.5	6	5
24	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
24	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	5	5
24	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	5
24	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
24	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5.5	5
25	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	4
25	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4	4.5
25	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	5	4.5
25	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	4
25	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
25	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
26	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	3.5	3.5
26	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	4.5	4
26	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5	4.5
26	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	4.5	4.5	4.5	4.5
26	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
26	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	4.5	5	4
27	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	4	3.5
27	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5	5
27	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5.5	5
27	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	5
27	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5	5
27	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	4.5
28	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5	4.5
28	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	6	5.5	5.5
28	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5	4.5

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
28	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
28	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5.5	5
28	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
29	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	3.5
29	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5.5	5	5
29	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4	3.5
29	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6.5	6.5	6.5	6
29	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6	6	5.5	5.5
29	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5	5
30	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3.5
30	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5	4.5
30	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5	4.5
30	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	5	4
30	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	4.5	5	4.5
30	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	4.5	4.5	4.5
31	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3	3
31	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4	4
31	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4	3
31	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	5
31	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
31	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	4
32	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5	4.5
32	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
32	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5	4.5
32	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	5
32	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5
32	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5	5
33	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	4
33	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	4.5
33	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5	4.5
33	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	5
33	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5.5	5	4.5
33	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	6	5
34	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	4
34	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	4.5
34	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	4.5	4
34	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	5
34	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5	5
34	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5	4.5
35	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5	3.5
35	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5	5.5
35	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5	5
35	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	4.5	4
35	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	4.5	4.5
35	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
36	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	3
36	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5	4
36	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4	4
36	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	5.5	5
36	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
36	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	4

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
38	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5	4
38	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	4.5
38	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4.5	4.5
38	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
38	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
38	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5	4.5
39	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5.5	5
39	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	5	4.5
39	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	5	5
39	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	5
39	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
39	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5	4.5
40	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3.5	4	3
40	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4	4	4
40	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4.5	4
40	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	4.5	4
40	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	4.5	4.5
40	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	4.5	4.5	4.5
41	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3.5	4	3.5
41	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4	4	3.5	3
41	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	4
41	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	4.5
41	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	4.5	4
41	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	4
42	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4.5	4	4
42	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4	4.5	4.5
42	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4	4
42	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6	5.5
42	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5	5
42	Sonic Massage Applicator	Eye Area	Firmness (palpation)	4.5	4.5	4	4
43	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	4	3.5
43	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4	4	3.5
43	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5.5	5	5
43	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	4
43	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
43	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4.5	4.5
44	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	4	3.5
44	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5.5	4.5
44	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4.5	4
44	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
44	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5
44	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5	5
45	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3	3.5	2.5
45	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	4
45	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4.5	5
45	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	5	5
45	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
45	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
46	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	6.5	5.5	5.5	5
46	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6.5	6.5	6	6.5
46	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	5	5

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
46	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
46	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	6.5	6.5	6	5.5
46	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5.5	5
47	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	4
47	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	5	4.5	4.5
47	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	4	5
47	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	6	5.5
47	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
47	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	5
48	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3.5	4	3.5
48	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5.5	5
48	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4	3.5
48	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	5	4.5
48	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
48	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5	4.5
49	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	4.5	5.5	5
49	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	6	5.5	5.5	5
49	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	4.5	4.5
49	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	4
49	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	5
49	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5.5	5
50	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3.5	3.5	4
50	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5.5	5	5
50	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4	4
50	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	4.5	4.5
50	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	4.5	4.5
50	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	5
51	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	3.5	3.5	2
51	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	5	5	4.5
51	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4.5	4	3.5
51	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5	6	5
51	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5	5
51	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5	5
52	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	4.5	4
52	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	4.5
52	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4.5	4
52	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5
52	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	4.5
52	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5.5	5	5
53	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5	5	5	4
53	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4.5	4.5	4
53	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	5	5	4
53	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5.5	5.5
53	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5
53	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5.5	5	5	4.5
54	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5	3.5
54	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
54	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4	4	3.5	3.5
54	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	4.5
54	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
54	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5.5	5.5

Subject Number	Treatment	Detail	Parameter	Post-screening/ Evaluation Baseline	Post_App	Week4	Week8
55	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	3.5	3.5
55	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	5	5
55	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4	3.5	4	4.5
55	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	5	5	5
55	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	5	5	5
55	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	5.5	6	5
56	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	5.5	5.5	.	5
56	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5.5	5	.	5
56	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4.5	.	5
56	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6.5	6.5	.	5.5
56	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	.	5.5
56	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	5.5	.	5.5
57	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4	3
57	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	4.5	4	4
57	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5.5	5	4.5	4
57	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5.5	5.5	5	4.5
57	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5	5	4.5
57	Sonic Massage Applicator	Eye Area	Firmness (palpation)	6	6	5.5	5
58	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4.5	4	4.5	5
58	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	5	5	4.5	5
58	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	5	4	4	5
58	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	6	6	5.5	5.5
58	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5.5	5.5	5.5	5.5
58	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	5	5
59	Sonic Massage Applicator	Crow's Feet	Fine lines: crow's feet	4	4	3.5	4
59	Sonic Massage Applicator	Crow's Feet	Wrinkles: crow's feet	4.5	4	4	3.5
59	Sonic Massage Applicator	Under Eye	Fine lines: under-eye	4.5	4	4	4
59	Sonic Massage Applicator	Under Eye	Wrinkles: under-eye	5	4.5	4.5	4.5
59	Sonic Massage Applicator	Eye Area	Skin Texture/Smoothness (visual)	5	4.5	4.5	4
59	Sonic Massage Applicator	Eye Area	Firmness (palpation)	5	5	4	4.5

III. Protocol, Protocol Deviation Log

Stephens Study Number: C17-D122

Sponsor Study Number: PBL-17-033

CONFIDENTIAL

This document contains confidential and proprietary information

Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area

STEPHENS STUDY NUMBER:	C17-D122
SPONSOR STUDY NUMBER:	PBL-17-033
SPONSOR:	Clarisonic 17275 NE 67th Court Redmond, Washington 98052
SPONSOR REPRESENTATIVE:	Katherine Ortblad Email: kortblad@clarisonic.com Phone: 425-285-1728
TESTING AND ADMINISTRATIVE FACILITY:	Thomas J. Stephens & Associates, Inc. Texas Research Center 1801 North Glenville Drive, Suite 200 Richardson, Texas 75081 Phone: 972-392-1529 Fax: 972-392-2347
INVESTIGATOR:	Lily Jiang, PhD
SUB-INVESTIGATOR/STUDY PHYSICIAN:	Peter D. Hino, MD, FAAD
SUB-INVESTIGATOR:	Summer Acevedo, PhD
PROPOSED STARTING DATE:	25 Sep 2017
PROPOSED COMPLETION DATE:	12 Jan 2017

Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area

SIGNATURE PAGE

Lily Jiang PhD 9/13/2017
Lily Jiang, PhD pp Thomas J. Stephens Date
Investigator
Thomas J. Stephens & Associates, Inc.

Peter D. Hino, MD
2017.09.25 08:06:14 -05'00'

Peter D. Hino, MD, FAAD Date
Sub-Investigator/Study Physician
Thomas J. Stephens & Associates, Inc.

Summer Acevedo Digitally signed by Summer Acevedo
DN: cn=Summer Acevedo, o=Stephens & Associates, Inc., ou=Dallas Research Center, email=sacevedo@stephens-associates.com, c=US
Date: 2017.09.13 15:54:31 -05'00'

Summer Acevedo, PhD Date
Sub-Investigator
Thomas J. Stephens & Associates, Inc.

Katherine Orchard 9/13/17
Sponsor Representative Date
Clarisonic

TABLE OF CONTENTS

1.0 BACKGROUND INFORMATION

Skin aging is affected by both intrinsic and extrinsic factors. Intrinsic aging is a continuous process that normally begins in the mid-twenties. Extrinsic aging is caused by environmental exposure, primarily UV light. Within normal skin (wrinkle-free), the dermis is composed of abundant type I and type VII collagen, as well as elastin, which provide tissue strength, resiliency, and recoil. The aging process results in a drastic loss of collagen and elastin over time. This results in skin laxity and fragility as well as visible signs associated with aging, such as fine lines/wrinkles at crow's feet and under eye, skin roughness around the eye and lack of firmness around the eye.

Clarisonic has developed an antiaging system consisting of a sonic eye massage applicator. This device consists of a handle and a polymer attachment with Aluminum tips.

- The handle that provides the oscillating motor motion is an existing OTC Clarisonic skin care device that is currently released for sale [key functional parameters of the handle (approximate values): Frequency-75Hz, Duty Cycle-10.9%, Loaded amplitude-average 4.5 degrees (peak to peak)]
- The attachment/applicator operates at oscillating frequency and amplitude similar to existing OTC Clarisonic face brushes. The applicator material is 6063-T6 Aluminum, which is hard anodized and Teflon impregnated.

Fig 1. Image of the sonic eye massage applicator

2.0 TRIAL OBJECTIVES AND PURPOSE

This single-center clinical trial is being conducted to assess the efficacy of the Sponsor's sonic eye massage applicator used with Clarisonic Profile handle and a placebo eye cream. Women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, around the eye area rough skin texture, and around the eye area lack of firmness, including those with self-perceived sensitive skin, will use the Sonic Massage Applicator over the course of an 8-week evaluation period. The clinical study will determine whether the Sonic Massage Applicator when used with the Clarisonic Profile handle to apply a study placebo eye cream provides enhanced efficacy when compared to baseline in women who have used the study placebo eye cream twice per day (morning and evening) for 4 weeks (phase-in period). This study is not an Investigational New Drug or New Drug Application study.

3.0 HYPOTHESIS

During the 8-week evaluation period, the Sponsor's sonic eye massage applicator used with Clarisonic Profile handle and a placebo eye cream will produce a statistically significant improvement in efficacy parameter clinical grading scores over the course of 8 weeks of use when compared with baseline scores.

4.0 STUDY ENDPOINTS

- Clinical grading of efficacy parameters at baseline (pre- and post-application), and weeks 4 and 8.

- VISIA-CR digital images taken at baseline and weeks 4 and 8.
- Monitoring of adverse events (AEs) throughout the course of the study

5.0 TEST MATERIAL INFORMATION

5.1 Study Identification Procedures

Stephens & Associates assigns each study product a unique test material identification number (TMIN) in order to provide proper identification in records and reports.

5.2 Characterization and Stability

The Sponsor assumes responsibility for chemical characterization and stability of the study product(s). Stephens & Associates will record the physical properties of the test materials.

5.3 Study Product Descriptions

The Sponsor will provide the following test materials to be evaluated during the study:

Product Name	Sponsor Code / Formula Number	Marketed or Investigational
Eye Cream	Fla# 818724 1	Investigational
Sonic Massage Applicator	5000797	Investigational
Clarisonic Profile handle	N/A	Marketed

Subjects will apply the placebo eye cream as directed by hand (manually) during the 4-week phase-in period. During the 8-week evaluation period, subjects will apply the placebo eye cream using the sonic eye massage applicator and Clarisonic Profile handle.

5.4 Method of Treatment Assignment

Subjects will be numbered sequentially in the order in which they qualify for entry into the study. All subjects will use the test materials as instructed.

5.5 Study Product Accountability

Upon receipt of the study products at the site, designated study personnel will conduct a complete inventory of all products and assume responsibility for their storage and dispensation. All products sent to the study site will be accounted for and in no case will be used in any unauthorized situation. All used and unused study products will be appropriately inventoried by Stephens.

All supplies sent to the study site will be accounted for and in no case will be used in any unauthorized situation. All used and unused study products will be appropriately inventoried by Stephens. Used eye cream units will be destroyed and unused eye cream units, eye massage applicators, and Clarisonic Profile handles will be returned to the Sponsor according to Stephens SOPs. Documentation will be provided in the study file for any used or unused products not returned by subjects.

5.6 Study Product Dispensing

All study products will be administered only to subjects enrolled in the study, at no cost to the subjects and in accordance with the conditions specified in the protocol.

5.7 Storage of Study Products

The Investigator will agree to keep all study products in a safe and secure area with restricted access in accordance with applicable regulatory requirement(s). Study products will be stored at room temperature.

5.8 Treatment Compliance

Subjects will complete a daily diary, recording test material applications and comments during the course of the study. Diaries will be reviewed for compliance at each post-baseline visit. Test materials will be visually inspected at each post-baseline study visit to evaluate treatment compliance. If subjects do not return their diary or test materials during the study, a verbal confirmation will be obtained for usage compliance and it will be documented as a deviation. Subjects will be reminded to return their diary and test materials at the next study visit (if applicable).

Any suspected noncompliance with the treatment or study instructions (eg, missing applications, not following usage instructions) will be addressed by the Investigator or designee. The Investigator will determine whether a subject's noncompliance will affect the study outcome and whether the subject should be discontinued and/or data should be excluded from statistical analyses.

6.0 SELECTION AND WITHDRAWAL OF SUBJECTS

6.1 Number of Subjects

At least 50 subjects meeting the eligibility requirements are expected to complete participation in the clinical trial.

6.2 Eligibility Criteria

Individuals will be enrolled in the study at the discretion of the Investigator or designee, based on medical history and findings of the pre-study interview and examination. Individuals will be screened for the eligibility criteria listed below prior to study enrollment.

6.2.1 Inclusion Criteria

Individuals who meet all of the following criteria will be eligible to participate in the study:

1. Female, 40 to 65 years of age.

2. In general good health (physical, mental, and social well-being, not merely the absence of disease/infirmity), according to self-report.

3. Having Fitzpatrick skin type I-III (refer to Appendix I: Fitzpatrick Skin Type).

4. Nonsmoker.

5. At screening/visit 1: Individuals with moderate (scores of **4.5** to **6.5** according to a modified Griffiths scale[1], where 0=none and 9=severe; half-points are acceptable to qualify) for the following parameters:
    - Crow's feet fine lines/wrinkles
    - Under eye area fine lines/wrinkles
    - Skin roughness around the eye area
    - Firmness around the eye area

6. At baseline/visit 3: Individuals with moderate (scores of **4.0** to **6.5** according to a modified Griffiths scale[1], where 0=none and 9=severe; half-points are acceptable to qualify) for the following parameters:
    - Crow's feet fine lines/wrinkles
    - Under eye area fine lines/wrinkles
    - Skin roughness around the eye area
    - Firmness around the eye area

7. To qualify for the 8-week evaluation period, subjects must have ≤ **0.5** change in clinical grading scores (change to be evaluated by someone other than the clinical graders) between post-screening week 2 (visit 2) and baseline (visit 3) for all the 4-week clinical grading parameters:
    - Crow's feet fine lines/wrinkles
    - Under eye area fine lines/wrinkles
    - Skin roughness around the eye area
    - Firmness around the eye area

8. At least 50% of subjects will have self-perceived sensitive skin.

9. Willing to provide written informed consent and able to read, speak, write, and understand English.

10. Willing to sign a photography release.

11. Willing to refrain from all facial treatments during the course of the study including facials, facial peels, photo facials, laser treatments, dermabrasion, botulinum toxin (Botox®), injectable filler treatments, intense pulsed light (IPL), acid treatments, tightening treatments, facial plastic surgery, or any other treatment administered by a physician or skin care professional designed to improve the appearance or firmness of facial skin. Waxing and threading are allowed but not facial laser hair removal.

12. Willing to cooperate and participate by following study requirements (including those outlined in section 7.3) for the duration of the study and to report any changes in health status or medications, AE symptoms, or reactions immediately.

13. Willing to agree to return the device in its original condition and not to share the device or take pictures of the study products, and who agree that failure to comply may result in legal action and forfeiture of compensation.

6.2.2 Exclusion Criteria

Individuals who meet any of the following criteria will not be eligible to participate in the study:

1. Who have participated in any antiaging applicator/device study in the past 12 months.

2. Who have an implanted device that is sensitive to magnets.

3. Diagnosed with known allergies to facial skin care products.

4. Who are nursing, pregnant, or planning to become pregnant during the study, according to subject self-report.

5. History of skin cancer within the past 5 years.

6. Having had any facial treatments within 6 months of study start, including facials, facial peels, photo facials, laser treatments, dermabrasion, botulinum toxin (Botox®), injectable filler treatments, intense pulsed light (IPL), acid treatments, tightening treatments, facial plastic surgery, or any other treatment administered by a physician or skin care professional designed to improve the appearance or firmness of facial skin. Waxing and threading are allowed but not facial laser hair removal.

7. Having routinely used any antiaging, antiwrinkle, skin lightening, or antioxidant product (containing alpha/beta/polyhydroxy acids, vitamin C, soy, coenzyme Q10, systemic or topical licorice extract, TEGO® Cosmo C 250, Giga White®, lemon juice extract, emblica extract, etc.), within 2 weeks of study start.

8. Having a health condition and/or pre-existing or dormant dermatologic disease on the face (eg, psoriasis, rosacea, acne, eczema, seborrheic dermatitis, severe excoriations) that the Investigator or designee deems inappropriate for participation or could interfere with the outcome of the study.

9. Who have observable suntan, scars, nevi, excessive hair, tattoos, or other dermal conditions on the face that might influence the test results in the opinion of the Investigator or designee.

10. Having a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (eg, azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or undergoing radiation as determined by study documentation.

11. Having an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc.

12. With any planned surgeries and/or invasive medical procedures during the course of the study.

13. Who are currently participating in any other clinical trial at Stephens, another research facility, or doctor's office or have participated in any clinical trial involving the test area within 2 weeks prior to inclusion into the study at Stephens, at another research facility or doctor's office.

14. Who started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or who plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.

7.0 TREATMENT OF SUBJECTS

7.1 **Informed Consent Form**

An IRB-approved informed consent form (ICF), consistent with the requirements in 21 Code of Federal Regulations (CFR) 50.25, will be given to each prospective subject before participation in any study procedures. The prospective subject will be given as much time as needed to read the ICF and will have the opportunity to have any study-related questions answered to their satisfaction prior to signing the ICF. If further questions exist, the prospective subject will be given sufficient time during the first visit to have questions answered regarding the study and/or the ICF by the Investigator, Sub-Investigator, or study coordinator prior to signing. An original signed ICF for each subject participating in the study will be retained in the study file, and each subject will receive a copy of the signed ICF. The prospective subject will be ineligible to participate in the study without a signed ICF.

Subjects are responsible for the return of the device in the original condition in which it was provided. Failure to comply may result in forfeiture of compensation.

7.2 Subject Identification

Subjects will be assigned a 3-digit number which, when used in conjunction with the clinical study number, will uniquely identify every subject on the study. This number will remain with the subject throughout the study and should be used in all references to the individual in this study. No number will be reassigned once the study begins.

7.3 Subject Instructions

Subjects will be provided with the following instructions to follow during the study:

7.3.1 4-Week Phase-in Period Usage Instructions

- **Eye Cream**: Apply eye cream by hand (manually) twice per day (morning and evening/bedtime) to the eye area using your normal technique after cleansing using your regular facial cleanser and cleansing procedure. Avoid getting the cream in your eyes.

7.3.2 8-Week Evaluation Period Usage Instructions

- Apply Eye Cream using the Sonic Massage Applicator (programmed to run on a 4-5 degree amplitude, 75 Hz and for 1 minute) with Clarisonic Profile handle [Setting 2 (4-5 degrees amplitude, 75 hz)] twice per day (morning and evening/bedtime) to the eye area after cleansing using your regular facial cleanser and cleansing procedure. No instructions on how to cleanse or how long to cleanse will be given.
- Apply a liberal amount of the Eye Cream by hand to the treatment zone outlined below, then use the sonic massage applicator for 30 seconds on each eye area (right and left eye area- specifically under the eye, onto the crow's feet, and above the brow bone).

7.3.3 Subject Instructions for Study Visits

- For visits 1-3 (screening, post-screening, and baseline): Remove all makeup at least 2 hours prior to each scheduled clinic visit. No other topical products (including sunscreen) should be applied to the face or eye area until the study visit has been completed. If you arrive having not removed all makeup, you will be required to remove the residual makeup at the clinic and wait at least 20 minutes prior to procedures.
- For visits 4 and 5 (weeks 4 and 8): Apply the Eye Cream to a clean face using the Sonic Massage Applicator and Clarisonic Profile handle as directed at least 2 hours prior to each study visit. Do not apply any other topical products (including sunscreen) to the face or eye area until the study visit has been completed.
- Bring all applicable test materials to each study visit.

7.3.4 General Study Instructions

- Avoid extended periods of sun exposure, all use of tanning beds, and sunless tanning products for the duration of the study. Extra care should be taken to wear protective clothing, including sunglasses, and avoid sun exposure from 10 AM to 2 PM. Individuals who plan to have sun exposure for greater than 30 minutes will be instructed to use their regular sunscreen (if applicable) or a sunscreen with a history of safe use prior to enrollment into the study.
- Continue use of all regular brands of facial cleanser, color cosmetics, makeup remover, and use the assigned test material for the duration of the study. Individuals must refrain from using any anti-aging products and beginning the use of any new facial products other than the assigned test material. Use of moisturizing foundation and sunscreen will be acceptable as long as the subject has a history of safe usage of the foundation or sunscreen prior to enrollment into the study.

8.0 STUDY DESIGN

8.1 Description

This single-center clinical trial is being conducted over the course of a 4-week phase-in period and a 8-week treatment period to assess the efficacy and tolerance of the Sponsor's sonic massage applicator when used by women with under eye facial fine lines and wrinkles, crow's feet fine lines and wrinkles, around the eye area rough skin texture, and around the eye area lack of firmness, including those with self-perceived sensitive skin.

Screened/candidate subjects will participate in a 4-week phase-in period, which will include screening and clinical grading of efficacy parameters. Subjects will apply the study eye cream twice daily manually (by hand) to the eye area during this time using the technique they normally use to apply eye cream. Subjects who do not have a clinical grading score change greater than 0.5 from visit 2 to visit 3 for the specified parameters will be enrolled in the 8-week evaluation period.

During the 8-week evaluation period, subjects will apply the study eye cream to the eye area twice per day using a sonic massage applicator with Clarisonic Profile handle. Efficacy will be assessed using clinical grading at baseline, post-application, and weeks 4 and 8.

8.2 Outline of Procedures

Procedures/Time Points	4-Week Phase-In Period					
			8-Week Evaluation Period			
	Visit 1	Visit 2	Visit 3		Visit 4	Visit 5
	Screening	Post-screening Week 2 ±3 days	Post-screening/ Evaluation Baseline Week 4 ±3 days	Post-App	Week 4 ±3 days	Week 8 ±3 days
Informed consent, medical history, qualification/enrollment paperwork	X					
Screen to qualify	X		X			
Calibration grading [a]	X					
Clinical Grading of Efficacy Parameters by calibrated grader	X	X	X	X	X	X
VISIA-CR Imaging Procedures [b]			X		X	X
In-clinic product application			X			
Daily diaries	D	C/R/D	C/R/D		C/R/D	C/R
Test material Eye Cream	D	I	I		I/D	C/I
Test material (Sonic Massage Applicator and Clarisonic Profile handle)			D		I	C/I

For test materials and/or daily diaries: D=Distribute, C=Collect, R=Review, , and I=Inspect (visually).
[a] At least 10 subjects (from a separate study) will be selected for repeated (total of twice) clinical grading (calibration grading) of the 4 efficacy parameters prior to study start to ensure reliability and repeatability.
[b] Sample VISIA images will be taken and sent to Sponsor for approval prior to study start.

9.0 CONDUCT OF STUDY

9.1 Prestudy Procedures

1. Prior to the start of the study, prospective subjects will be screened for eligibility requirements by telephone through use of an IRB-approved script.

2. Prospective subjects will be informed of the study instructions as described in section 7.3.4.

3. Prospective subjects will be assigned an appointment time for visiting the clinic.

9.2 Visit 1: Screening for 4-Week Phase-In Period

1. Prospective subjects will be given an IRB-approved ICF (as described in section 7.0) to read and sign. They will have all of their study-related questions answered by the Investigator or designated staff, and if they agree, they will sign the ICF. They will be given a copy of the signed ICF, and the original signed ICF will be kept in the study file.

2. Prospective subjects who sign the ICF will be assigned a screening number and acclimate to ambient temperature and humidity conditions for 15 minutes.

3. Prospective subjects will be screened by the Investigator or designee for qualification criteria.

4. Prospective subjects who pass the initial screening will be graded for all efficacy parameters as described in section 10.1.

5. Screened subjects will complete an eligibility and health questionnaire. Those who meet eligibility requirements will be enrolled into the study and assigned a subject number.

6. Subjects will be provided with a unit of the study eye cream. Usage instructions will be explained as described in section 7.3.1.

7. Subjects will be provided with a calendar of study visits, written study instructions as described in sections 7.3.1, 7.3.3, and 7.3.4, and a daily diary.

9.3 Visit 2: Post-Screening Week 2 (±3 days)

1. A clinician will record concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an AE is reported then the Investigator will be informed and an AE form will be completed. Refer to section 11.0 for AE reporting procedures.

2. Daily diaries will be collected and reviewed for compliance. Subjects who are noncompliant will be counseled that if they continue to be noncompliant, they will be dropped from the study. Diaries will be retained by the testing facility and new diaries will be distributed to the subjects.

3. Test material (eye cream) units will be visually inspected to verify usage compliance. Test material units will be returned to the subjects or new units will be distributed as needed.

4. Subjects will acclimate to ambient temperature and humidity conditions for 15 minutes. Upon acclimation, subjects will participate in clinical grading of efficacy parameters as described in section 10.1.

9.4 Visit 3: Post-Screening Week 4 (±3 days) / Baseline of 8-Week Evaluation Period

1. A clinician will record concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an adverse event (AE) is reported then the Investigator will be informed and an AE form will be completed. Refer to section 11.0 for AE reporting procedures.

2. Daily diaries will be collected and reviewed for compliance. Subjects who are noncompliant will be counseled that if they continue to be noncompliant, they will be dropped from the study. Diaries will be retained by the testing facility and new diaries will be distributed to subjects.

3. Test material (eye cream) units will be visually inspected to verify usage compliance. Test material units will be returned to subjects or new units will be distributed as needed.

4. Subjects will acclimate for 15 minutes in ambient temperature. The designated rooms will be maintained at a temperature of 68-75°F and the relative humidity will range from 35-65%.

5. Subjects will participate in the following procedures:
    - Clinical grading of efficacy parameters as described in section 10.1.

6. Each subject's qualification for entry in the 8-week evaluation period will be reviewed and confirmed. In addition to meeting all study eligibility requirements, subjects must not have a change >0.5 in any of the clinical grading scores for any efficacy grading parameter from visit 2 to visit 3.

7. Subjects who do not qualify for the 8-week evaluation period will be dismissed from the study.

8. Subjects who qualify for the 8-week evaluation period will participate in the following procedures:
    - Digital imaging procedures as described in section 10.2.

9. Subjects will be provided with a Clarisonic Profile handle and Sonic Massage Applicator for application of the study eye cream during the 8-week evaluation period. Subjects will be provided with oral and written usage instructions and will perform the first test material application in the clinic, under supervision of clinic personnel, as described in section 7.3.2.

10. At least 15 minutes after test material application, subjects will participate in the following procedures:
    - Clinical grading of efficacy parameters as described in section 10.1.

9.5 Visit 4: Week 4 (±3 days) of 8-Week Evaluation Period

1. A clinician will record concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an AE is reported, then the Investigator will be informed and an AE form will be completed. Refer to section 11.0 for AE reporting procedures.

2. Daily diaries will be collected and reviewed for compliance. Subjects who are noncompliant will be counseled that if they continue to be noncompliant, they will be dropped from the study. Diaries will be retained by the testing facility and new diaries will be distributed to subjects.

3. All test materials will be visually inspected to verify usage compliance. Test materials will be returned to subjects and/or new units of eye cream will be distributed as needed.

4. Subjects will acclimate for 15 minutes in ambient temperature. The designated rooms will be maintained at a temperature of 68-75°F and the relative humidity will range from 35-65%. Upon acclimation, subjects will participate in the following procedures:
    - Clinical grading of efficacy parameters as described in section 10.1.
    - Digital imaging procedures as described in section 10.2.

9.6 Final Visit: Visit 5: Week 8 (±3 days) of 8-Week Evaluation Period

1. A clinician will record concomitant medications and will ask subjects if they have experienced any changes in their health since the previous visit. If an AE is reported, the Investigator will be informed and an AE form will be completed. Refer to section 11.0 for AE reporting procedures.

2. Daily diaries will be collected and reviewed for compliance. Subjects that are non-compliant may be dropped from the study. Diaries will be retained by the testing facility.

3. All test materials will be visually inspected to verify usage compliance and retained by the testing facility.

4. Subjects will acclimate for 15 minutes in ambient temperature. The designated rooms will be maintained at a temperature of 68-75°F and the relative humidity will range from 35-65%. Upon acclimation, subjects will participate in the following procedures:
    - Clinical grading of efficacy parameters as described in section 10.1.
    - Digital imaging procedures as described in section 10.2.

10.0 ASSESSMENTS

Note that the order of the assessment listed below may be altered from the order indicated in the study visits to help study flow, or at the recommendations of the Sponsor or Investigator. Any change in the order of procedures will not compromise study data.

10.1 **Clinical Grading of Efficacy Parameters**

Clinical grading of efficacy parameters will be performed at screening, post-screening week 2, post-screening week 4/baseline, post-application, and weeks 4 and 8. The efficacy parameters will be assessed on the indicated locations on the subject's face according to the listed numerical definitions (half point scores may be used as necessary to more accurately describe the skin condition):

<u>Fine Lines/Wrinkles: crow's feet</u>
0= No fine lines
1= A few indistinct, shallow fine lines observable
2= A few distinct, shallow fine lines observable
3= Several distinct shallow fine lines observable
4= Distinct shallow and few deeper fine lines observable
5= Deeper fine lines observable
6= Distinct deeper fine lines observable
7= Much deeper fine lines observable
8= Pronounced fine lines observable
9= Significant (severe) fine lines observable

<u>Fine Lines/Wrinkles: under-eye</u>
0= No fine lines
1= A few indistinct, shallow fine lines observable
2= A few distinct, shallow fine lines observable
3= Several distinct shallow fine lines observable
4= Distinct shallow and few deeper fine lines observable
5= Deeper fine lines observable
6= Distinct deeper fine lines observable
7= Much deeper fine lines observable
8= Pronounced fine lines observable
9= Significant (severe) fine lines observable

<u>Tactile Skin Texture/Smoothness (palpation)</u>
0 = No palpable skin roughness, drag and/or surface bumps/depressions
1 = Barely palpable skin roughness, drag and/or surface bumps/depressions
2 = Slightly palpable skin roughness, drag and/or surface bumps/depressions
3 = Slight to mildly palpable skin roughness, drag and/or surface bumps/depressions
4 = Mildly to moderately palpable skin roughness, drag and/or surface bumps/depressions
5 = Moderately palpable skin roughness, drag and/or surface bumps/depressions
6 = Moderately to pronounced palpable skin roughness, drag and/or surface bumps/depressions
7 = Pronounced palpable skin roughness, drag and/or surface bumps/depressions
8 = Pronounced to significantly palpable skin roughness, drag and/or surface bumps/depressions
9 = Significantly (severe) palpable skin roughness, drag and/or surface bumps/depressions

Firmness (palpation)
0=A significantly pliant or flexible skin feel
1=A pronounced to significantly pliant or flexible skin feel
2=A pronounced pliant or flexible skin feel
3=A moderate to pronounced pliant or skin flexible feel
4=A moderate pliant or flexible skin feel
5=A mild to moderate pliant or flexible skin feel
6=A mildly pliant or flexible skin feel
7=A slight to mildly pliant or flexible skin feel
8=A slight to barely detectable pliant or flexible skin feel
9=No evidence of pliant or flexible skin feel

10.2 **VISIA-CR Imaging Procedures**

Digital imaging will be performed at baseline and weeks 4 and 8.

Prior to imaging procedures, clinic personnel will ensure that subjects have a clean face with no makeup as described in the study procedures. Subjects will remove any jewelry from the areas to be photographed and acclimate for at least 15 minutes to ambient conditions within the clinic before any photographs are taken. Subjects will be provided with a black or gray matte headband to keep hair away from the face. A black or gray matte cloth will be draped over the subjects' clothing.

Subjects will be instructed to adopt neutral, nonsmiling expressions with their eyes gently closed, and will be carefully positioned for each photograph.

A total of 15 full-face digital images will be taken of each subject's face (left, right, and center views) using the VISIA CR photo-station (Canfield Imaging Systems, Fairfield, New Jersey) with a Canon Mark II digital SLR camera (Canon Incorporated, Tokyo, Japan) under the following lighting conditions:
Standard lighting 1: visible (bright)
Standard lighting 2: visible
Standard lighting 3: raking light for crow's feet area
Cross-polarized
Parallel polarized

11.0 ADVERSE EVENTS

11.1 **Definition of an AE**

An AE is any untoward medical occurrence in a clinical investigation where a subject is administered a pharmaceutical product/biologic (at any dose), over-the-counter (OTC), cosmetic product, or medical device and which does not necessarily require a causal relationship with a test article. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a product, whether or not considered related to the product. AEs will be recorded on the appropriate case report forms (CRFs) and source documents.

11.2 **Assessment of Severity and Relationship**

The Investigator or designee will evaluate all AEs as to their severity and relation to the test article.

The severity of an AE will be graded as follows:

Mild: Awareness of a sign or symptom but easily tolerated

Moderate: Discomfort sufficient to cause interference with usual activity or to affect clinical status

Severe: Incapacitating with inability to do usual activity or to significantly affect clinical status

The relationship of an AE to the use of the study article will be assessed using the following guidelines, based upon available information:

Unlikely No temporal association, or the cause of the event has been identified, or the test article cannot be implicated

Possible Temporal association, but other etiologies are likely to be the cause; however, involvement of the test article cannot be excluded

Probable Temporal association, other etiologies are possible, but not likely

Definite Clear-cut temporal association¶

Unknown

11.3 **Definition of a Serious Adverse Event**

A serious adverse event (SAE) is any experience or reaction occurring at any dose that results in any of the following outcomes:

- Death,
- Is life-threatening,
- Hospitalization (initial or prolonged),
- Persistent or significant disability/incapacity, or
- Congenital anomaly/birth defect,
- Required intervention to prevent permanent impairment or damage (devices)
- Other Serious (Important Medical Events)

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent 1 of the outcomes listed in this definition. [Note: The term “life-threatening” refers to an event in which the subject was at risk of death at the time of event; it does not refer to an event that hypothetically might have caused death if it was more severe.]

Hospitalization solely for the purpose of diagnostic tests, even if related to an AE, elective hospitalization for an intervention which was already planned before the inclusion of the subject in the study, and admission to a day-care facility may not themselves constitute sufficient grounds to be considered a SAE. Hospitalization is defined as being admitted to a hospital as an in-patient for greater than 24 hours.

11.4 **Procedures for Reporting AEs**

At each visit, the Investigator or designee will question each subject about AEs using an open question and taking care not to influence the subject’s answer (eg, “Have you experienced any changes in your health or medications since the last visit?”). Directed questioning and examination will be performed when appropriate. All reported AEs will be documented on the appropriate forms without omitting any requested and known information. Every time a concomitant therapy is reported during the study, an AE form will be completed if appropriate and the reason for the treatment noted.

The Investigator or designee will have the final authorization to determine if a reaction will be considered an AE. It is the responsibility of the subject to immediately report any adverse reaction or any unresolved reactions or skin changes that occur during and after the study is over.

The Sponsor will be notified of all AEs within 5 business days. Photographs will be taken to document any AEs if possible.

When an AE persists at the end of the study, the Investigator or designee will ensure follow-up with the subject until the Investigator and Sponsor agree that the event is satisfactorily resolved, according to Stephens SOPs.

11.5 **Procedures for Reporting SAEs**

Any SAE that occurs during the study whether related to the treatment or not, expected or not, will be reported to the Sponsor Representative immediately (within 24 hours of being reported to the Investigator) via phone, fax, or email and to the IRB according to their requirements. The applicable form(s) will be issued promptly (within 48 hours of the information being reported to the Investigator) by the Investigator to the Sponsor via fax or email.

11.6 **Procedures for Reporting Pregnancies**

All pregnancies occurring during clinical studies must be reported to the Sponsor by the Investigator or designee within 24 hours of observation or notification of the occurrence. All efforts should be made to obtain follow-up information regarding the outcome of pregnancy and any postnatal sequelae in the infant. Although the occurrence of pregnancy is not an SAE, complications or serious outcomes of the pregnancy must be reported as appropriate. Pregnancy is considered an exclusion criterion for this study. Any subject who becomes pregnant during study participation must promptly discontinue further administration of the test material(s). If any of the test material ingredient(s) are known to cause possible complications with pregnancies and/or birth defects, subjects will be made aware of this information during the informed consent process.

11.7 **Medical Treatment for AEs and SAEs**

For the duration of the study, medical assistance will be provided to the subject for study related problems at no expense, if in the opinion of the study Investigator and Sponsor, the reaction was caused by the use of the study product. Stephens will make all medical arrangements and will provide appropriately selected doctors.

Should a subject choose to see their own doctor, or seek any post-study medical treatment (except for any study-related treatment that is due to the negligence of Thomas J. Stephens & Associates, Inc. or the Sponsor), no reimbursement will be offered.

11.8 **Unanticipated Adverse Reactions**

The Investigator participating under this clinical study plan must report any unanticipated adverse reactions occurring during an investigation to the Sponsor as soon as possible, but no later than 5 working days, after the Investigator first learns of the event.

Unanticipated adverse reactions are defined as any adverse reactions not listed as one of the anticipated reactions listed in the protocol and was not previously identified in nature, severity, or degree of incidence.

11.9 **Anticipated Reactions**

All test materials have the potential to cause some side effects or other reactions. Possible reactions to the test material(s) may include (but are not limited to) subjective sensations (such as itching, burning, stinging, tingling), scaling/dryness, and redness. Additionally, test material(s) applied to the eye areas have the potential to cause eye watering/tearing, redness of the eyes, corneal erosions, and foreign body sensation in the eyes.

It is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, asthma and/or hives. Subjects will be instructed to notify the clinic immediately if they experience an allergic reaction including rash, hives, and itching.

Symptoms of mild irritation, including the examples discussed above, will not be treated as adverse reactions if they are mild in nature. These conditions may or may not resolve over time. Symptoms that are persistent and moderate to severe in nature, or that involve elevation (eg, edema, papules, vesicles, spreading) will be considered AEs.

The Investigator or designee will have the final authorization to determine if a reaction will be considered an AE.

12.0 ATTRITION

Clinical studies may experience attrition. Subjects will be made aware that they are free to withdraw from the study at any time for any reason, without prejudice. Otherwise, every effort will be made to have subjects complete the study as stated in this protocol, ensuring subject safety and following the provisions of the ICF. Reasons for subject withdrawal may include an AE, SAE, subject's request, protocol violation, lost to followup, or other reasons. Subjects lost from the study will be documented on a screening/enrollment log.

If a subject fails to return for a scheduled examination, a representative of Stephens will attempt to contact the subject and determine whether the subject has continued to follow study instructions and intends to continue participation in the study. If so, then the subject will be processed as soon as possible. If a subject is unable to reschedule the visit within the appropriate window, the rescheduled visit outside of the time frame window will be recorded in a note to file and any other applicable Case Report Forms.

A subject who misses 1 study visit may be allowed to continue study participation at the discretion of the Investigator and the Sponsor, provided that the subject has continued to comply with study instructions. In this case, the missed visit will be noted in the screening/enrollment log and recorded as a protocol deviation.
The missed visit cannot be the screening (visit 1), 2 weeks post-screening (visit 2), baseline (visit 3) or last study visit (Visit 5).

13.0 ADVERSE WEATHER PROVISION

Study visits may be delayed if adverse weather conditions present a risk to the safety of persons traveling to the test facility. Visits will be resumed immediately with the earliest acceptable improvement of travel conditions and staff availability. The Sponsor will be notified of changes in scheduled visit dates. Changes will be documented in a note to file.

14.0 PROTOCOL MODIFICATIONS

Protocol amendments will be written to record any changes or formal clarification to the procedures outlined in the protocol. Any violations to the protocol that might significantly affect the completeness, accuracy and/or reliability of the study data or might affect the subjects' rights, safety or well-being will be documented as protocol deviations.

All protocol amendments will be forwarded to the IRB for review and approval prior to implementation. In cases in which the safety of the subjects may be in jeopardy, an amendment or change may be implemented prior to IRB review/approval. Deviations will be submitted to the IRB if it meets the IRB regulations or Sponsor's requirements for review.

Notes to file will be used to identify study discrepancies, provide clarification to anything related to the study and slight variations that do not qualify as a protocol amendment or deviation as determined by the Investigator, Sub-Investigator, Sponsor or IRB. Notes to file are for internal clarification purposes only and will only be submitted to the Sponsor or IRB as needed.

15.0 ETHICAL AND REGULATORY PROCEDURES

15.1 Research Standards/Good Clinical Practice

This study will be conducted in accordance with all applicable guidelines for the protection of human subjects for research as outlined in 21 CFR 50, the accepted standards for Good Clinical Practice (GCP) and the standard practices of Stephens & Associates.

15.2 Quality Control and Quality Assurance

The study will be monitored by Stephens & Associates quality personnel and may be monitored by Sponsor representatives, to ensure that the protocol and GCP guidelines are being followed, and to assist in resolving any difficulties encountered while the study is in progress. Stephens monitoring will be conducted according to Stephens SOPs. Sponsor monitoring may include site visits and frequent communications (telephone, fax, email, letters). Any contact concerning this study will be made with the Sponsor's representative. The criteria for termination of the study will be determined by the Sponsor.

15.3 Institutional Review Board

This study (protocol, ICF and all addenda) will be reviewed and approved by Integ Review IRB. The study will not be activated and subjects will not be consented, receive any study products, or participate in any study procedures until such time as the IRB has approved the protocol and the ICF. In addition, the IRB will review the study before any significant change in the protocol is initiated. After each review, the IRB's approval will be documented in a letter to the Investigator and a copy of the IRB approval letter will be forwarded to the Sponsor.

16.0 STATISTICS

16.1 Statistical Analysis Populations and Demographics

The per-protocol (PP) population will be the primary population for all statistical analyses. The PP population will include all subjects who received treatment and completed the study in general accordance with the protocol. Only the data of completing subjects will be analyzed.

Subjects may be removed from the analysis in the case of an AE, SAE, noncompliance, or Investigator decision. The reason for any subject(s) excluded from an analysis population will be documented in a note to file and included in the study report.

Demographic data and baseline characteristics, including age, gender, race, ethnicity, Fitzpatrick skin type, and sensitive skin (yes/no), will be summarized according to the analysis population for all subjects combined. For continuous variables, descriptive statistics including number of subjects (N), mean, median, standard deviation (SD), minimum (MIN) and maximum (MAX) values will be presented. For categorical variables, the frequency and percentage of each category will be provided.

16.1.1 Determination of Sample Size

The sample size determination of this study is based on the recommendations of the Sponsor.

16.2 Statistical Analysis Plan

The statistical analyses for all evaluations will be conducted separately for the 4-week phase-in period and the 8-week evaluation period.

For the 4-week phase-in period, a descriptive statistical summary will be provided for all efficacy grading parameters. The descriptive statistical summary includes the N, mean, median, SD, MIN, and MAX of scores at all applicable time points. A similar summary table will be provided for the difference between the 2 week post-screening visit (visit 2) and baseline visit (visit 3).

For the 8-week evaluation period, a descriptive statistical summary will be provided for all efficacy grading parameters. The descriptive statistical summary includes the N, mean, median, SD, MIN, and MAX of scores/values at all applicable time points.

The following will be calculated and reported for each evaluation parameter at applicable post-baseline time point(s):

$$\text{Percent mean change from baseline} = \frac{(\text{visit mean score} - \text{baseline mean score}) \times 100}{\text{baseline mean score}}$$

$$\text{Percent of subjects improved/worsened} = \frac{(\text{number of subjects improved/worsened from baseline}) \times 100}{\text{total number of subjects}}$$

Calibration grading raw data will be sent to the sponsor directly. Stephens will not perform statistical analysis.

A more appropriate analysis may be performed, which will be recorded in a note to file and/or in the study report.

Statistical Analysis Plan

Evaluation	Change from baseline	Notes/Interpretation
Clinical Grading of Efficacy Parameters (4-week phase-in period)	Not required	The descriptive statistical summary will be reported including the N, mean, median, SD, MIN, and MAX for the raw score and for the difference between post-screening week 2 (visit 2) and baseline (visit 3).
Clinical Grading of Efficacy Parameters (8-week evaluation period)	Wilcoxon signed-rank test	A decrease in scores indicates an improvement for the indicated parameter.
VISIA-CR Imaging	Not required	Not applicable

All statistical tests will be 2-sided at significance level alpha=0.05 unless specified. P-values will be reported to 3 decimal places (0.000). No multiple testing corrections will be considered in the study. Statistical analyses are performed using SAS software version 9.4 (SAS Statistical Institute). The statistical results will be sent to the Sponsor along the raw data in a Microsoft Excel document at the completion of the study.

17.0 DATA HANDLING AND RECORD KEEPING

Original records (including the study protocol, clinical grading records, medical histories, ICFs, screening/enrollment logs, and any other CRFs used in the study) and a copy of the final study report will be retained on file in the Stephens archives for a minimum of 2 years from study completion. When the archiving time has expired, the study information will either be destroyed or sent to the Sponsor at the Sponsor's expense.

Subject information will be maintained in the strictest confidence. The sponsor will permit trial-related monitoring, audits, IRB review (if applicable) and regulatory review by providing direct access to source data/documents.

17.1.1 Data Processing

At the completion of the study, photographs will be forwarded to the Sponsor according to Stephens SOPs.

17.2 **Data Management and Review**

Clinical grading will be recorded using Stephens electronic data capture (EDC) system, if available, which documents the identity of the evaluator/technician as well as the time and date of all entries, or all corrected entries. Subject report forms can also be provided by Stephens at the Sponsor's request. Paper grading forms will be completed if EDC is unavailable.

The Stephens EDC is a computerized system designed for the collection of clinical data in electronic format. The 3 major aspects of EDC are a graphical user interface for data entry, a validation component to check for user data, and a reporting tool for analysis of the collected data.

The Stephens EDC is compliant with the Food and Drug Administration (FDA) regulations, namely the FDA's 21 CFR Part 11 regulation "Electronic Records; Electronic Signatures" as well as the guidance document entitled, Guidance for Industry, Computerized Systems Used in Clinical Investigations which regulates the use of EDC in clinical trials. A content validation study was performed to ensure proper execution of critical EDC system features.

Data review and analyses will be performed by an independent data committee. The data committee will consist of selected representatives from clinical services, quality assurance and the statistical department of Stephens & Associates. When requested, it will be the responsibility of the independent data committee to send interim topline data within 10 business days of the completion of Visit 3 (baseline and post-application) and after Visit 4 (week 4) to the Sponsor and topline data at 10 business days after completion of Visit 5 (week 8).

18.0 CLINICAL STUDY REPORT

Two (2) clinical study reports (CSR) (separately for the 4-week phase-in period and 8-week evaluation period) will be drafted using Stephens' standard report template and incorporating any documented Sponsor preferences on file with the Stephens Report Department. The draft reports will be submitted to the Sponsor for approval prior to finalization, and revisions may be made at the Sponsor's request.

The draft report will be submitted to the sponsor 30 business days after completion of each study phase. Any additions and changes to the statistical analysis after study completion may delay the issuing of the draft report. Once each draft report has been sent to the Sponsor, the Sponsor will have 6 months to make revisions. If no revisions or comments are received after 6 months, the report will be considered to be approved for finalization. The final report will be sent to the Sponsor at least 10 business days after Sponsor approval or the 6 month period has passed.

Each of the reports will present the information and data obtained during the applicable study period:

- 4-week phase-in period: screening, post-screening week 2, and post-screening week 4
- 8-week evaluation period: baseline, post-application, and weeks 4 and 8

The final report will include (but is not limited to) the following information as applicable:

- Descriptions of test materials
- Subject demographic information
- Summary table of Adverse Events
- Dates of study initiation and completion
- Protocol amendments and deviations
- Biostatistics / data analyses (as applicable)
- Conclusions and data interpretation
- Copies of Case Report Forms (CRFs): Screening/Enrollment Log, Adverse Event Forms, Clinical Grading Records, etc.
- Copy of Final Report on Electronic File Transfer

19.0 REFERENCES

1. Griffiths CE, Wang TS, Hamilton TA, Voorhees JJ, Ellis CN. A photonumeric scale for the assessment of cutaneous photodamage. *Arch Dermatol*. 1992;128(3):347-351.

APPENDIX I: FITZPATRICK SKIN TYPE

The Fitzpatrick skin classification is based on the skin's unprotected response to the first 30 to 45 minutes of sun exposure after a winter season without sun exposure. The categories of skin types are as follows:

I	White; very fair; red or blonde hair; blue eyes; freckles	Always burns easily; never tans
II	White; fair; red or blonde hair; blue, hazel, or green eyes	Always burns easily; tans minimally
III	Cream white; fair with any eye or hair color; very common	Burns moderately; tans gradually
IV	Brown; typical Mediterranean white skin	Burns minimally; always tans well
V	Dark brown; mid-eastern skin types, black hair, olive skin	Rarely burns; tans profusely
VI	Black; black hair, black eyes, black skin	Never burns; deeply pigmented

APPENDIX II: INGREDIENT LIST

Composition of ingredients from **818724 1**

○ View the CAS numbers ◉ View the US INCI names ○ View the EU INCI names

INCI US Name
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER
PHENOXYETHANOL
SODIUM HYDROXIDE
CITRIC ACID
SORBITAN ISOSTEARATE
WATER
POLYSORBATE 60
METHYLPARABEN

APPENDIX III: SUBJECT INSTRUCTIONS

Instructions for Use

Please use the sonic massage applicator to apply the eye cream for **30 seconds** to each eye area per instructions below:

- Clean your skin using your usual cleansing products and routine.
- Closely examine your eye area prior to using the study device.
- Using the spatula measure one scoop of the eye cream (see image).
- Evenly apply the eye cream under the eye, onto the crow's feet, and above brow bone using your ring finger.

- **Do not** use the sonic massage applicator on the **eyelids** or **soft tissues** under the eye area.

- To activate the sonic massage applicator press the on/off button located on the handle.

- **Step 1**: Starting underneath the eye near the nose place the nubs of the sonic massage applicator on the rim of the orbital bone.

- Slowly and gently glide the sonic massage applicator without pressure outwards from the inner corner to the outer corner of the eye area following the orbital bone. Lift the applicator off the skin and repeat 2 more times for a total of 3 repetitions, approximately 10 seconds.

- **Step 2**: Move to the crow's feet area, slowly and gently glide the sonic massage applicator without pressure outward and upward in a lifting motion. Lift the applicator off the skin and repeat 4 more times for a total of 5 repetitions, approximately10 seconds.

- **Step 3**: Move to the upper brow near the bridge of the nose, slowly and gently glide the sonic massage applicator without pressure along the brow bone. Lift the applicator off the skin and repeat 2 more times for a total of 3 repetitions, approximately 10 seconds.

- The Sonic handle has a built-in timer that will automatically turn off after 30 seconds of use.

- Repeat above steps on opposite eye area.

- Use the sonic massage applicator for the recommended 30 seconds for each eye area.

- After Use: Clean the sonic massage applicator with warm soapy water after each use to remove any residue buildup.

Please Remember:

- The study products are for external use only.
- Keep device and all study products away from small children and out of children's

reach.

- Device contains magnets.
- **Do not** get wall adaptor wet.
- Use only the wall adaptor provided.
- **Do not** store the charger in shower or bath and do not immerse in water.
- **Do not** use the charger outdoors.
- Keep the cord away from heated surfaces.
- **Do not** use on open wounds, broken skin, infected or inflamed areas, or skin eruptions.
- Keep the study eye cream out of your eyes.
- **Do not** use on soft tissue of the eye area.
- Choking Hazard.
- Only use the study eye cream provided.
- **Do not** use device if any parts come off or if damaged.
- Charge device as directed.
- **Do not** share device with another user.
- Clean only as directed.
- **Do not** share study details and products on social media.

Protocol Deviations

Subject Number	Date of Deviation Occurrence	Timepoint of Deviation Occurrence	Protocol Section Affected	Description of Deviation
026	1/8/2018	Visit 5: Week 8 (+/- 3 days) of 8 Week Evaluation Period	9.6 - Visit 5: Week 8 (+/- 3 days) of 8 Week Evaluation Period	Subject completed the week 8 visit at 7 day(s) after the ± 3 day window specified in the protocol.
018	10/12/2018	Visit 2: Post Screening (Week 2)	9.3 - Visit 2: Post Screening Week 2 (+/-3 Days)	Subject 018 had grading performed 2 minutes prior to completion of the 20 minute acclimation period specified in the protocol due to not coming to clinic with a clean face.
028	12/6/2017	Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	9.5 - Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	Subject completed the week 4 visit at 3 day(s) after the ± 3 day window specified in the protocol.
020	11/28/2017	Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	9.5 - Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	Subject completed the week 4 visit at 4 day(s) after the ± 3 day window specified in the protocol.
055	12/28/2017	Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	9.5 - Visit 4: Week 4 (+/- 3 days) of 8 Week Evaluation Period	Subject completed the week 4 visit at 6 day(s) after the ± 3 day window specified in the protocol.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:24:45 -05'00'

Lily Jiang, PhD Date

Thomas J. Stephens & Associates, Inc.

IV. IRB Documents

IRB Approval Letters
Member Roster
IRB Site Closure Letter

IRB Statement of Compliance

IntegReview IRB, an independent IRB located in Austin, Texas, was established in 1999 and offers five weekly meetings for review of U.S., Latin American and Japan research sites, quality review by experienced individuals, competitive fees, and quality assurance/control. Designed to accelerate the IRB process without compromising accuracy or the protection of human subjects, IntegReview IRB delivers study documents to the investigator within two business days of board review.

IntegReview IRB is committed to meeting rigorous standards for quality and maintaining sound policies and procedures involved in the protection of human research participants. IntegReview IRB was initially awarded full accreditation of its human research protection program (HRPP) by the Accreditation of Human Research Protection Programs, Inc.® (AAHRPP) in June 2007. AAHRPP accreditation will expire in September of 2020.

Written standard operating procedures govern IntegReview IRB for initial, continuing, full board, expedited and exempt review of clinical research studies. IntegReview IRB complies with the regulations as defined in the United States Food and Drug Administration (FDA), Code of Federal Regulations, Title 21, Parts 50, 54, 56, 312 and 812, International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices, E6, the Department of Health and Human Services (DHHS) regulations as identified in the Code of Federal Regulations, Title 45, Part 46, other regulations as applicable, as well as local and state laws.

Melissa Meyer

Melissa Meyer, CCRP
President

INTEGREVIEW IRB

September 13, 2017

Principal Investigator: Lily Jiang, Ph.D.
Sponsor: Clarisonic
Protocol Number: C17-D122 (PBL-17-033)
Study Title: "Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area"

Dear Dr. Jiang:

The above-referenced study meets the requirements for a research study that may be reviewed through expedited review procedures set forth in federal regulations. Therefore, utilizing the expedited review procedures, initial approval was granted on the above referenced date by **Matthew Pfeiffer, Ph.D.** for IntegReview on the initial review of the above-referenced study.

Approved:

Principal Investigator
Investigative site(s) as submitted with initial submission documents
Protocol Version 1.0 dated 13 Sep 2017
Informed Consent, English language, dated September 13, 2017 (refer to IntegReview modifications as reflected on the following document containing revision marks)

Recruiting/miscellaneous materials:

Six advertisements
One study details
Two questionnaires
One recruiting screener
One study participant interest form

The reviewer reviewed the Package insert, for the study drug(s), as appropriate

Previous study information for the device(s) has also been reviewed.

The reviewer has confirmed this study to be of non-significant risk.

IMPORTANT

- **The following changes in approved research may not be implemented until you have received approval from IntegReview <u>except</u> where necessary to eliminate apparent immediate hazards to the human subjects:**
  - **Protocol Amendments**
  - **Change in the Principal Investigator and/or Sub Principal Investigators (only if the Sub PI's will be performing study-related procedures that the PI is not qualified through expertise to perform)**

  - **Change in the address at the study site or the addition of a study site(s)**
- **Only Informed Consent documents containing IntegReview's approval stamp may be utilized:**
  - **There must be procedures in place to guarantee that consent has been voluntarily obtained and properly documented.**
  - **For participants that do not speak English, the informed consent document must be in a language understandable to them.**
  - **Only IntegReview staff may initiate modifications to Informed Consent documents. The Informed Consent document will be maintained in our computer files, and IntegReview will make all revisions following IRB approval**.
- **Only recruiting materials containing IntegReview's approval stamp may be utilized. All audio/video recording(s) must be submitted for IRB approval prior to broadcast.**
- **Revision requests should be submitted on IntegReview's forms, which are available in IRBManager.**
- **Visit our Website at www.integreview.com for information on research regulations, reporting requirements, Sponsor training, Investigator and research personnel training, etc.**

IntegReview approval for this study expires **September 12, 2018**.

In order to obtain extended IRB approval, IntegReview must receive your form for continuing review two weeks prior to the IRB expiration date. Appropriate forms will be forwarded to you approximately four weeks prior to the approval expiration date. Should the study end before you receive notification, submit a Closure Notification form.

REPORTING REQUIREMENTS

To ensure compliance with the applicable federal regulations as well as International Conference on Harmonisation (ICH), E6: Good Clinical Practice: Consolidated Guideline, and/or IntegReview's requirements, notification of the following are required for review/approval:

- **Report immediately:**
  - Changes in research that were initiated without IRB review and approval to eliminate apparent immediate hazards to the human subjects to ensure the continued safety and welfare of subjects
  - Modifications to previously approved documents
  - Receipt of investigator/site 483, Determination letter or Warning letter
  - If your license is suspended, revoked, placed on probation or restricted in any state or country
  - Safety information that may help to provide additional protections for subject's safety and well-being, throughout the course of the study and after study completion.
  - Communication of results from a research study to subjects when those results directly affect their safety or medical care
  - Reports of pregnancy
- **Report within 10 calendar days of discovery:**
  - Revisions to the report of prior investigations, as applicable
  - Unanticipated adverse device effects, as applicable
  - Non-compliance – Failure by an investigator and/or sponsor to follow IntegReview's requirements, applicable regulations or to protect human research subjects, including but not limited to the principles of the Belmont Report

- Serious non-compliance issues - non-compliance as defined as above and as determined to be serious in a way that adversely affects the rights and welfare of human subjects following the investigation and review by the IRB
- Continuing non-compliance issues – A pattern of repeated non-compliance or serious non-compliance as determined by the IRB
- Significant deviations – Significant deviations are those that deviate from the approved protocol, informed consent process and affect or potentially affect the safety of subjects. IntegReview does not consider protocol deviations to be different from protocol violations.
- Unanticipated problems should be reported regardless of whether they occur during the study, after the study completion, or after participant withdrawal or completion. Any unanticipated problems involving risks to human subjects or others that are (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Examples of problems or events that may meet the definition of unanticipated problems involving risk to subjects or others may include, but are not limited to the following:
  - Imminent threat of a reportable event that has not yet occurred
  - Information indicating a change to the risk/benefit ratio of the research
  - Death
  - Breach of confidentiality, including lost or stolen study documents/data

- **Report within 30 days of acquisition or discovery**
  - New or additional conflicts of interests
- **Submit prior to publication/distribution:**
  - Any modification(s) to the previously approved Informed Consent document
  - New and/or modifications to previously approved recruiting/miscellaneous materials to be seen or heard by subjects
- **Submit two weeks prior to IntegReview approval expiration date:**
  - Continuing review documents
- **Submit upon completion of the study (**that is when all data has been collected):
  - Notification of study closure

At its discretion, IntegReview IRB reserves the right to visit the study site.

IntegReview IRB is organized and operates in accordance with the applicable federal regulations, and ICH Guidelines for Good Clinical Practices, E6. In addition, Standard Operating Procedures have been created to ensure compliance with these regulations and guidelines.

If you have any questions regarding these procedures or if you wish to appeal the decision, you may address your comments to IntegReview. Your comments will be reviewed, discussed and you will receive a response after your request has been considered.

Failure to comply with the Code of Federal Regulations or the requirements or determinations of IntegReview IRB can result in suspension or termination of IntegReview approval.

Sincerely,

Bridget Briseno
Assistant IRB Coordinator

INTEGREVIEW IRB

October 3, 2017

Principal Investigator: Lily Jiang, Ph.D.
Sponsor: Clarisonic
Protocol Number: C17-D122 (PBL-17-033)
Study Title: "Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area"

Dear Dr. Jiang:

The following item(s) received IRB approval on October 3, 2017 via expedited review by Matthew Pfeiffer, Ph.D.:

- One New Eye Massage User Instructions

If you have any questions, please contact me at (512) 326-3001.

Sincerely,

Anthony Mercado
IRB Administrative Associate I

INTEGREVIEW IRB

MEMBERSHIP ROSTER
As of September 5, 2017

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
[M] M. Alexander Kenaston, Chairman [T] M. Alexander Kenaston	Ph.D., M.S. (Toxicology), R.N., CIP	Scientific	Toxicology Research Scientist, representative for first time in human studies, Pharmacology/ Toxicology, Licensed Registered Nurse; previously employed as Project Manager, CRA and CRC for CRO	Non-affiliated Paid Consultant	Scientific members
[M, Th] Susan Parker Ginnings	R.Ph.	Scientific	Previously employed as Hospital Pharmacy Supervisor	Non-affiliated Paid Consultant	Scientific members
[M] Jami Brackeen, Co-chair	CST, CCRP	Scientific	IRB Coordinator, Co-chair, administrative support for IntegReview; former Quality Control Associate for IRB Regulatory Compliance; Certified Surgical Technologist	Full time Employee	Scientific members
[M] Olga Obrda	B.S. (Chemistry)	Scientific	BD Representative; previously employed as Project Management and Business Development for CRO	Non-affiliated Paid Consultant	Scientific members
[M] Bryson Michael Duhon	Pharm.D., BCPS	Scientific	Clinical Assistant Professor UT College of Pharmacy; Adjoint Professor at UT Health Science Center (UTHSCSA) Department of Medicine	Non-affiliated Paid Consultant	Scientific members
[M] Karen Haslund	M.D.	Scientific	Licensed physician, Pediatrics	Non-affiliated Paid Consultant	Scientific members
[M] Ashley Hutson		Non-scientific	Previously volunteered as research subject in clinical trials; homemaker	Non-affiliated Paid Consultant	Non-scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
[F] Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
Non-scientific members represent the general perspective of study participants
Note: In addition to our regular members, we have access to specialists in therapeutic areas not represented on this roster.

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
[T] Charles F. Ryan, Chairman [W] Charles F. Ryan	Ph.D., M.S. (Pharmacology & Toxicology), R.Ph.	Scientific	Representative for first time in human studies; Pharmacology, Toxicology, Radiation Safety, Radioisotope, Nutritional/Food supplements and Medical Foods	Non-affiliated Paid Consultant	Scientific members
[T] Tonya Reed, Co-chair		Non-scientific	IRB Coordinator, administrative support for IntegReview; previously employed as a Project Assistant for CRO	Full time Employee	Non-scientific members
[T] Sara Bartos	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated Paid Consultant	Scientific members
[T] Marcy Goodfleisch	B.S., M.A. (Liberal Studies); Mediator (Civil & Family Dispute Resolution); Graduate work in Communications and English	Non-scientific	Adjunct University Professor; Ethicist; Management & Communication Consultant. Former Clinic Administrator for nationally recognized HIV Clinic and large FQHC community health center.	Non-affiliated Paid Consultant	Non-scientific members
[T] Michael D. Aldridge	Ph.D. (Nursing Education), R.N., CNE	Scientific	Assistant Professor of Nursing; previously employed in various Nursing roles for pediatric intensive care unit, including Specialty Education Coordinator for pediatric ICU, previous experience as an IRB member	Non-affiliated Paid Consultant	Scientific members
[T] Christine du Castel	M.D.	Scientific	Medical Advisor; previously licensed to practice General Medicine in France	Non-affiliated Paid Consultant	Scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
[F] Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
Non-scientific members represent the general perspective of study participants
Note: In addition to our regular members, we have access to specialists in therapeutic areas not represented on this roster.

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
[W] Carolyn Hensler, Chairman	B.S. (Physical Education)	Non-scientific	Quality Assurance and Quality Control Administrator for CRO; previously employed as a Clinical Research Monitor; and Project Manager	Non-affiliated Paid Consultant	Non-scientific members
[W] Angelica Martinez, Co-chair	CCRP	Non-scientific	IRB Coordinator, administrative support for IntegReview	Full time Employee	Non-scientific members
[W] Raymond Carr	R.Ph.	Scientific	Staff Pharmacist	Non-affiliated Paid Consultant	Scientific members
[W] Christopher P. Martin	Pharm.D., M.S., BCPS	Scientific	Clinical Assistant Professor, Division of Pharmacotherapy UT; Clinical Pharmacy Coordinator; Assistant Professor University of Oklahoma Health Sciences Center, College of Pharmacy	Non-affiliated Paid Consultant	Scientific members
[W] Robert A. Blum	Pharm.D.	Scientific	Various experience as a principal investigator for research studies	Non-affiliated Paid Consultant	Scientific members
[Th] Frederick Kopec, Chairman	J.D., B.A. (Philosophy)	Non-scientific	Licensed, Practice of Law, Ethicist	Non-affiliated Paid Consultant	Non-scientific members
[Th] Michael Romain	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated Paid Consultant	Scientific members
[Th] Mary O'Connell		Scientific	Quality & Regulatory Affairs Manager; previously employed as Clinical Research Recruiter, Data Associate, Coordinator and QC Auditor for CRO, IRB Administrator, Emergency Medical Technician Paramedic	Non-affiliated Paid Consultant	Scientific members
[Th] Matthew Pfeiffer	Ph.D. (Pharmacology & Toxicology)	Scientific	Project Manager and CRA for CRO; Representative for first in human studies; clinical and research experience; Pharmacology, Toxicology; CNS, Infectious disease, Metabolic/Endocrine Disorders, Oncology	Non-affiliated Paid Consultant	Scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
[F] Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
Non-scientific members represent the general perspective of study participants
Note: In addition to our regular members, we have access to specialists in therapeutic areas not represented on this roster.

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
[F] Mary Ruwart, Chairman	Ph.D. (Biophysics); B.S. (Biochemistry)	Scientific	Research Scientist, Drug Delivery Systems, Diabetes, GI Diseases, Drug Metabolism	Non-affiliated Paid Consultant	Scientific members
[F] Tamara Britt, Co-chair	B.S., M.A., CIP, CCRP	Scientific	IRB Coordinator, administrative support for IntegReview; previously employed as CRA for CRO, Research/Regulatory Coordinator (Oncology, Psychiatry, Neurology, emergency medicine, military research)	Full time Employee	Scientific members
[F] Laurajo Ryan	Pharm.D., MSc (Clinical Investigations), BCPS, CDE	Scientific	Clinical Associate Professor of Pharmacotherapy UT Austin, Department of Medicine UTHSCSA, Clinical Pharmacist Specialist South Texas Veterans Administration	Non-affiliated Paid Consultant	Scientific members
[F] Dennis Brannon	R.Ph., B.S. (Animal Science)	Scientific	Clinical Research Consultant, Director of Pharmacy; Executive Director Clinical Development; previously employed as Senior Project Manager and CRA for CRO	Non-affiliated Paid Consultant	Scientific members
[F] Bennie C. Lopez	MBA	Non-scientific	Representative for adult and juvenile prisoner population; Teacher with Austin ISD Alternative Learning Center; previously employed as Corrections Officer and retired military	Non-affiliated Paid Consultant	Non-scientific members
[F] Eduardo E. Sandoval	M.D., MBA (Healthcare Administration)	Scientific	Clinical Research Consultant; previously employed as Medical Affairs/Medical Officer, Regional Senior Clinical Research Associate, Quality Assurance Auditor, Clinical Research Manager	Non-affiliated Paid Consultant	Scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
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NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
Victoria Govea	CCRP	Non-scientific	Management support for IntegReview; former IRB Coordinator, Co-chair for IntegReview	Full time Employee	Non-scientific members
Christina H. Walker	M.D., B.S.	Scientific	Physician	Non-affiliated Paid Consultant	Scientific members
Rosa S. Sandoval	B.S. (Chemistry), CCRP	Scientific	Administrative support for IntegReview; former Senior IRB Coordinator, Co-chair; previously employed as Clinical Research Coordinator and Medical Research Assistant for University	Full time Employee	Scientific members
Lynn Goldman	B.S. (Nutrition), MSHP (Healthcare Administration), RD, LD, CCRP	Scientific	Management support for IntegReview; former IRB Coordinator, Co-chair; previously employed as Research Coordinator, Health Care Administration and Education, Clinical Nutrition, Registered Dietician/Certified Pediatric Nutrition Specialist	Full time Employee	Scientific members
Levi Machado	CCRP	Non-scientific	IRB Training Administrator; former IRB Coordinator, Co-chair; previously provided administrative support for IntegReview	Full time Employee	Non-scientific members

[M] Denotes regular Monday board members [T] Denotes regular Tuesday board members [W] Denotes regular Wednesday board members [Th] Denotes regular Thursday board members
[F] Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
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INTEGREVIEW IRB

June 18, 2018

Principal Investigator: Lily Jiang, Ph.D.
Sponsor: Clarisonic
Protocol Number: C17-D122 (PBL-17-033)
Study Title: "Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area"

Dear Dr. Jiang:

The Closure Notification Form submitted on June 18, 2018, for the above referenced study, was reviewed by Matthew Pfeiffer, Ph.D. on June 18, 2018. As a result of this submission, this study site is considered closed in our files.

Please feel free to contact me with any questions at 512-326-3001.

Regards,

Anthony Mercado
IRB Administrative Associate I

V. Sample Forms

Informed Consent Form
Eligibility and Health Questionnaire
Screening Form
Clinical Grading Records
Daily Diary
Instruction for Use/User Guide

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INTEGREVIEW IRB
SEPTEMBER 13, 2017

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	**Thomas J. Stephens & Associate, Inc.**
PROTOCOL NUMBER AND TITLE OF STUDY:	**C17-D122 (PBL-17-033); "Efficacy of a Sonic Eye Massage Applicator to Apply a Placebo Eye Cream on Women With Signs Associated With Aging Skin Around the Eye Area"**
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (INVESTIGATOR/STUDY DOCTOR):	**Lily Jiang, PhD**
TELEPHONE NUMBER DAYTIME:	**972-392-1529**
AFTER HOURS:	**469-766-4781**

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc. is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

This single-center clinical trial is being conducted to assess the efficacy of the Sponsor's Sonic Eye Massage Applicator used with Clarisonic Profile handle and a placebo eye cream. Women with under eye fine lines and wrinkles, crow's feet fine lines and wrinkles, around the eye area rough skin texture, and around the eye area lack of firmness, including those with self-perceived sensitive skin, will use the Sonic Eye Massage Applicator over the course of an 8-week evaluation period. The clinical study will determine whether the Sonic Eye Massage Applicator when used with the Clarisonic Profile handle to apply a study placebo eye cream provides enhanced efficacy when compared to baseline in women who have used the study placebo eye cream twice per day (morning and evening) for 4 weeks (phase-in period). This study is not an Investigational New Drug or New Drug Application study.

"Investigational" means the products are not approved for use to the general public but is under investigation in clinical trials regarding its safety and efficacy.

If you qualify for the study, you will receive:

- Eye Cream
- Sonic Eye Massage Applicator

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- Clarisonic Profile Handle

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last 12 weeks and involve up to 5 visits at the facility. About 70 women in general good health, ages 40 through 65, are expected to be enrolled in this study.

TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last 2 weeks or have participated in any antiaging applicator/device study in the past 12 months.

Subject Responsibilities:

While participating in this research study, you will need to:

- Avoid extended periods of sun exposure, all use of tanning beds, and sunless tanning products for the duration of the study. Extra care should be taken to wear protective clothing, including, sunglasses, and avoid sun exposure from 10 AM to 2 PM
- For visits 1-3(screening, post-screening, and baseline) remove all make-up at least 2 hours prior to each scheduled visit. No other topical products (including sunscreen) should be applied to the face or eye area until the study visit is completed
- For visits 4 and 5 (weeks 4 and 8): Apply the Eye Cream to a clean face using the Sonic Eye Massage Applicator and Clarisonic Profile handle as directed at least 2 hours prior to each study visit. Do not apply any other topical products (including sunscreen) to the face or eye area until the study visit has been completed.
- Continue use of all regular brands of color cosmetics, makeup remover, and use the assigned test material for the duration of the study. Individuals must refrain from using any anti-aging products and beginning the use of any new facial products other than the assigned test material.
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the grader or the study staff if you change your mind about staying in the study.

WHAT WILL HAPPEN DURING THE STUDY

Visit 1-Screening: (will last approximately 1.0-1.5 hours)

Before the study starts, you will be asked to sign 2 copies of this consent form which includes a photography release & HIPAA disclosure (1 copy will be for your records, and 1 copy for clinic records), give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs or supplements.

- Wait and adjust to the temperature of the clinic for 15 minutes
- Have your face looked at by a trained clinical grader to see if you qualify

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If you qualify for the 4-week Phase-In Period, the following procedures will be performed:

1. Receive a unit of the study eye cream and usage instructions
2. Receive a daily diary to record test material use
3. Make your next appointment

Visit 2-Post Screening Week 2: (will last approximately 1-2 hours)
1. Asked about any changes in your health or medications
2. Have your test material visually inspected and returned (new product will be issued as needed)
3. Have your daily diary collected and get a new diary
4. Wait and adjust to the temperature of the clinic for 15 minutes
5. Have your face looked at by a trained clinical grader
6. Make your next appointment

Visit 3-Post Screening/Evaluation/Baseline: (will last approximately 1-1.5 hours)
1. Asked about any changes in your health or medications
1. Have your test material visually inspected and returned (new product will be issued as needed)
2. Have your daily diary collected and get a new diary
3. Wait and adjust to the temperature of the clinic for 15 minutes
4. Have your face looked at by a trained clinical grader for re-qualification to continue on into 8-week evaluation period

If you qualify, the following procedures will be performed:

5. Have photos taken of your face
6. Be given a Sonic and Clarisonic Profile Handle with instructions to use the study products on each eye area for 30 seconds twice per day (morning and evening/bedtime). The Clarisonic Profile Handle has the ability to record how often and how long (in minutes) you use the handle. Subjects that are not compliant with the usage instructions will be dropped from the study.
7. Perform an in-clinic application using the Sonic Eye Massage Applicator with the study eye cream
8. Wait for 15 minutes after product application
9. Have your face looked at by a trained clinical grader

If you do not qualify for the 8-week evaluation period, you will be dismissed from the study.

Visit 4 -(Weeks 4: (will last approximately 1 hours)
1. Asked about any changes in your health or medications
2. Have your test material visually inspected, returned and/or distributed as needed
3. Have your daily diary collected, returned and distributed new diary
4. Wait and adjust to the temperature of the clinic for 15 minutes
5. Have photos taken of your face
6. Have your face looked at by a clinical grader

Visit 5 -(Week 8) : (will last approximately 1 hour)
1. Asked about any changes in your health or medications
2. Have your test material visually inspected, collected
3. Have your daily diary collected.

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4. Wait and adjust to the temperature of the clinic for 15 minutes
5. Have photos taken of your face
6. Have your face looked at by a clinical grader

You are responsible for the return of the device in the original condition in which it was provided. Failure to comply could result in forfeiture of any compensation due

Do not give the test material to other people and keep it out of the reach of children.

POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because these test materials are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Possible side effects of the study products can include:

- Itching
- Burning
- Stinging
- Tingling
- Scaling / Dryness
- Redness

Additionally, test material(s) applied to the eye areas have the potential to cause eye watering/tearing, redness of the eyes, corneal erosions (corneal injury), and foreign body sensation in the eyes.

It is possible for you to develop allergic reactions to the test product. This risk is increased for individuals with a history of allergies, asthma and/or hives. Please notify the clinic immediately if you experience an allergic reaction including rash, hives, and itching.

There may also be rare and unknown side effects, including reactions that may be life threatening.

The Clarisonic Profile handle contains magnets.

ADDITIONAL RISKS OR DISCOMFORTS

There should be no additional risks or discomforts from your participation on this study.

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BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, the study products or procedure may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test material and inform the investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the study test material is safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You may receive a chance to be in a research study that may help others.

There is no promise that your condition will get better. It might stay the same or it might get worse.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The study investigator and study site
- Sponsor company (including monitor(s) and auditor(s))
- Other state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

If you experience a research injury, Thomas J. Stephens & Associates, Inc., will provide or arrange for medical treatment at no cost to you. The sponsor will cover the costs of this treatment. If you choose to see your own personal doctor we will not pay for your expenses. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. Payment for things such as lost wages, expenses other than medical care, or pain and suffering is not offered. To help avoid injury, it is very important to follow all study directions.

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Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Lily Jiang, Ph.D.
*Daytime: (972) 392-1529
*After hours (emergency only) (469)766-4781

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $275.00 for being in the study. You will be paid per completed visit as follows:

Visit #	Compensation (amount)
Visit 1	$50.00
Visit 2	$50.00

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Visit 3	$50.00
Visit 4	$50.00
Visit 5	$75.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit and will receive payment in the form of a check within 2 weeks of your last visit and after the return of the study products.

If you do not qualify to participate in this study you will be paid $20.00 and will receive payment in the form of a check within 2-3 weeks.

Unforeseen circumstances may arise that can result in study visits lasting longer than anticipated (up to 3 hours); no additional compensation is provided in these situations.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

The investigator, the sponsor company, or IntegReview, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information obtained from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you provided before you left the study will be used.

ADDITIONAL COSTS

There are no costs to you for being in the study other than time and travel.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

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THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please circle **YES** or **NO** to the following questions:

A.	Is this document in a language you understand?	YES	NO
B.	Do you understand the information in this consent form?	YES	NO
C.	Have you been given enough time to ask questions and talk about the study?	YES	NO
D.	Have all of your questions been answered to your satisfaction?	YES	NO
E.	Do you think you received enough information about the study?	YES	NO
F.	Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff?	YES	NO
G.	Do you know that you can leave the study at any time without giving a reason and without affecting your health care?	YES	NO
H.	Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities?	YES	NO
I.	Do you know that you cannot be in another study while you are in this study?	YES	NO

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a copy of this consent form to keep for your records.

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SEPTEMBER 13, 2017

Permission To Release Personal Health Information

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study investigator and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The FDA
- Department of Health and Human Services (DHHS) agencies; and
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study investigator in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- developing a better understanding of the disease;
- improving the design of future actual use trials

After the study staff or the study investigator discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study investigator will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study investigator at the address below:

Thomas J. Stephens & Associates, Inc.
1801 N. Glenville, Suite 200
Richardson, Texas 75081

You have the right to see and get a copy of your records related to the study for as long as the study investigator has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study investigator will stop collecting your personal health information unless the information concerns a side effect (a bad effect) related to the study. If a side effect occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about a side effect related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study investigator would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study investigator would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study investigator at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the study investigator conducting this study.

_____
Printed Name of Subject

_____
Signature of Subject

_____
Date

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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SEPTEMBER 13, 2017

PHOTO RELEASE FORM

You give the company paying for this research study the right to use, copy, and give out the pictures taken of your face.

Your pictures may be used on the product package, for advertising or in scientific journals or magazines.

Your pictures may be used as part of a larger presentation, along with other pictures, videos or things like that. Your pictures may also be edited.

The company paying for this research study may give other people or companies permission to use your pictures.

We will try to hide your identity. Your name will not be on the pictures. You have the right to review your pictures and cancel this Photo Release Form.

Statement of Consent:

I have read this release and understand its meaning. I understand I do need to sign this Photo Release Form in order to be in the study.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

You will be given a copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
bgb/9-13-17

Approved
September 13, 2017
IntegReview IRB

Subject Screening Number: _____
Subject Number: _____
Subject Initials: _____

HEALTH & ELIGIBILITY QUESTIONNAIRE

Please use BLACK ink only

Date of Birth: _____ / _____ / _____ **Sex:** ☐ Male ☐ Female

Race: (Mark one or more)
☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander ☐ White

Ethnicity ☐Not Hispanic or Latino ☐Hispanic or Latino

	Please mark (✓) Agree or Disagree to the following questions:	**Agree**	**Disagree**
1.	I am a woman 40-65 years of age		
2.	I am in general good health (physical, mental, and social well-being, not merely the absence of disease/infirmity), according to self report		
3.	I am a nonsmoker.		
4.	I am willing to provide written informed consent and able to read, write, speak and understand English		
5.	I am willing to sign a photography release		
6.	I have not participated in any anti-aging applicator/device studies within 12 months prior to enrollment.		
7.	I am available for **all** study visits, and I am willing to participate by following study requirements for the duration of the study, and to report any changes in health status or medications, adverse event symptoms, or reactions immediately: • For visits 1-3 (screening, post-screening, and baseline): Remove all makeup at least 2 hours prior to each scheduled clinic visit. No other topical products (including sunscreen) should be applied to the face or eye area until the study visit has been completed. If you arrive having not removed all makeup, you will be required to remove the residual makeup at the clinic and wait at least 20 minutes prior to procedures. • For visits 4 and 5 (weeks 4 and 8): Apply the Eye Cream to a clean face using the Sonic Massage Applicator and Clarisonic Profile handle as directed at least 2 hours prior to each study visit. Do not apply any other topical products (including sunscreen) to the face or eye area until the study visit has been completed. • Bring all applicable test materials to each study visit. • Avoid extended periods of sun exposure, all use of tanning beds, and sunless tanning products for the duration of the study. Extra care should be taken to wear protective clothing, including sunglasses, and avoid sun exposure from 10 AM to 2 PM. • Continue use of all regular brands of facial cleanser, color cosmetics, makeup remover, and use the assigned test material for the duration of the study. Individuals must refrain from using any anti-aging products and beginning the use of any new facial products other than the assigned test material. Use of moisturizing foundation will be acceptable as long as the subject has a history of safe usage of the foundation prior to enrollment		

-CONTINUED ON THE BACK-

	Please mark (✓) Agree or Disagree to the following questions:	Agree	Disagree
8.	I have an implanted device that is sensitive to magnets		
9.	I have been diagnosed with known allergies to facial skin care products		
10.	I am nursing, pregnant, or planning to become pregnant during the study		
11.	I have had any facial treatments within 6 months of study start, including facials, facial peels, photo facials, laser treatments, dermabrasion, botulinum toxin (Botox®), injectable filler treatments, intense pulsed light (IPL), acid treatments, tightening treatments, facial plastic surgery, or any other treatment administered by a physician or skin care professional designed to improve the appearance or firmness of facial skin. Waxing and threading are allowed but not facial laser hair removal.		
12.	I am willing to refrain from all facial treatments during the course of the study including facials, facial peels, photo facials, laser treatments, dermabrasion, botulinum toxin (Botox®), injectable filler treatments, intense pulsed light (IPL), acid treatments, tightening treatments, facial plastic surgery, or any other treatment administered by a physician or skin care professional designed to improve the appearance or firmness of facial skin. Waxing and threading are allowed but not facial laser hair removal.		
13.	I routinely use antiaging, antiwrinkle, skin lightening, or antioxidant product (containing alpha/beta/polyhydroxy acids, vitamin C, soy, coenzyme Q10, systemic or topical licorice extract, TEGO® Cosmo C 250, Giga White®, lemon juice extract, emblica extract, etc.), within 2 weeks of study start.		
14.	I am willing to agree to return the device in its original condition and not to share the device or take pictures of the study products, and who agree that failure to comply may result in legal action and forfeiture of compensation.		
15.	I have a history of cancer within the past 5 years		
16.	I have an uncontrolled disease such as asthma, diabetes, high blood pressure, high/low thyroid.		
17.	I have planned surgeries and/or invasive medical procedures during the course of the study		
18.	I have participated in an anti-aging applicator or device study within 12 months prior to enrollment		
19.	I am currently participating in another usage study or have participated in any clinical trial at Stephens or at another research facility or doctor's office within 2 weeks prior to inclusion into the study		
20.	I have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (eg, azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or undergoing radiation		
21.	I have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or I plan on starting, stopping, or changing doses or HRT or hormones for birth control during the study		
22.	I have a health condition and/or pre-existing or dormant dermatologic disease on the face (eg, psoriasis, rosacea, acne, eczema, seborrheic dermatitis, severe excoriations) that the Investigator or designee deems inappropriate for participation or could interfere with the outcome of the study		
23.	I have observable suntan, scars, nevi, excessive hair, tattoos, or other dermal conditions on the face that might influence the test results in the opinion of the Investigator or designee.		

Please mark (✓) your skin sensitivity.

22.	☐ Sensitive ☐ Non-sensitive

Subject Screening Number: _____
Subject Number: _____
Subject Initials: _____

Are you currently participating in any other clinical studies at this time? ☐ **YES** ☐ **NO**

Have you participated in any other clinical studies in the past 2weeks? ☐ **YES** ☐ **NO**

If YES to any of the above questions, please complete the chart below (if NO, please **LEAVE BLANK**)**:**

Type of Study / Study Number or Brief Description of Study	**Test Area on the Body**	**Name of the Research Facility**	**Start Date**	**End Date**
The study listed below is used as example only on how to complete this section, if you are on this type of study, please list it below:				
Patch Test	***Upper Back***	***Stephens & Associates***	***5/2/2013***	***6/13/2013***

This information is correct to the best of my knowledge.*

MEDICAL HISTORY AND MEDICATION QUESTIONNAIRE

Please use BLACK ink only

- **Are you currently taking any medication on a regular basis?** **YES NO**
- **Do you currently have any medical conditions for which you are taking medication or undergoing treatment?** **YES NO**
- **Do you currently have any medical conditions for which you are <u>NOT</u> taking medication or undergoing treatment?** **YES NO**

If YES to any of the questions above, please complete the chart below (if NO to all, please **LEAVE BLANK**):

Medical Conditions or reason for preventative treatment	Date diagnosed or NA if preventative	Name of medication or treatment or NA if not currently taking medication or treatment	Amount (dosage) or NA if not currently taking medication or treatment	Times per day or NA if not currently taking medication or treatment	Start date of medication or treatment or NA if not currently taking medication or treatment	End date of medication or treatment or NA if currently taking medication or treatment
The conditions listed **<u>below are used as examples only</u>** on how to complete this section. **If you currently have any of these conditions, please list them below:**						
***Examples*:** Depression, High Blood Pressure	***8-24-92***	*Examples:* Proloft, Crestopril	***5mg***	***1***	***3-5-12***	***NA***
Examples: Birth control, Heart health	***NA***	*Example:* Seasonaz, Aspirin	***UNK***	***once***	***2010***	***2014***
Examples: Tubal ligation, Hysterectomy	***1992***	*NA*	***NA***	***NA***	***NA***	***NA***

The information in this questionnaire is correct and represents, to the best of my knowledge, an accurate picture of my general health and medications.*

_____

* Subject Signature Date

This Subject qualifies for admission to this 4-Week Phase-In Period: ☐ YES ☐ NO

_____

Interviewer's Signature (Screening) Date

This Subject qualifies for admission to this 8Week Evaluation Period: ☐ YES ☐ NO

_____

Interviewer's Signature (Baseline) Date

Study Number: C17-D122
Sponsor Study Number: PBL-17-033
Screening Number: _____
Subject Number: _____
Subject Initials: _____

Screening Form (Visit 1)

1. Fitzpatrick skin type:

I	II	III	IV	V	VI

2. Moderate (4.5-6.5) Fine lines on **crow's feet area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

3. Moderate (4.5-6.5) Fine Wrinkles on **crow's feet area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

4. Moderate (4.5-6.5) Fine lines on **under eye area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

5. Moderate (4.5-6.5) Wrinkles on **under eye area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

6. Moderate (4.5-6.5) Skin roughness **around the eye area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

7. Moderate (4.5-6.5) Firmness **around the eye area**:

0	1.0	2.0	3.0	4.0	4.5	5.0	5.5	6.0	6.5	7.0	8.0	9.0

8. Does the subject have a health condition and/or pre-existing or dormant dermatologic disease on the face(e.g., psoriasis, rosecea, acne, eczema, seborrheic dermatitis, severe excoriations etc.) deems inappropriate for participation or could interfere with the outcome of the study

No Yes-**DQ**

9. Does the subject have observable sunburn, suntan, scars, nevi, excessive hair, etc. or other dermal conditions on the face that might influence the test results

No Yes-**DQ**

10. Does the subject have a implanted device that is sensitive to maganets?

No Yes- **DQ**

11. Is the subject's medication usage acceptable per protocol?

Yes/NA No-**DQ**

Does the subject qualify for 4-Week Phase-In?

Yes **No-DQ**

Grader's Initials: _____ **Date:** _____

Screening Form (Visit 3)

1. Moderate (4.0-6.5) Fine lines on **crow's feet area**:

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

2. Moderate (4.0-6.5) Wrinkles on **crow's feet area**:

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

3. Moderate (4.0-6.5) Fine lines on **under eye area** :

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

4. Moderate (4.0-6.5) Wrinkles on **under eye area** :

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

5. Moderate (4.0-6.5) Skin roughness **around the eye area** :

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

6. Moderate (4.0-6.5) Firmness **around the eye area**:

0	**1.0**	**2.0**	**3.0**	**4.0**	**4.5**	**5.0**	**5.5**	**6.0**	**6.5**	**7.0**	**8.0**	**9.0**

7. Does the subject have observable sunburn, suntan, scars, nevi, excessive hair, etc. or other dermal conditions on the face that might influence the test results?

No **Yes-DQ**

8. Does the subject qualify for the 8-Week Evaluation Period?

Yes **No-DQ**

Grader's Initials: _____ **Date:** _____
* If answered no, the subject does not qualify for enrollment and will be dismissed from the study.

1. **Does the subject have equal to or less than a 0.5 change in clinical grading scores between the 2 week post-screening visit (visit 2) and baseline visit (visit 3) for all of the following 4-week phase-in period clinical grading parameters?**

Crow's Feet Fine lines/Wrinkles
Under eye are Fine lines/ Wrinkles
Skin roughness around the eye area
Firmness around the eye area

Yes **No-DQ**

Evaluator's Initials: _____ **Date:** _____

Study No: **C17-D122**

Subject: _____

Visit: ☐ Screening ☐ Wk2 Screen ☐ Baseline ☐ Post App

☐ Week 4 ☐ Week 8

Visit Date: _____

Efficacy (Grading)

Site	Parameter	Best Score	Worst Score	Score
Crows Feet	Fine lines	0	9	
Crows Feet	Wrinkles	0	9	
Under Eye	Fine lines	0	9	
Under Eye	Wrinkles	0	9	
Eye Area	Tactile Skin Texture / Smoothness (palpation)	0	9	
Eye Area	Firmness (palpation)	0	9	

Subject Initials: __ __ __ Subject Number:__ __ __

Sample Diary

Please record daily (in INK) the time you applied the product. DO NOT use pencil or white out, or draw arrows ↓ or quotation marks (" "). If you have any problems, please contact **Matthew M.** at **(972) 852-5807 immediately!**

USAGE INSTRUCTIONS:

Apply eye cream by hand (manually) twice per day (morning and evening/bedtime) to the eye area using your normal technique after cleansing using your regular facial cleanser and cleansing procedure. Avoid getting the cream in your eyes.

Date	Day	Application Time		Comments
9/25/2017 Visit 1	Monday	**AM**	**PM**	
9/26/2017	Tuesday	**AM**	**PM**	
9/27/2017	Wednesday	**AM**	**PM**	
9/28/2017	Thursday	**AM**	**PM**	
9/29/2017	Friday	**AM**	**PM**	
9/30/2017	Saturday	**AM**	**PM**	
10/1/2017	Sunday	**AM**	**PM**	
10/2/2017	Monday	**AM**	**PM**	
10/3/2017	Tuesday	**AM**	**PM**	
10/4/2017	Wednesday	**AM**	**PM**	
10/5/2017	Thursday	**AM**	**PM**	
10/6/2017	Friday	**AM**	**PM**	
10/7/2017	Saturday	**AM**	**PM**	
10/8/2017	Sunday	**AM**	**PM**	
10/9/2017 Visit 2	**Monday**	**AM**	**Remove all makup at least 2 hours prior to your appointment time**	

• Avoid extended periods of sun exposure, all use of tanning beds, and sunless tanning products for the duration of the study. Extra care should be taken to wear protective clothing, including sunglasses, and avoid sun exposure from 10 AM to 2 PM. Individuals who plan to have sun exposure for greater than 30 minutes will be instructed to use their regular sunscreen (if applicable) or a sunscreen with a history of safe use prior to enrollment into the study.

• Continue use of all regular brands of facial cleanser, color cosmetics, makeup remover, and use the assigned test material for the duration of the study. Individuals must refrain from using any anti-aging products and beginning the use of any new facial products other than the assigned test material. Use of moisturizing foundation and sunscreen will be acceptable as long as the subject has a history of safe usage of the foundation or sunscreen prior to enrollment into the study.

User Guide

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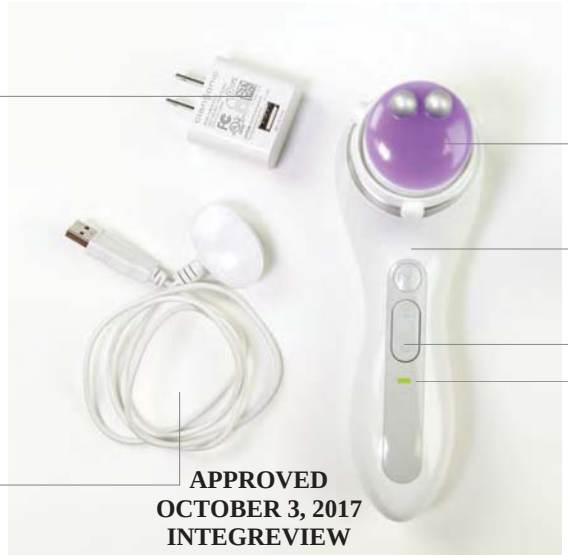

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IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including but not limited to the following:

READ ALL INSTRUCTIONS BEFORE USE

DANGER – To reduce the risk of electrocution:

1. **Do not** place or store the charger or adapter where it can fall or be pulled into a tub or sink.
2. **Do not** place the charger in or drop the charger or plug into water or other liquid. Charger unit is not for immersion or for use in the shower.
3. **Do not** reach for a charger that has fallen into water. Unplug immediately.

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WARNING – To reduce the risk of burns, electrocution, fire, or injury to persons:

1. Close supervision is necessary when this product is used by, on, or near children or physically challenged persons.

2. Use this product only for its intended use as described in this manual.

3. Keep the cord away from heated surfaces.

4. Do not use the charger outdoors.

5. Use only the adapter and accessories supplied by the manufacturer.

Never operate the device handle if it is damaged. Do not operate the charger if it has a damaged cord or adapter, if it is not working properly, if it has been damaged, or dropped into water.

SAVE THESE INSTRUCTIONS

The handle, charger and power adapter have no serviceable parts. If the cord is damaged, the charger must be unplugged and replaced.

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IMPORTANT CAUTIONS AND WARNINGS

If you are under a doctor's care for any skin condition or if you think you may have a skin condition, please consult your physician before using the the sonic massage applicator.

Please **do not** share the applicator.

This product uses magnets.

FCC Statement: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 and Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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With the sonic massage applicator attached, this device automatically adjusts power and timing.

TO USE
Prior to the first use, charge the device for 24 hours.

Please refer to volunteer instructions.

Note: Keep the massage applicator head flush to the skin. Pressing too hard could impede the motion and reduce effectiveness.

The handle is waterproof for use in the shower or bathtub. Refer to Important Safeguards regarding the charger.

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CHARGING

The USB-enabled charger allows the device to be rechargeable using either a traditional wall mount AC adaptor or USB port on a computer. A wall mount AC adaptor and USB plug are included.

The convenient charger magnetically attaches to the device handle as shown.

CHARGING INDICATORS

Action	**Indicator**
Attach charger	Handle emits two pulses.
Charge the handle	The battery life indicator will flash from red to green as it charges.
When fully charged	The battery life indicator will illuminate solid green. Allow 24 hours for a full charge.

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The charger is compatible with 100-240 Volts AC; 50/60Hz, allowing it to be used worldwide with the appropriate country adapter. If the shape of the plug does not fit the power outlet, use an attachment plug adapter of the proper configuration for the power outlet.

BATTERY LIFE

This device has a battery life indicator located just below the applicator head indicator. During and at the end of a cleansing cycle the light will appear green or red depending on the amount of battery life available on the device.

Indicator	Battery Life Level
Solid Green	Full
Flashing Green	High
Flashing Red	Low
Flashing Red, Beeps + Pulses	Empty

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To check the battery life on your handle, press the Turbo button **while the charger is attached** to the handle.

Percentage of Battery Life	**Indicator**
75 – 100%	Numbers 1, 2, 3 & 4 illuminate
50 – 74%	Numbers 1, 2 & 3 illuminate
25 – 49%	Numbers 1 & 2 illuminate
5 – 24%	Number 1 illuminates
Less than 5%	None

STORING

Store it in a cool dry place away from direct sunlight.

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CARING FOR YOUR DEVICE

To keep your device in optimum condition, care for it as follows. Do not use abrasive cleansers or chemicals to clean any part of the device. Do not put any part of the device in the dishwasher.

HANDLE
There are no negative effects created by using common disinfectants such as isopropanol or a bleach solution. However, we suggest gently cleansing the handle with warm soapy water to remove any residue. The handle is sealed and fully waterproof. Never attempt to open the handle for any reason.

CHARGER
IMPORTANT: Unplug the charger, then wipe it with a soft, damp cloth. Do not immerse the charger in water.

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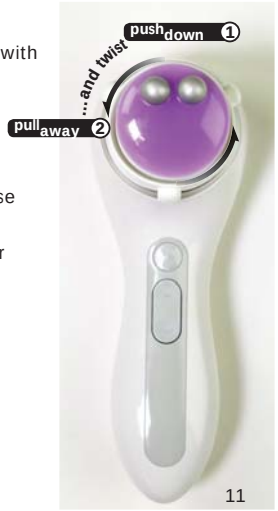
APPLICATOR HEAD
Once a week, remove the applicator head from the handle and rinse with warm soapy water to remove any residue.

To remove the brush head,
1. Grip the applicator head firmly, then push down and twist it counterclockwise (like a medicine cap).
2. Pull the head away from the handle.

To attach the applicator head, push down and twist the head clockwise until it snaps into place. Be sure you hear a tight snap.

TIP: Use the applicator cap to easily remove and attach the applicator head with a simple twist.



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VI. Screening/Enrollment Log

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
A01	JMR	001	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A02	CMH	002	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A06	LSH	003	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A12	TLJ	004	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A13	SKC	005	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A11	K-D	006	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A07	MLI	007	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A08	MLS	008	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A20	KSW	009	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A15	SPW	010	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
A18	MNK	011	09/25/2017	10/23/2017	12/18/2017			Non-Compliance	PP	White or Caucasian	Not Hispanic or Latino	F
A17	I-B	012	09/25/2017	10/23/2017	12/18/2017			Non-Compliance	PP	White or Caucasian	Not Hispanic or Latino	F
A19	DKM	013	09/25/2017	10/23/2017	12/18/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B16	CMR	014	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B02	JAR	015	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B03	JEJ	016	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B09	KKB	017	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B19	YML	018	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B18	CAW	019	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B06	Q-L	020	09/28/2017	10/26/2017	12/19/2017				PP	Asian	Not Hispanic or Latino	F
B21	HTL	021	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B23	TAP	022	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Not Hispanic or Latino	F
B12	NSZ	023	09/28/2017	10/26/2017	12/19/2017				PP	White or Caucasian	Hispanic or Latino	F
C01	LGV	024	10/03/2017	11/01/2017	12/29/2017				PP	White or Caucasian	Not Hispanic or Latino	F

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
C03	SAK	025	10/03/2017	11/01/2017	12/29/2017				PP	White or Caucasian	Not Hispanic or Latino	F
C14	AMS	026	10/03/2017	11/01/2017	01/24/2018				PP	White or Caucasian	Not Hispanic or Latino	F
C02	LMF	027	10/03/2017	11/01/2017	12/29/2017				PP	White or Caucasian	Not Hispanic or Latino	F
C15	JDC	028	10/03/2017	11/01/2017	12/28/2017				PP	White or Caucasian	Not Hispanic or Latino	F
C09	JSC	029	10/03/2017	11/01/2017	12/29/2017				PP	White or Caucasian	Not Hispanic or Latino	F
C19	DJM	030	10/03/2017	11/01/2017	12/29/2017				PP	White or Caucasian	Not Hispanic or Latino	F
D01	R-C	031	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D07	JMR	032	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D11	LHF	033	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D06	M-W	034	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D02	DMM	035	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D09	DLD	036	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
D12	EGH	037	10/11/2017	11/08/2017	12/01/2017			Requested Withdrawal	PP	White or Caucasian	Hispanic or Latino	F
D13	CKW	038	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D20	CLD	039	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D27	Y-U	040	10/11/2017	11/08/2017	01/03/2018				PP	Asian	Not Hispanic or Latino	F
D25	KJT	041	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D18	BRF	042	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D23	SDM	043	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
D24	MMH	044	10/11/2017	11/08/2017	01/03/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E03	C-K	045	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E08	JTP	046	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E14	C-B	047	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E06	T-S	048	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E12	JWJ	049	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E10	JEH	050	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E16	TCK	051	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
E07	DES	052	10/20/2017	11/17/2017	01/12/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F01	LKB	053	10/25/2017	11/20/2017	01/16/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F09	DKC	054	10/25/2017	10/25/2017	01/16/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F13	DJB	055	10/25/2017	11/21/2017	01/16/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F05	DAB	056	10/25/2017	10/25/2017	01/16/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F08	MPS	057	10/25/2017	11/21/2017	01/16/2018				PP	White or Caucasian	Not Hispanic or Latino	F
F07	KTN	058	10/25/2017	11/21/2017	01/16/2018				PP	Asian	Hispanic or Latino	F
F06	T-H	059	10/25/2017	11/21/2017	01/16/2018				PP	Asian	Hispanic or Latino	F

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
C18	EBJ		10/03/2017			Did not meet Inclusion/Exclusion criteria	I5					
S01	TN		11/09/2017									
A03	RAT		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A04	RLK		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A09	SMB		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A10	DAB		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A16	CLB		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A14	D-K		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A21	DLA		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A22	BJM		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A23	RJS		09/25/2017		09/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
B01	CSR		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B04	STH		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B05	JPK		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B07	GCP		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B08	FHK		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B10	S-M		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B11	LCH		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
B13	S-A		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B14	KJS		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B15	N-N		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B17	MKC		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B20	AML		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B22	CLC		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
B24	MLC		09/28/2017		09/28/2017	Did not meet Inclusion/Exclusion criteria	I5					
C04	J-T		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C06	NLW		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C07	ABS		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C08	SEB		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C13	KHK		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C17	AVZ		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C22	DFM		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C23	CCR		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
C24	ARZ		10/03/2017		10/03/2017	Did not meet Inclusion/Exclusion criteria	I5					
D08	HKP		10/11/2017		11/08/2017			Requested Withdrawal				
D03	CDN		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
D05	JLF		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D10	DCS		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D14	JAM		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D15	J-H		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D16	SLL		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D17	ZLF		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	E6					
D19	M-A		10/11/2017		10/11/2017	Did not meet Inclusion/Exclusion criteria	I5					
D21	BMC		10/11/2017		10/11/2017	Full Panel						
D22	NJD		10/11/2017		10/11/2017	Full Panel						
D26	RSJ		10/11/2017		10/11/2017	Full Panel						
E01	KMT		10/20/2017		10/20/2017	Full Panel						
E02	AMB		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E04	L-C		10/20/2017		10/20/2017	Full Panel						
E05	LAG		10/20/2017		10/20/2017	Full Panel						
E09	P-B		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E11	HCP		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I3					
E13	KJJ		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E15	EAB		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E17	PJG		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E18	MAM		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E19	JLS		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I5					
E20	L-S		10/20/2017		10/20/2017	Did not meet Inclusion/Exclusion criteria	I10					

Screening No.	Initials	Subject No.	Consent Signed Date	Enrollment Date	Completion Date	Screen Failure Reason	Failure Detail	Early Term Reason	Data Management	Race	Ethnicity	Gender
E21	HJC		10/20/2017		10/20/2017	Subject Declined Participation						
F03	SSP		10/25/2017		10/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
F10	MGF		10/25/2017		10/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
F04	GMF		10/25/2017		10/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
F11	JGW		10/25/2017		10/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
F12	GRB		10/25/2017		10/25/2017	Did not meet Inclusion/Exclusion criteria	I5					
A05	R-M		09/25/2017		10/23/2017			Exclusion/Inclusion Criteria				
C05	DPB		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
C10	RJE		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
C12	TJG		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
C11	JDB		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
C20	D-B		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
C21	T-R		10/03/2017		11/01/2017			Exclusion/Inclusion Criteria				
D04	BAS		10/11/2017		11/08/2018			Exclusion/Inclusion Criteria				
F02	DGL		10/25/2017		11/21/2017			Exclusion/Inclusion Criteria				
C16	KAL		10/03/2017		11/01/2017			Non-Compliance				

Screening No.	Initials	Subject No.	Birth Date	Age	Fitzpatrick	Sensitive Skin?	Phase 2 Data Managment	Screening	Wk2 Screen	Baseline	Post App	Week 4	Week 8
A01	JMR	001	12/18/1951	65 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A02	CMH	002	02/25/1953	64 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A06	LSH	003	02/22/1954	63 Y	II	Yes	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A12	TLJ	004	12/06/1952	64 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A13	SKC	005	05/17/1956	61 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A11	K-D	006	11/06/1964	52 Y	III	Yes	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A07	MLI	007	08/22/1960	57 Y	III	Yes	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A08	MLS	008	04/14/1953	64 Y	II	Yes	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A20	KSW	009	09/19/1957	60 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A15	SPW	010	02/21/1960	57 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
A18	MNK	011	03/01/1972	45 Y	I	No	ITT	9/25/2017	10/9/2017	10/23/2017	10/23/2017		
A17	I-B	012	11/22/1956	60 Y	II	No	ITT	9/25/2017	10/9/2017	10/23/2017	10/23/2017		
A19	DKM	013	05/13/1960	57 Y	II	No	PP	9/25/2017	10/9/2017	10/23/2017	10/23/2017	11/20/2017	12/18/2017
B16	CMR	014	04/21/1954	63 Y	II	Yes	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B02	JAR	015	04/09/1959	58 Y	II	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B03	JEJ	016	11/22/1955	61 Y	II	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B09	KKB	017	01/29/1962	55 Y	II	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B19	YML	018	10/18/1962	54 Y	II	Yes	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B18	CAW	019	06/16/1961	56 Y	II	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B06	Q-L	020	03/18/1960	57 Y	III	Yes	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/28/2017	12/19/2017
B21	HTL	021	02/22/1961	56 Y	II	Yes	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B23	TAP	022	01/22/1962	55 Y	III	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
B12	NSZ	023	11/19/1955	61 Y	III	No	PP	9/28/2017	10/12/2017	10/26/2017	10/26/2017	11/21/2017	12/19/2017
C01	LGV	024	05/12/1961	56 Y	III	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	12/29/2017

Screening No.	Initials	Subject No.	Birth Date	Age	Fitzpatrick	Sensitive Skin?	Phase 2 Data Managment	Screening	Wk2 Screen	Baseline	Post App	Week 4	Week 8
C03	SAK	025	04/24/1965	52 Y	II	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	12/29/2017
C14	AMS	026	05/16/1960	57 Y	II	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	1/8/2018
C02	LMF	027	09/25/1963	54 Y	III	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	12/29/2017
C15	JDC	028	10/01/1957	60 Y	II	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	12/6/2017	12/28/2017
C09	JSC	029	06/22/1953	64 Y	II	Yes	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	12/29/2017
C19	DJM	030	12/26/1959	57 Y	II	No	PP	10/3/2017	10/17/2017	11/1/2017	11/1/2017	11/28/2017	12/29/2017
D01	R-C	031	04/23/1963	54 Y	III	No	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D07	JMR	032	02/27/1955	62 Y	III	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D11	LHF	033	08/15/1955	62 Y	III	No	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D06	M-W	034	05/27/1953	64 Y	II	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D02	DMM	035	03/30/1954	63 Y	II	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D09	DLD	036	08/04/1965	52 Y	II	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018

Screening No.	Initials	Subject No.	Birth Date	Age	Fitzpatrick	Sensitive Skin?	Phase 2 Data Managment	Screening	Wk2 Screen	Baseline	Post App	Week 4	Week 8
D12	EGH	037	07/17/1952	65 Y	III	Yes	ITT	10/11/2017	10/25/2017	11/8/2017	11/8/2017		
D13	CKW	038	01/13/1968	49 Y	III	No	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D20	CLD	039	10/24/1951	65 Y	III	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D27	Y-U	040	05/09/1959	58 Y	III	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D25	KJT	041	03/11/1955	62 Y	I	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D18	BRF	042	04/23/1976	41 Y	III	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D23	SDM	043	02/06/1970	47 Y	III	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
D24	MMH	044	11/22/1955	61 Y	II	Yes	PP	10/11/2017	10/25/2017	11/8/2017	11/8/2017	12/6/2017	1/3/2018
E03	C-K	045	01/07/1959	58 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E08	JTP	046	12/27/1952	64 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E14	C-B	047	08/05/1966	51 Y	III	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/11/2018
E06	T-S	048	10/05/1957	60 Y	III	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E12	JWJ	049	07/19/1958	59 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E10	JEH	050	05/25/1964	53 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E16	TCK	051	05/22/1958	59 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
E07	DES	052	08/11/1956	61 Y	II	Yes	PP	10/20/2017	11/3/2017	11/17/2017	11/17/2017	12/15/2017	1/12/2018
F01	LKB	053	01/17/1964	53 Y	II	Yes	PP	10/25/2017	11/8/2017	11/20/2017	11/20/2017	12/19/2017	1/16/2018
F09	DKC	054	10/01/1952	65 Y	III	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017	12/19/2017	12/19/2017
F13	DJB	055	10/23/1952	65 Y	III	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017	12/28/2017	1/16/2018
F05	DAB	056	01/03/1952	65 Y	I	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017		1/16/2018
F08	MPS	057	06/11/1953	64 Y	II	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017	12/19/2017	1/16/2018
F07	KTN	058	12/08/1955	61 Y	III	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017	12/19/2017	1/16/2018
F06	T-H	059	06/03/1958	59 Y	III	Yes	PP	10/25/2017	11/8/2017	11/21/2017	11/21/2017	12/19/2017	1/16/2018

VII. Adverse Event Forms

SUBJECT NUMBER	SUBJECT INITIALS	ADVERSE EVENT (MeDRA CODE) Preferred Term	MeDRA VERSION	LOCATION OF EVENT	DATE STARTED DD-MMM-YYYY	DATE ENDED DD-MMM-YYYY	SEVERITY	RELATIONSHIP TO IP	ACTION TAKEN WITH IP	MEDICATION USED?	RESOLUTION	EVENT SERIOUS?
036	DLD	Muscle spasms (10028334)	20.1	Lower Back	20 Oct 2017	05 Nov 2017	Mild	Unlikely	None	Yes	Resolved	No
037	EGH	Vision Blurred (10047513)	20.1	Left and Right Eyes	22 Nov 2017	29 Nov 2017	Mild	Unlikely	Discontinued	No	Resolved	No
053	LKB	burning sensation (10006784)	20.1	Left and Right Eyes	22 Nov 2017	05 Jan 2018	Moderate	Probable	None	Yes	Resolved	No
053	LKB	Eye irritation (10015919)	20.1	Left and Right Eyes	22 Nov 2017	05 Jan 2018	Moderate	Probable	None	Yes	Resolved	No

I confirm that the information given is accurate and complete.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:13:56 -05'00'

Investigator's Signature & Date

AE Narrative

Adverse Event	Description	Initials	Date
Muscle Spasms	The subject contacted the study coordinator on 10/24/2017. The subject informed the study coordinator that she had lower back spasms which started on 10/20/2017. The subject further explained that she had not performed any activities out of her usual daily routine. The subject's symptoms persisted and the subject went to a walk in clinic on 10/23/2017. The walk in clinic physician stated the subject was having back spasms and that she should follow up with her Primary care physician if symptoms continue to persist in a week. The physician prescribed the subject Flexeril for a week to ease the pain and instructed the subject refrain from exercise heavy lifting for the next week. Per the PI, the study coordinator will follow up with the subject on 10/25/2017 during Visit 2.	MM	10/24/2017
Muscle Spasms	The subject came in for her visit 2: screening week 2 visit on 10/31/2017. The subject stated that nothing had changed since she had spoken to the study coordinator on 10/24/2017. Per the PI, she could still stay on the study and will be further evaluated at her baseline visit on 11/08/2017.	MM	10/26/2017
Muscle Spasms	The subject came in for her visit 3: baseline evaluation visit on 11/8/2017. The subject stated that she had	MM	1/3/2018

CONCOMITANT MEDICATION / THERAPY

Drug Name / Therapy	Dosage	Route	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Check if Ongoing (end of study)	Indication
Flexeril	10mg	oral	23-Oct-2017	5-Nov-2017		Back Spasms

I confirm that the information given is accurate and complete.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:15:22 -05'00'

Investigator's Signature & Date

AE Narrative

Adverse Event	Description	Initials	Date
Burred Vision	Subject came in to clinic on 11/29/2017 unannounced and asked to speak with the clinic coordinator for the study. She stated that she no longer wished to participate in the study due to vision being changed/blurred over the past week starting on 11/22/2017. The PI examined and probed the subject further. The subject explained she has a history of cataracts and wears bifocals already due to her vision, although she insisted she felt that the device was changing her vision. Per the PI, the subject declined participation from the reminder of the study and the AE is resolved for study purposes. Also, it was in the opinion of the PI that the device did not change the sight of the subject but was due to her history of cataracts and already lack of superior vision.	MM	12/5/2017

CONCOMITANT MEDICATION / THERAPY

Drug Name / Therapy	Dosage	Route	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Check if Ongoing (end of study)	Indication

I confirm that the information given is accurate and complete.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:17:16 -05'00'

Investigator's Signature & Date

AE Narrative

Adverse Event	Description	Initials	Date
burning sensation/ eye irritation	Subject 053 came into clinic on 12/19/2017 for her Visit 4: Week4 for visit for the evaluation period. The subject explained to the clinic coordinator at check in that she was experiencing	MM	1/3/2018
burning sensation/ eye irritation	The study coordinator attempted to contact that subject on 1/3/2018. The study coordinator left a message for the subject asking about her condition and symptoms. The study leader will	MM	1/3/2018
burning sensation/ eye irritation	The subject came in for her final visit on 1/16/2018. A clinic coordinator followed up with the subject concerning her symptoms. The subject stated she was no longer experiencing any	MM	1/3/2018

CONCOMITANT MEDICATION / THERAPY

Drug Name / Therapy	Dosage	Route	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY	Check if Ongoing (end of study)	Indication
steroidal eye drops	UNK	eyes	27-Nov-2017	4-Dec-2017		burning sensation

I confirm that the information given is accurate and complete.

Digitally signed by Lily Jiang PhD
DN: cn=Lily Jiang PhD, o=Stephens & Associates, ou, email=ljiang@stephens-associates.com, c=US
Date: 2018.06.18 23:19:21 -05'00'

Investigator's Signature & Date

VIII. Room Temperature and Humidity Log

Thomas J. Stephens & Associates, Inc.
SOP-CLN-901-F119
Revised 03 Aug 2017

Study Number:C17-D122
Sponsor Study Number:PLB-17-033

TEMPERATURE AND HUMIDITY LOG

Location: Clinic

Date	Time	Clinician's Initials	Device ID	Temperature (°F)	Relative Humidity (%)	Specified Location
9/25/17	3:00 AM/PM	MM	20 DC	69.4 °F	69 %	Green Blue Red
9/25/17	4:00 AM/PM	MM	20 DC	71.2 °F	62 %	Green Blue Red
9/25/17	5:00 AM/PM	MM	20 DC	70.9 °F	61 %	Green Blue Red
9/28/17	10:00 AM/PM	MM	29 DC	70.2 °F	60 %	Green Red Blue
9/28/17	11:00 AM/PM	MM	29 DC	70.0 °F	57 %	Green Red Blue
10/3/17	4:00 AM/PM	MM	20 DC	71.4 °F	54 %	Green Blue Red
10/3/17	5:00 AM/PM	MM	20 DC	71.3 °F	51 %	Green Blue Red
10/3/17	6:00 AM/PM	MM	20 DC	71.4 °F	50 %	Green Blue Red
10/9/17	3:00 AM/PM	MM	20 DC	68.9 °F	67 %	Green Blue Red
10/9/17	4:00 AM/PM	MM	20 DC	70.2 °F	67 %	Green Blue Red
10/11/17	8:30 AM/PM	MM	20 DC	64.9 °F	45 %	Green Blue Red
10/11/17	9:30 AM/PM	MM	20 DC	64.9 °F	46 %	Green Blue Red
10/11/17	10:30 AM/PM	MM	20 DC	65.1 °F	47 %	Green Blue Red
10/11/17	11:30 AM/PM	MM	20 DC	65.5 °F	47 %	Green Blue Red
10/12/17	10:00 AM/PM	MM	20 DC	68.4 °F	55 %	Green Blue Red
10/12/17	11:00 AM/PM	MM	20 DC	69.8 °F	53 %	Green Blue Red
10/17/17	3:45 AM/PM	MM	20 DC	68.9 °F	38 %	Green Blue Red
10/17/17	4:45 AM/PM	MM	20 DC	69.3 °F	38 %	Green Blue Red
10/20/17	9:30 AM/PM	MM	2 16 mm 10/20/17 DC	70.2 °F	51 %	Green Blue Red

Ambient conditions will be recorded hourly during each study visit.

Thomas J. Stephens & Associates, Inc.
SOP-CLN-901-F119
Revised 03 Aug 2017

Study Number:C17-D122
Sponsor Study Number:PLB-17-033

TEMPERATURE AND HUMIDITY LOG

Location: Clinic

Date	Time	Clinician's Initials	Device ID	Temperature (°F)	Relative Humidity (%)	Specified Location
10/20/17	10:30 AM/PM	MM	16 DC	70.3 °F	53 %	Green Red Blue
10/20/17	11:30 AM/PM	MM	16 DC	70.3 °F	53 %	Green Red Blue
10/23/17	3:00 AM/PM	MM	29 DC	69.4 °F	41 %	Green Red Blue
10/23/17	4:00 AM/PM	MM	29 DC	70.2 °F	44 %	Green Red Blue
10/23/17	5:00 AM/PM	MM	29 DC	71.4 °F	41 %	Green Red Blue
10/23/17	6:00 AM/PM	MM	29 DC	71.1 °F	42 %	Green Red Blue
10/24/17	9:00 AM/PM	MM	26 DC	69.9 °F	40 %	Green Red Blue
10/24/17	10:06 AM/PM	MM	26 DC	68.9 °F	41 %	Green Red Blue
10/26/17	11:00 AM/PM	MM	26 DC	69.0 °F	40 %	Green Red Blue
11/1/17	3:15 AM/PM	MM	16 DC	68.2 °F	55 %	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)
	AM/PM		DC	°F	%	Green Red Blue (1)

Ambient conditions will be recorded hourly during each study visit.

(1) MM 1/25/18

Thomas J. Stephens & Associates, Inc.
SOP-CLN-901-F119
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Study Number:C17-D122
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TEMPERATURE AND HUMIDITY LOG

Location: Clinic

Date	Time	Clinician's Initials	Device ID	Temperature (°F)	Relative Humidity (%)	Specified Location
10/25/17	9:00 AM/PM	MM	20 DC	70.1 °F	53 %	Green (Red) Blue
10/25/17	10:00 AM/PM	MM	20 DC	70.5 °F	53 %	Green (Red) Blue
10/25/17	11:00 AM/PM	MM	20 DC	70.4 °F	54 %	Green (Red) Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue

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① MM 1/25/18

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TEMPERATURE AND HUMIDITY LOG

Location: Clinic

Date	Time	Clinician's Initials	Device ID	Temperature (°F)	Relative Humidity (%)	Specified Location
11/3/17	9:45 AM/PM	MM	16 DC	70.1 °F	55 %	Green Red Blue
11/3/17	10:45 AM/PM	MM	16 DC	69.6 °F	55 %	Green Red Blue
11/17/17	9:45 AM/PM	MM	26 DC	72.1 °F	63 %	Green Red Blue
11/17/17	10:45 AM/PM	MM	26 DC	72.0 °F	63 %	Green Red Blue
11/17/17	11:45 AM/PM	MM	26 DC	72.7 °F	61 %	Green Red Blue
11/20/17	3:00 AM/PM	MM	26 DC	70.1 °F	50 %	Green Red Blue
11/20/17	4:00 AM/PM	MM	26 DC	70.5 °F	50 %	Green Red Blue
11/20/17	5:00 AM/PM	MM	26 DC	70.2 °F	51 %	Green Red Blue
11/21/17	8:45 AM/PM	MM	26 DC	67.8 °F	50 %	Green Red Blue
11/21/17	9:45 AM/PM	MM	26 DC	68.8 °F	49 %	Green Red Blue
11/21/17	10:45 AM/PM	MM	26 DC	70.0 °F	47 %	Green Red Blue
11/28/17	3:00 AM/PM	MM	26 DC	69.1 °F	40 %	Green Red Blue
11/28/17	4:00 AM/PM	MM	26 DC	69.9 °F	41 %	Green Red Blue
11/28/17	5:00 AM/PM	MM	26 DC	70.0 °F	41 %	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue

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MM 1/25/18

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TEMPERATURE AND HUMIDITY LOG

Location: Clinic

Date	Time	Clinician's Initials	Device ID	Temperature (°F)	Relative Humidity (%)	Specified Location
11/8/17	9:00 AM/PM	MM	26 DC	72.3 °F	44 %	Green Blue Red
11/18/17	10:00 AM/PM	MM	26 DC	72.3 °F	44 %	Green Blue Red
11/18/17	3:00 AM/PM	MM	26 DC	70.1 °F	53 %	Green Blue Red
11/18/17	4:00 AM/PM	MM	26 DC	70.1 °F	54 %	Green Blue Red
11/18/17	5:00 AM/PM	MM	26 DC	70.3 °F	55 %	Green Blue Red
12/06/17	9:00 AM/PM	MM	26 DC	69.1 °F	50 %	Green Blue Red
12/06/17	10:00 AM/PM	MM	26 DC	69.7 °F	50 %	Green Blue Red
12/06/17	11:00 AM/PM	MM	26 DC	70.0 °F	50 %	Green Blue Red
12/15/17	10:00 AM/PM	MM	26 DC	73.3 °F	52 %	Green Blue Red
12/15/17	11:00 AM/PM	MM	26 DC	73.3 °F	52 %	Green Blue Red
12/19/17	9:00 AM/PM	MM	26 DC	70.1 °F	44 %	Green Blue Red
12/19/17	10:00 AM/PM	MM	26 DC	70.1 °F	42 %	Green Blue Red
12/19/17	11:00 AM/PM	MM	26 DC	70.6 °F	42 %	Green Blue Red
12/19/17	12:00 AM/PM	MM	26 DC	70.7 °F	42 %	Green Blue Red
	AM/PM		DC	°F	%	Green Blue Red (1)
	AM/PM		DC	°F	%	Green Blue Red (1)
	AM/PM		DC	°F	%	Green Blue Red (1)
	AM/PM		DC	°F	%	Green Blue Red (1)
	AM/PM		DC	°F	%	Green Blue Red (1)

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12/29/17	4:30 AM/PM	MM	26 DC	72.3 °F	30 %	Green Red Blue
1/3/17	3:00 AM/PM	MM	26 DC	71.1 °F	31 %	Green Red Blue
1/3/17	4:00 AM/PM	MM	26 DC	71.2 °F	31 %	Green Red Blue
1/12/17	9:30 AM/PM	MM	26 DC	71.1 °F	32 %	Green Red Blue
1/12/17	10:30 AM/PM	MM	26 DC	71.7 °F	32 %	Green Red Blue
1/16/18	9:00 AM/PM	Kgc	26 DC	70.5 °F	33 %	Green Red Blue
1/16/18	10:00 AM/PM	Kgc	26 DC	72.7 °F	33 %	Green Red Blue
1/16/18	11:00 AM/PM	Kgc	26 DC	74.5 °F	32 %	Green Red Blue
1/16/18	3:45 AM/PM	Kgc	32 DC	73.9 °F	27 %	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue
	AM/PM		DC	°F	%	Green Red Blue

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