Essex Testing Clinic, Inc.

ETC

AMENDED
FINAL REPORT

TEWL/MOISTURIZATION EVALUATION OF A SKIN CARE PRODUCT

Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

Sponsor

Obagi Medical Products
3760 Kilroy Airport Way, Suite 500
Long Beach, CA 90806

Sponsor Representative

JoAnne Watson, DPM

Clinical Testing Facility

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

Sponsor Code: O11
ETC Panel No.: 12250
ETC Entry No.: 22271

Date of Final Report Amendment

9-28-12

ETC Panel No: 12250
ETC Entry No.: 22271

SIGNATURE PAGE

TEWL/MOISTURIZATION EVALUATION OF A SKIN CARE PRODUCT

Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

Reason for Amendment: To correct a typographical error in Section 13.2, page 8.

Bonnie Reilly
Project Manager
Study Director

9/27/12
Date

Toni F. Miller, PhD, DABT, BCFE
Scientific Director
Principal Investigator

9/27/12
Date

QUALITY ASSURANCE STATEMENT

This study (ETC Panel No.: 12250; ETC Entry No.: 22271) was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects – Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

For purposes of this clinical study:

X	Informed Consent was obtained.
____	Informed Consent was not obtained.
X	An IRB review was not required.
____	An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This amended report is considered a true and accurate reflection of the testing methods and source data.

Sherri L. Sayles, MS
Manager, Quality Assurance

28 Sep 2012
Date

TABLE OF CONTENTS

APPENDICES

TEWL/MOISTURIZATION EVALUATION OF A SKIN CARE PRODUCT

Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

1.0 OBJECTIVE

The objective of this study was to determine if the use of a skin care product improved the skin barrier function and moisture content of the skin on a panel 30 female subjects, aged 35-65 years, after a single application.

2.0 SPONSOR

Obagi Medical Products
3760 Kilroy Airport Way, Suite 500
Long Beach, CA 90806

2.1 Sponsor Representative

JoAnne Watson, DPM

3.0 INVESTIGATORS

Study Director:	Bonne Reilly Project Manager
Principal Investigator:	Toni F. Miller, PhD, DABT, BCFE Scientific Director

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 STUDY DATES

	Group 1	Group 2	Group 3	Group 4
Washout Visit:	July 25, 2012	July 26, 2012	July 27, 2012	July 30, 2012
Study Start:	August 1, 2012	August 2, 2012	August 3, 2012	August 6, 2012
Study Finish:	August 1, 2012	August 2, 2012	August 3, 2012	August 6, 2012

6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

7.0 TEST ARTICLE

The test article used in the study was provided by:

Obagi Medical Products
3760 Kilroy Airport Way, Suite 500
Long Beach, CA 90806

It was received on July 11, 2012 and identified as follows:

ETC Entry No.	Qty. Received	Test Article I.D.	Physical Description
22271	1 jar	Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131) Lot# RND06-0104	Off-white Cream

8.0 TEST SUBJECTS

A sufficient number of female subjects, ranging in age from 35 to 65 years of age and in general good health, were to be empanelled so that at least 30 would complete the study.

Each subject was to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

9.0 STUDY DESIGN

9.1 Overall Study Design

The study was an 8-hour study. A sufficient number of female subjects meeting the inclusion/exclusion criteria were enrolled so that 30 subjects would complete the test procedure.

9.2 Study Population

A total of 32 female subjects were enrolled in accordance with the following inclusion/exclusion criteria:

9.2.1 Inclusion Criteria

1. Females between the ages of 35 and 65 years (inclusive) in general good health (no physical required).
2. Individuals with Skin Type I, II or III.
3. Individuals whose arms were free of any cuts, abrasions, etc. that would have interfered with the conduct of the study.
4. Individuals who could read, understand and sign the Informed Consent Form.
5. Individuals who anticipated the ability to follow the study directions, to participate in the study and to return for all visits as per instructions.
6. Individuals who were willing to remain at the Testing Facility for the 8-hour study period.

9.2.2 Exclusion Criteria

1. Women who were pregnant, planning a pregnancy, lactating and/or nursing a child.
2. Individuals with any visible skin disease that might have interfered with the evaluations.
3. Individuals with sunburn, suntan on the arms or planning a vacation with sun-exposure or planning the use of a tanning booth during the course of the study.
4. Individuals engaged in a concurrent research project where the arms were the target site.
5. Individuals taking medications which might have interfered with the test results including the use of steroidal/non-steroidal anti-inflammatory drugs or antihistamines.
6. Individuals with acne, active atopic dermatitis/eczema or psoriasis on the arms.
7. Treatment or history of any type of cancer.
8. Individuals who were currently under treatment for asthma or diabetes.
9. Individuals with a known sensitivity to cosmetics or personal care products.
10. Individuals who had participated in a research project where the arms were the target site within 3 weeks of the study start.
11. Individuals who had undergone a laser re-surfacing or dermabrasion procedure on the arm in the past 2 years or a deep peel in the past 1 year; superficial peel in the past 2 months.

9.0 STUDY DESIGN (CONT'D)

9.3 Test Procedure

The study was designed as an 8-hour study in which the test article was applied to a pre-designated test site by a trained technician.

Subjects reported to the Testing Facility to begin the one-week washout period. Subjects were given a bar of Ivory® soap to use on their arms for the duration of the washout period. Following the one-week washout period, subjects reported to the Testing Facility for the study visit and acclimatized to room conditions for a period of fifteen (15) minutes. Following the 15-minute acclimatization period, a trained technician marked one (1) test site on the right or left volar arm of each subject (measuring 1 x 1 inch) and took a baseline Tewameter® reading and Corneometer® reading at the test site on the forearm. A thin layer of the test material (15 mg) was applied to the designated test site and gently messaged into the skin until absorbed using a finger cot.

At 15 and 30 minutes and 1, 2, 3, and 8 hours post-application, additional Tewameter® and Corneometer® measurements were taken at the test site on the right or left arm. Subjects were required to remain at the Testing Facility until after the 8-hour measurements had been recorded and the study concluded.

Evaluations of efficacy were based on a comparison of pre-application vs. post-application evaluations for the test product.

9.4 Clinical Evaluation Procedures

Evaluations for all parameters were conducted according to the scales and procedures outlined below.

9.4.1 Tewameter® Measurements

Pre- and post-application, skin barrier function was measured at the test site using the Tewameter® (Courage & Khazaka). A decrease in Tewameter® measurements indicated an improvement (increase) in skin barrier function (a decrease in transepidermal water loss). An increase represented a worsening.

9.4.2 Corneometer® Measurements

Pre- and post-application, moisture content of the skin was measured at the test site using the Corneometer® (Courage & Khazaka). An increase in Corneometer® measurements indicated an improvement (increase) in the moisture content of the skin. A decrease represented a worsening.

9.0 STUDY DESIGN (CONT'D)

9.4 Clinical Evaluation Procedures (Cont'd)

9.4.3 Irritation Evaluation

Pre- and post-application, a trained technician evaluated the test site on the arm of each subject for irritation according to the scale below. This evaluation was for safety purposes only and was not used in determining efficacy.

Scale for Scoring Skin Irritation
0 = No evidence of any irritation
+ = Barely perceptible irritation present
1 = Mild irritation present
2 = Moderate irritation present
3 = Marked irritation present
4 = Severe irritation present

10.0 SUBJECT WITHDRAWAL

Subjects may have discontinued voluntarily at any time their participation in the study. However, the Investigator was to record the reason for the discontinuation. The Investigator may also have discontinued a subject. Reasons for withdrawal may include (but were not limited to):

Adverse event
Significant protocol deviation
New event, which was in violation of the Inclusion/Exclusion
New risks discovered in association with the test article
Lost to follow-up
Voluntary withdrawal for personal reasons

When a subject is withdrawn, the Investigator was to document which data, if any, would be analyzed for the discontinued subject. Discontinued subjects were not to be replaced.

Subjects that withdraw from the study due to an adverse event were to be contacted periodically during the 30 days following the event to determine the resolution.

11.0 ADVERSE EVENTS

Any adverse reactions (including stinging, burning, rash, etc.) related to product use was to be reported to the Investigator as soon as possible and recorded on an Adverse Event Form. If, according to the subject, any reported symptoms caused intolerable discomfort or were severe enough in nature, the subject may elect to discontinue or be discontinued by the Testing Facility from further participation in the study.

11.0 ADVERSE EVENTS (CONT'D)

Procedures for Reporting a Serious Adverse Event (SAE)

SAEs were to be reported to OMP, Inc., either by phone or FAX, using the designated OMP, Inc. SAE form within 24 hours of the Investigator becoming aware of the event. If initially reported by phone, a written report was to be provided within 3 business days to the Medical Monitor:

JoAnne Watson
Associate Director, Clinical Affairs
OMP, Inc.
3760 Kilroy Airport Way, Suite 500
Long Beach, CA 90802

Telephone (Pacific Standard Time):	(562) 256-3053
Mobile (After Hours):	(949) 500-3045
Fax (Attention: JoAnne Watson)	(562) 432-5912
Email:	joannew@obagi.com

Pregnancy

Any pregnancy which comes to the attention of the Investigator occurring during the study and up to 30 days after completion of the study must be reported to the **Medical Monitor**, **JoAnne Watson, at OMP,** Inc. as soon as the Investigator becomes aware of the pregnancy. The OMP, Inc. Pregnancy Report Form should be completed by the Investigator. Subjects who became pregnant during the study were to be required to discontinue study treatment products immediately and return to the study site for Study Exit/Early Termination assessments. Subjects may be followed until completion of pregnancy. Every attempt should be made by the Investigator to follow the pregnancy to term with the subject and/or subject's OB/GYN. Pregnancy itself is not considered an AE. A congenital anomaly or birth defect will be reported as an SAE.

12.0 STATISTICAL ANALYSIS

All data points collected post-application were compared to the pre-application data of the test material for differences between the time points. The Investigator was to determine which data, if any, was to be analyzed for discontinued subjects. Discontinued subjects were not to be replaced.

The summation of the difference was analyzed using the Wilcoxon Signed-Rank Test. A response was considered a statistically significant difference from baseline when the p-value was ≤ 0.05.

13.0 RESULTS AND DISCUSSION

A total of 31 female subjects between the ages of 35 and 61 years and with skin types I, II, or III were enrolled onto the study. All 31 (31/31) subjects successfully completed the test procedure. The demographics/skin type of the subjects are presented in Appendix 1. Individual Corneometer® scores and statistical analyses are presented in Appendix 2. Individual Tewameter® scores and statistical analyses are presented in Appendix 3.

13.1 Adverse Events, Deviations, Protocol Amendments

There were no adverse events of any nature to report during the course of the study.

There were no deviations to the protocol to report during the course of the study.

There was no amendment made to the protocol during the course of the study.

13.2 Corneometer® Measurements

At each evaluation a trained technician measured the moisture content of the skin using the Corneometer®. Individual Corneometer® scores for the test article and the statistical analyses are presented in Appendix 2. A summary of the analysis of the mean scores is presented below.

The following table presents a summary of mean Corneometer® scores for each evaluation.

13.0 RESULTS AND DISCUSSION (CONT'D)

13.2 Corneometer® Measurements (Cont'd)

Mean Corneometer® Scores
(% Change from Baseline)

Time Point	Mean Score (% Change from Baseline)
Baseline	42.2 -
15 Minutes	69.0* (63.5%)
30 Minutes	74.2* (75.8%)
1 Hour	79.1* (87.4%)
2 Hours	80.8* (91.5%)
3 Hours	79.2* (87.7%)
8 Hours	64.3* (52.4%)

*Statistically significant difference from baseline, $p \leq 0.05$.

When measurements taken 15 and 30 minutes and 1, 2, 3 and 8 hours post-application were compared with baseline there was:

- a 63.5%, 75.8%, 87.4%, 91.5%, 87.7%, and 52.4% increase (improvement) in the moisture content of the skin at 15 and 30 minutes and 1, 2, 3, and 8 hours, respectively, for Test Article: **Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131) Lot# RND06-0104.**

The greatest improvement in skin moisture was observed at 2 hours post-application (91.5%) when compared with baseline.

The improvements observed at all evaluations were statistically significant ($p<0.001$) when compared with baseline.

13.0 RESULTS AND DISCUSSION (CONT'D)

13.3 Tewameter® Measurements

At each evaluation a trained technician measured the skin barrier function of the skin using the Tewameter®. Individual Tewameter® scores for the test article and the statistical analyses are presented in Appendix 3. A summary of the analysis of the mean scores is presented below.

The following table presents a summary of mean Tewameter® scores for each evaluation.

Mean Tewameter® Scores
(% Change from Baseline)

Time Point	Mean Score (% Change from Baseline)
Baseline	8.8 -
15 Minutes	5.8* (-34.1%)
30 Minutes	5.0* (-43.2%)
1 Hour	4.7* (-46.6%)
2 Hours	4.7* (-46.6%)
3 Hours	4.6* (-47.7%)
8 Hours	4.3* (-51.1%)

*Statistically significant difference from baseline, $p \leq 0.05$

When measurements taken 15 and 30 minutes and 1, 2, 3 and 8 hours post-application were compared with baseline there was:

- a 34.1%, 43.2%, 46.6%, 46.6%, 47.7%, and 51.1% decrease (improvement) in transepidermal water loss at 15 and 30 minutes and 1, 2, 3, and 8 hours, respectively.

The greatest improvement in transepidermal water loss was observed at 8 hours post-application (51.1%) when compared with baseline.

The improvements observed in transepidermal water loss at all evaluations were statistically significant ($p<0.001$) when compared with baseline.

14.0 CONCLUSIONS

An 8-hour TEWL/moisturization evaluation was conducted in 31 subjects with Test Article: **Obagi Moisturizer Formula #006-40-012 (GS #BK-12-0131) Lot# RND06-0104.**

Improvements in skin moisture were observed throughout the 8-hour observation time, and all were statistically significant.

Improvements in skin barrier function, indicated by decreases in transepidermal water loss, were observed throughout the 8-hour observation time, and all were statistically significant.

ETC Panel No.: 12250
ETC Entry No.: 22271

APPENDIX 1

TABLE 1

SUBJECT DEMOGRAPHICS

Test Articles: Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131) Lot# RND06-0104

Subject No.	Initials	Age	Sex	Race	Subject No.	Initials	Age	Sex	Race
1	CLC	50	F	CA	17	TMA	43	F	CA
2	GEM	57	F	CA	18	TAM	49	F	CA
3	C-K	47	F	CA	19	C-C	51	F	CA
4	M-M	47	F	CA	20	M-C	54	F	CA
5	JLP	57	F	CA	21	DMP	46	F	CA
6	T-V	50	F	CA	22	KSD	49	F	CA
7	R-T	54	F	CA	23	K-K	42	F	CA
8	E-D	56	F	CA	24	LMV	50	F	CA
9	ESW	61	F	CA	25	NMB	53	F	CA
10	M-S	54	F	CA	26	PAW	51	F	CA
11	NAS	49	F	CA	27	K-B	47	F	CA
12	K-B	58	F	CA	28	EEM	56	F	CA
13	JMC	53	F	CA	29	C-Z	35	F	HS
14	CAR	52	F	CA	30	L-H	48	F	CA
15	L-L	52	F	CA	31	JAJ	58	F	CA
16	HRS	51	F	CA					

CA = Caucasian
HS = Hispanic

ETC Panel No.: 12250
ETC Entry Nos.: 22271

APPENDIX 1 (CONT'D)

TABLE 2

SKIN TYPE CLASSIFICATION – FITZPATRICK SCALE

Test Articles: Obagi Moisturizer Formula #006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

Subject No.	Skin Type Classification	Subject No.	Skin Type Classification
1	III	17	II
2	I	18	III
3	II	19	II
4	II	20	II
5	III	21	II
6	III	22	III
7	III	23	III
8	II	24	III
9	III	25	III
10	III	26	II
11	III	27	III
12	II	28	I
13	III	29	II
14	III	30	III
15	III	31	I
16	III		

Skin Classification Fitzpatrick Scale:
Skin Type I – Always burns easily; never tans (sensitive)
Skin Type II – Always burns easily; tans minimally (sensitive)
Skin Type III – Burns moderately; tans gradually (light brown/normal)
Skin Type IV – Burns minimally, always tans well (moderate brown/normal)
Skin Type V – Rarely burns; tans profusely (dark brown/insensitive)

ETC Panel No.: 12250
ETC Entry No.: 22271

APPENDIX 2

CORNEOMETER® MEASUREMENTS

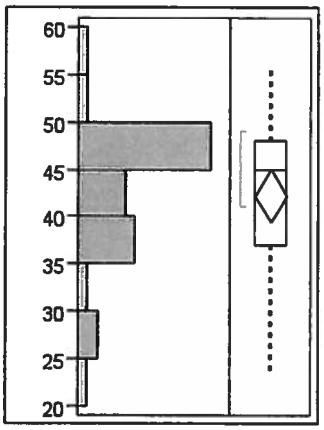
Test Article: Obagi Moisturizer Formula# 006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

Subject No.	Baseline	15 Mins	30 Mins	1 Hours	2 Hours	3 Hours	8 Hours
1	37	65	69	71	78	78	52
2	40	84	86	87	88	70	59
3	49	62	63	67	69	71	58
4	23	46	48	70	76	79	67
5	49	51	62	71	72	75	67
6	54	75	75	78	79	75	61
7	45	59	64	67	75	77	59
8	38	66	68	72	74	77	59
9	49	80	81	83	83	72	68
10	47	62	77	83	84	79	69
11	41	77	83	81	84	82	64
12	46	72	81	87	84	87	72
13	37	81	86	88	87	93	70
14	38	74	79	81	82	80	58
15	28	72	71	74	75	75	53
16	42	67	75	79	83	59	51
17	45	66	79	80	82	87	60
18	47	77	79	88	88	87	64
19	48	78	79	75	80	87	64
20	28	73	71	71	77	76	58
21	41	78	81	83	82	88	69
22	32	60	60	73	74	72	68
23	49	77	79	80	82	77	68
24	37	73	74	82	84	84	82
25	49	70	80	85	84	86	78
26	45	62	82	85	86	89	77
27	56	66	81	83	83	81	70
28	46	57	65	85	90	83	58
29	36	74	79	80	82	83	85
30	46	78	76	84	80	75	59
31	41	58	67	79	78	70	46
MEAN	**42.2**	**69.0**	**74.2**	**79.1**	**80.8**	**79.2**	**64.3**

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
Baseline

B



Quantiles

100.0%	maximum	56
99.5%		56
97.5%		56
90.0%		49
75.0%	quartile	48
50.0%	median	45
25.0%	quartile	37
10.0%		28.8
2.5%		23
0.5%		23
0.0%	minimum	23

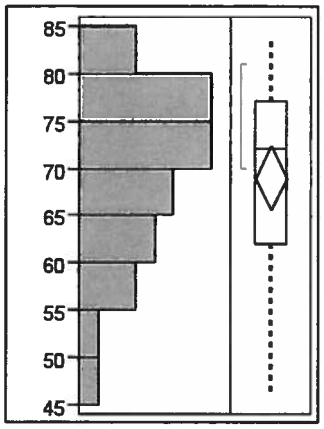
Moments

Mean	42.225806
Std Dev	7.6319927
Std Err Mean	1.3707463
Upper 95% Mean	45.025244
Lower 95% Mean	39.426369
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
15 Minutes

15



Quantiles

100.0%	maximum	84
99.5%		84
97.5%		84
90.0%		79.6
75.0%	quartile	77
50.0%	median	72
25.0%	quartile	62
10.0%		57.2
2.5%		46
0.5%		46
0.0%	minimum	46

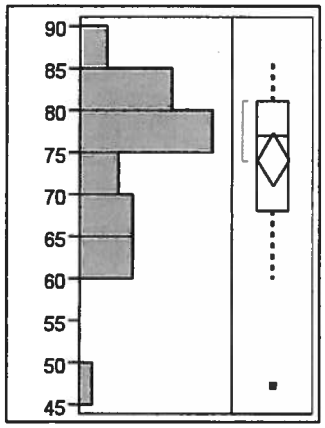
Moments

Mean	69.032258
Std Dev	9.2285205
Std Err Mean	1.6574912
Upper 95% Mean	72.417307
Lower 95% Mean	65.647209
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
30 Minutes

30



Quantiles

100.0%	maximum	86
99.5%		86
97.5%		86
90.0%		82.8
75.0%	quartile	81
50.0%	median	77
25.0%	quartile	68
10.0%		62.2
2.5%		48
0.5%		48
0.0%	minimum	48

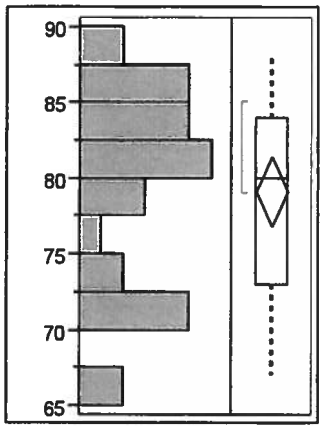
Moments

Mean	74.193548
Std Dev	8.707925
Std Err Mean	1.5639895
Upper 95% Mean	77.387641
Lower 95% Mean	70.999456
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
1 Hour

1hr



Quantiles

100.0%	maximum	88
99.5%		88
97.5%		88
90.0%		87
75.0%	quartile	84
50.0%	median	80
25.0%	quartile	73
10.0%		70.2
2.5%		67
0.5%		67
0.0%	minimum	67

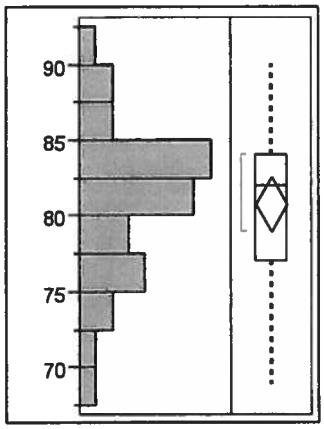
Moments

Mean	79.096774
Std Dev	6.3105987
Std Err Mean	1.133417
Upper 95% Mean	81.41152
Lower 95% Mean	76.782028
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
2 Hour

2hr



Quantiles

100.0%	maximum	90
99.5%		90
97.5%		90
90.0%		87.8
75.0%	quartile	84
50.0%	median	82
25.0%	quartile	77
10.0%		74
2.5%		69
0.5%		69
0.0%	minimum	69

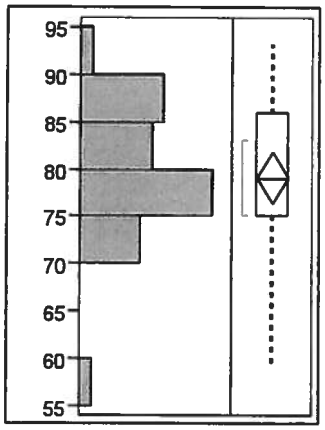
Moments

Mean	80.806452
Std Dev	5.0359994
Std Err Mean	0.9044922
Upper 95% Mean	82.653671
Lower 95% Mean	78.959232
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
3 Hour

3hr



Quantiles

100.0%	maximum	93
99.5%		93
97.5%		93
90.0%		87.8
75.0%	quartile	86
50.0%	median	79
25.0%	quartile	75
10.0%		70.2
2.5%		59
0.5%		59
0.0%	minimum	59

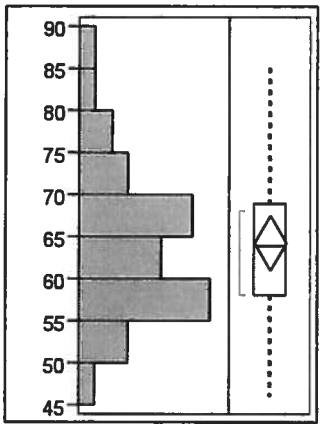
Moments

Mean	79.16129
Std Dev	7.2161706
Std Err Mean	1.2960625
Upper 95% Mean	81.808203
Lower 95% Mean	76.514378
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
8 Hour

8 hr



Quantiles

100.0%	maximum	85
99.5%		85
97.5%		85
90.0%		77.8
75.0%	quartile	69
50.0%	median	64
25.0%	quartile	58
10.0%		52.2
2.5%		46
0.5%		46
0.0%	minimum	46

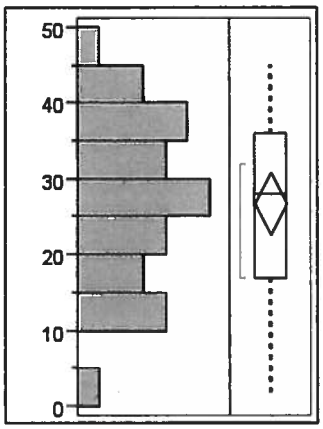
Moments

Mean	64.290323
Std Dev	8.9561657
Std Err Mean	1.6085748
Upper 95% Mean	67.575471
Lower 95% Mean	61.005174
N	31

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
15 Minutes

15-B



Quantiles

100.0%	maximum	45
99.5%		45
97.5%		45
90.0%		44
75.0%	quartile	36
50.0%	median	28
25.0%	quartile	17
10.0%		11.4
2.5%		2
0.5%		2
0.0%	minimum	2

Moments

Mean	26.806452
Std Dev	11.142769
Std Err Mean	2.0013003
Upper 95% Mean	30.893652
Lower 95% Mean	22.719251
N	31

Test Mean=value

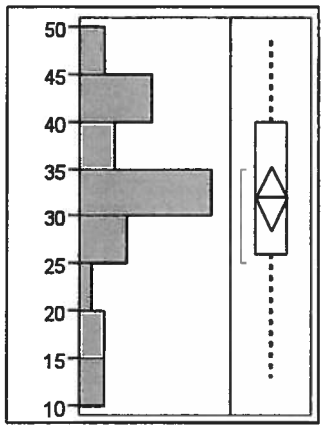
Hypothesized Value	0
Actual Estimate	26.8065
DF	30
Std Dev	11.1428

	t Test	Signed-Rank
Test Statistic	13.3945	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
30 Minutes

30-B



Quantiles

100.0%	maximum	49
99.5%		49
97.5%		49
90.0%		43
75.0%	quartile	40
50.0%	median	32
25.0%	quartile	26
10.0%		19
2.5%		13
0.5%		13
0.0%	minimum	13

Moments

Mean	31.967742
Std Dev	9.0718755
Std Err Mean	1.6293569
Upper 95% Mean	35.295333
Lower 95% Mean	28.640151
N	31

Test Mean=value

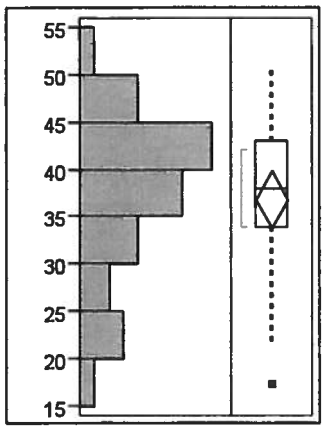
Hypothesized Value	0
Actual Estimate	31.9677
DF	30
Std Dev	9.07188

	t Test	Signed-Rank
Test Statistic	19.6199	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
1 Hour

1hr-B



Quantiles

100.0%	maximum	51
99.5%		51
97.5%		51
90.0%		46.8
75.0%	quartile	43
50.0%	median	38
25.0%	quartile	34
10.0%		22.4
2.5%		18
0.5%		18
0.0%	minimum	18

Moments

Mean	36.870968
Std Dev	8.1802279
Std Err Mean	1.4692123
Upper 95% Mean	39.8715
Lower 95% Mean	33.870436
N	31

Test Mean=value

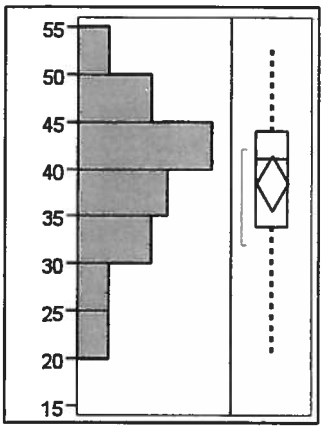
Hypothesized Value	0
Actual Estimate	36.871
DF	30
Std Dev	8.18023

	t Test	Signed-Rank
Test Statistic	25.0957	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
2 Hour

2hr-b



Quantiles

100.0%	maximum	53
99.5%		53
97.5%		53
90.0%		48.8
75.0%	quartile	44
50.0%	median	41
25.0%	quartile	34
10.0%		25.4
2.5%		20
0.5%		20
0.0%	minimum	20

Moments

Mean	38.580645
Std Dev	8.1149007
Std Err Mean	1.4574792
Upper 95% Mean	41.557215
Lower 95% Mean	35.604076
N	31

Test Mean=value

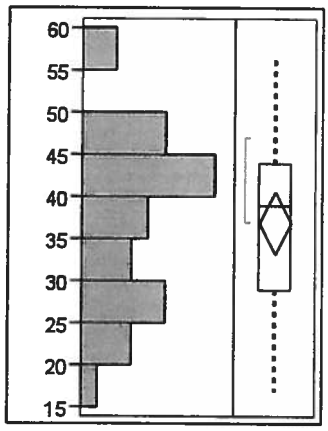
Hypothesized Value	0
Actual Estimate	38.5806
DF	30
Std Dev	8.1149

	t Test	Signed-Rank
Test Statistic	26.4708	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
3 Hour

3hr-B



Quantiles

100.0%	maximum	56
99.5%		56
97.5%		56
90.0%		47.8
75.0%	quartile	44
50.0%	median	39
25.0%	quartile	29
10.0%		22.2
2.5%		17
0.5%		17
0.0%	minimum	17

Moments

Mean	36.935484
Std Dev	10.109189
Std Err Mean	1.8156639
Upper 95% Mean	40.643564
Lower 95% Mean	33.227403
N	31

Test Mean=value

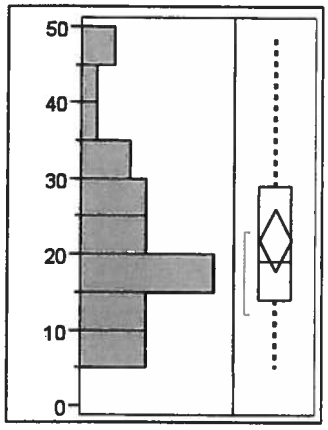
Hypothesized Value	0
Actual Estimate	36.9355
DF	30
Std Dev	10.1092

	t Test	Signed-Rank
Test Statistic	20.3427	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No. 12250
Corneometer Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
8 Hour

8hr-B



Quantiles

100.0%	maximum	49
99.5%		49
97.5%		49
90.0%		42.4
75.0%	quartile	29
50.0%	median	19
25.0%	quartile	14
10.0%		9
2.5%		5
0.5%		5
0.0%	minimum	5

Moments

Mean	22.064516
Std Dev	11.108362
Std Err Mean	1.9951207
Upper 95% Mean	26.139096
Lower 95% Mean	17.989936
N	31

Test Mean=value

Hypothesized Value	0
Actual Estimate	22.0645
DF	30
Std Dev	11.1084

	t Test	Signed-Rank
Test Statistic	11.0592	248.0000
Prob > |t|	<.0001*	<.0001*
Prob > t	<.0001*	<.0001*
Prob < t	1.0000	1.0000

ETC Panel No.: 12250
ETC Entry No.: 22271

APPENDIX 3

TEWAMETER® MEASUREMENTS

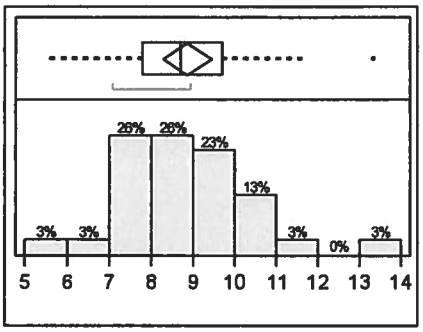
Test Article: Obagi Moisturizer Formula# 006-40-12 (GS #BK-12-0131)
Lot# RND06-0104

Subject No.	Baseline	15 Mins	30 Mins	1 Hour	2 Hours	3 Hours	8 Hours
1	8.4	5.8	5.6	5.3	5.1	6.4	6.6
2	7.9	5.5	5.4	5.0	4.0	5.3	5.0
3	7.1	4.2	4.9	5.8	4.4	5.2	6.1
4	8.3	6.4	4.6	4.9	4.5	4.7	3.8
5	7.7	5.0	5.0	6.4	5.1	5.6	7.1
6	7.8	4.3	6.6	4.4	3.6	4.9	5.1
7	7.2	6.2	5.7	4.6	6.2	4.1	4.5
8	7.1	4.1	4.3	4.1	5.1	4.9	4.5
9	13.3	5.8	5.4	4.5	5.6	5.1	5.2
10	8.3	7.1	5.6	4.9	6.5	3.4	4.8
11	6.9	6.4	4.1	5.0	4.4	3.4	2.9
12	10.3	7.3	4.3	5.0	4.9	4.5	2.7
13	9.7	4.9	5.2	4.8	4.4	4.6	5.8
14	9.7	6.5	4.8	4.7	5.3	5.5	4.6
15	11.8	7.0	6.5	5.3	5.5	4.1	3.3
16	8.3	4.5	4.2	3.3	4.4	3.9	4.5
17	10.3	5.7	4.6	6.3	4.8	4.0	3.4
18	9.6	4.9	3.8	2.9	4.8	4.6	2.1
19	9.8	5.0	5.1	4.6	6.3	4.0	2.6
20	5.6	5.5	4.8	4.0	3.7	4.5	1.7
21	10.8	8.3	6.8	4.0	5.1	5.6	5.3
22	9.5	4.3	4.2	3.3	3.5	3.8	5.5
23	9.1	8.2	8.9	6.7	6.1	5.2	6.3
24	10.3	6.9	4.1	3.8	2.4	3.5	5.5
25	8.7	5.0	4.2	6.7	4.7	5.1	3.4
26	7.8	6.5	4.9	5.0	4.6	4.4	4.6
27	8.9	6.7	6.3	5.7	4.5	4.2	4.7
28	8.8	5.6	3.3	3.1	3.4	3.9	1.7
29	8.1	4.2	3.8	4.2	5.0	3.7	3.3
30	9.7	5.6	5.2	4.1	2.8	4.0	4.0
31	7.2	5.8	4.3	4.3	4.3	5.0	4.2
MEAN	**8.8**	**5.8**	**5.0**	**4.7**	**4.7**	**4.6**	**4.3**

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
Baseline

B



Quantiles

100.0%	maximum	13.3
99.5%		13.3
97.5%		13.3
90.0%		10.7
75.0%	quartile	9.7
50.0%	median	8.7
25.0%	quartile	7.8
10.0%		7.1
2.5%		5.6
0.5%		5.6
0.0%	minimum	5.6

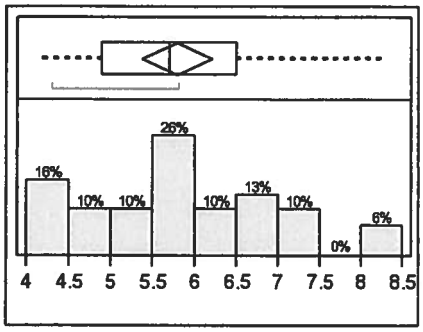
Moments

Mean	8.8387097
Std Dev	1.5789611
Std Err Mean	0.2835898
Upper 95% Mean	9.4178773
Lower 95% Mean	8.2595421
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
15 Minutes

15



Quantiles

100.0%	maximum	8.3
99.5%		8.3
97.5%		8.3
90.0%		7.26
75.0%	quartile	6.5
50.0%	median	5.7
25.0%	quartile	4.9
10.0%		4.22
2.5%		4.1
0.5%		4.1
0.0%	minimum	4.1

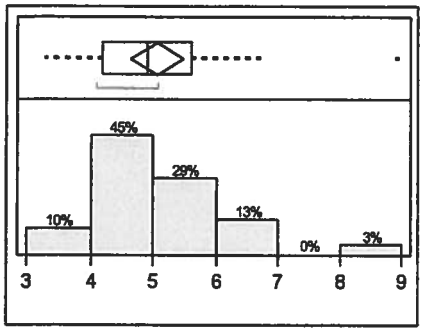
Moments

Mean	5.7806452
Std Dev	1.1440919
Std Err Mean	0.205485
Upper 95% Mean	6.2003015
Lower 95% Mean	5.3609889
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
30 Minutes

30



Quantiles

100.0%	maximum	8.9
99.5%		8.9
97.5%		8.9
90.0%		6.58
75.0%	quartile	5.6
50.0%	median	4.9
25.0%	quartile	4.2
10.0%		3.86
2.5%		3.3
0.5%		3.3
0.0%	minimum	3.3

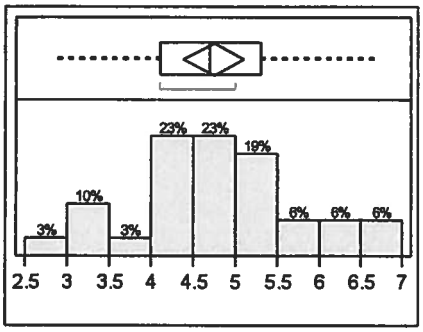
Moments

Mean	5.0483871
Std Dev	1.1209731
Std Err Mean	0.2013327
Upper 95% Mean	5.4595633
Lower 95% Mean	4.6372109
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
1 Hour

1hr



Quantiles

100.0%	maximum	6.7
99.5%		6.7
97.5%		6.7
90.0%		6.38
75.0%	quartile	5.3
50.0%	median	4.7
25.0%	quartile	4.1
10.0%		3.3
2.5%		2.9
0.5%		2.9
0.0%	minimum	2.9

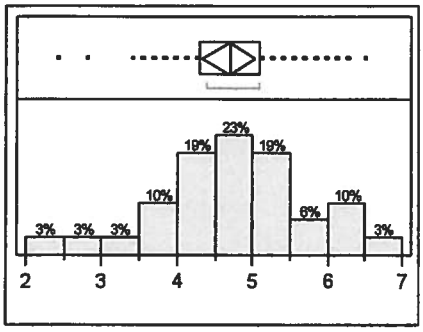
Moments

Mean	4.7322581
Std Dev	0.9931053
Std Err Mean	0.178367
Upper 95% Mean	5.096532
Lower 95% Mean	4.3679841
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
2 Hour

2hr



Quantiles

100.0%	maximum	6.5
99.5%		6.5
97.5%		6.5
90.0%		6.18
75.0%	quartile	5.1
50.0%	median	4.7
25.0%	quartile	4.3
10.0%		3.42
2.5%		2.4
0.5%		2.4
0.0%	minimum	2.4

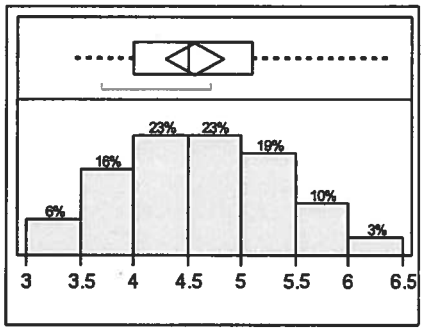
Moments

Mean	4.6774194
Std Dev	0.9649558
Std Err Mean	0.1733112
Upper 95% Mean	5.031368
Lower 95% Mean	4.3234707
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
3 Hour

3hr



Quantiles

100.0%	maximum	6.4
99.5%		6.4
97.5%		6.4
90.0%		5.58
75.0%	quartile	5.1
50.0%	median	4.5
25.0%	quartile	4
10.0%		3.54
2.5%		3.4
0.5%		3.4
0.0%	minimum	3.4

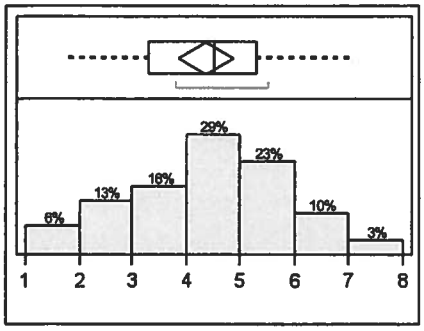
Moments

Mean	4.5516129
Std Dev	0.7384086
Std Err Mean	0.1326221
Upper 95% Mean	4.8224634
Lower 95% Mean	4.2807624
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Descriptive Statistics
8 Hour

8 hr



Quantiles

100.0%	maximum	7.1
99.5%		7.1
97.5%		7.1
90.0%		6.26
75.0%	quartile	5.3
50.0%	median	4.5
25.0%	quartile	3.3
10.0%		2.2
2.5%		1.7
0.5%		1.7
0.0%	minimum	1.7

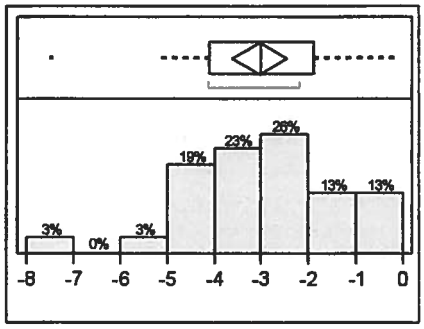
Moments

Mean	4.3483871
Std Dev	1.4002074
Std Err Mean	0.2514847
Upper 95% Mean	4.8619873
Lower 95% Mean	3.8347869
N	31

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
15 Minutes

15-B



Quantiles

100.0%	maximum	-0.1
99.5%		-0.1
97.5%		-0.1
90.0%		-0.92
75.0%	quartile	-1.9
50.0%	median	-3
25.0%	quartile	-4.1
10.0%		-4.8
2.5%		-7.5
0.5%		-7.5
0.0%	minimum	-7.5

Moments

Mean	-3.058065
Std Dev	1.6152965
Std Err Mean	0.2901158
Upper 95% Mean	-2.465569
Lower 95% Mean	-3.65056
N	31

Test Mean=value

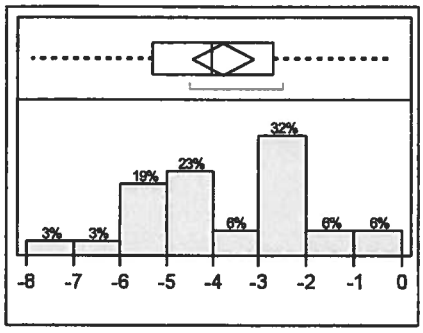
Hypothesized Value	0
Actual Estimate	-3.0581
DF	30
Std Dev	1.6153

	t Test	Signed-Rank
Test Statistic	-10.541	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
30 Minutes

30-B



Quantiles

100.0%	maximum	-0.2
99.5%		-0.2
97.5%		-0.2
90.0%		-1.26
75.0%	quartile	-2.7
50.0%	median	-4
25.0%	quartile	-5.3
10.0%		-5.96
2.5%		-7.9
0.5%		-7.9
0.0%	minimum	-7.9

Moments

Mean	-3.790323
Std Dev	1.7609382
Std Err Mean	0.3162738
Upper 95% Mean	-3.144405
Lower 95% Mean	-4.43624
N	31

Test Mean=value

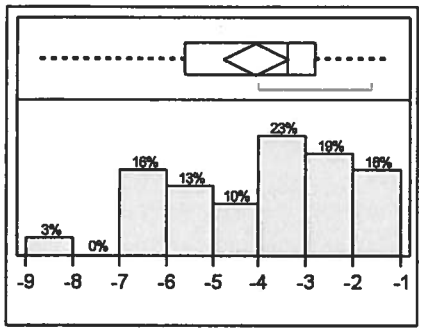
Hypothesized Value	0
Actual Estimate	-3.7903
DF	30
Std Dev	1.76094

	t Test	Signed-Rank
Test Statistic	-11.984	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
1 Hour

1hr-B



Quantiles

100.0%	maximum	-1.3
99.5%		-1.3
97.5%		-1.3
90.0%		-1.66
75.0%	quartile	-2.8
50.0%	median	-3.4
25.0%	quartile	-5.6
10.0%		-6.66
2.5%		-8.8
0.5%		-8.8
0.0%	minimum	-8.8

Moments

Mean	-4.106452
Std Dev	1.8904912
Std Err Mean	0.3395422
Upper 95% Mean	-3.413014
Lower 95% Mean	-4.799889
N	31

Test Mean=value

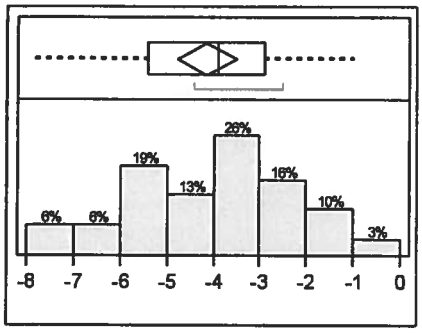
Hypothesized Value	0
Actual Estimate	-4.1065
DF	30
Std Dev	1.89049

	t Test	Signed-Rank
Test Statistic	-12.094	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
2 Hour

2hr-b



Quantiles

100.0%	maximum	-1
99.5%		-1
97.5%		-1
90.0%		-1.92
75.0%	quartile	-2.9
50.0%	median	-3.9
25.0%	quartile	-5.4
10.0%		-6.78
2.5%		-7.9
0.5%		-7.9
0.0%	minimum	-7.9

Moments

Mean	-4.16129
Std Dev	1.7335277
Std Err Mean	0.3113508
Upper 95% Mean	-3.525427
Lower 95% Mean	-4.797153
N	31

Test Mean=value

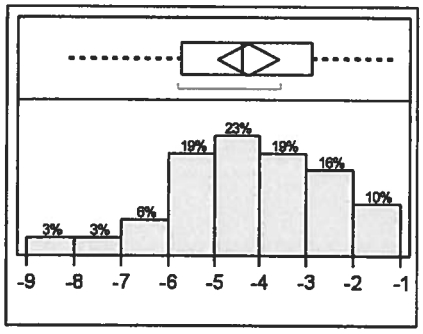
Hypothesized Value	0
Actual Estimate	-4.1613
DF	30
Std Dev	1.73353

	t Test	Signed-Rank
Test Statistic	-13.365	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
3 Hour

3hr-B



Quantiles

100.0%	maximum	-1.1
99.5%		-1.1
97.5%		-1.1
90.0%		-2.02
75.0%	quartile	-2.9
50.0%	median	-4.4
25.0%	quartile	-5.7
10.0%		-6.7
2.5%		-8.2
0.5%		-8.2
0.0%	minimum	-8.2

Moments

Mean	-4.287097
Std Dev	1.7522827
Std Err Mean	0.3147193
Upper 95% Mean	-3.644354
Lower 95% Mean	-4.929839
N	31

Test Mean=value

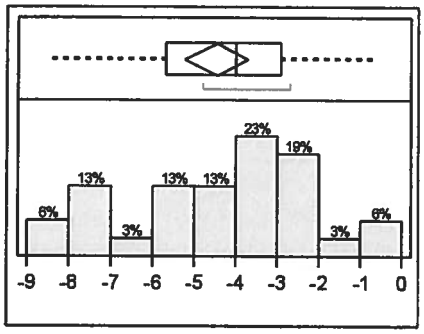
Hypothesized Value	0
Actual Estimate	-4.2871
DF	30
Std Dev	1.75228

	t Test	Signed-Rank
Test Statistic	-13.622	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*

ETC Panel No. 12250
Tewameter Measurements
Baseline, 15-, 30-Minutes, Hour 1, 2, 3, 8
(JMP Statistical Software v8, SAS Institute, Cary NC)

Change from Baseline
8 Hour

8hr-B



Quantiles

100.0%	maximum	-0.6
99.5%		-0.6
97.5%		-0.6
90.0%		-1.96
75.0%	quartile	-2.9
50.0%	median	-4
25.0%	quartile	-5.7
10.0%		-7.58
2.5%		-8.5
0.5%		-8.5
0.0%	minimum	-8.5

Moments

Mean	-4.490323
Std Dev	2.0658097
Std Err Mean	0.3710304
Upper 95% Mean	-3.732577
Lower 95% Mean	-5.248068
N	31

Test Mean=value

Hypothesized Value	0
Actual Estimate	-4.4903
DF	30
Std Dev	2.06581

	t Test	Signed-Rank
Test Statistic	-12.102	-248.000
Prob > |t|	<.0001*	<.0001*
Prob > t	1.0000	1.0000
Prob < t	<.0001*	<.0001*