CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FINAL REPORT

CLIENT: Pantoscopic Readers Development & Patent Holding
677 Church Avenue
Woodmere, NY 11598

ATTENTION: Jerry Stulberger

TEST: Product Performance Evaluation of Pantoscopic Readers
Protocol No.: PAGL01-001
Protocol Date: 11/12/21

TEST MATERIAL: Pantoscopic Flat-Fold Readers

STUDY NUMBER: C21-6194.01

Approved by: Joy Frank, R.N.
Executive Vice President, Clinical Evaluations

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without authorization. Results indicated in this Report apply only to the items tested.

QUALITY ASSURANCE UNIT STATEMENT

Study Number: C21-6194.01

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period with no further notice in a manner that renders them useless.

Quality Assurance Representative

12-10-21
Date

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Objective:

To assess improvement in visual acuity through the wear of Pantoscopic Readers by comparing normal tilt scores to tilted lens scores.

To determine consumer perception of Pantoscopic Readers, utilizing a Sponsor-supplied questionnaire.

Participants:

Seventeen subjects, 4 males and 13 females, aged 51 to 73 years, were recruited and qualified for this trial. All 17 subjects completed the trial.

Inclusion Criteria:

1. Subjects who read, signed, and dated an Informed Consent Form that included a HIPAA statement;
2. Approximately 16 male and female subjects, aged 40 to 75 years, inclusive;
3. Subjects must have been farsighted;
4. Subjects must have been regular users of readers glasses with a magnification power of +1.75; and
5. Subjects who were considered dependable and able to follow directions, as outlined in the protocol.

Exclusion Criteria:

1. Subjects who were in ill health, as determined by the Principal Investigator;
2. Subjects who were taking medication, that, in the opinion of Investigator, may have influenced the purpose, integrity, or outcome of the trial;
3. Females who were pregnant, planning to become pregnant or lactating; or
4. Subjects who exhibited an improper fit while wearing the test material.

Test Material:

Pantoscopic Flat-Fold Readers

Trial Schedule:

Initiation Date	Completion Date
November 29, 2021	November 29, 2021

Trial Design:

This was a single center, subject perception trial design of 1 day duration.

Methodology:

Test Phase (Day 0)

Potential subjects reported to the Testing Facility at their appointed time. Those who completed at ICF became subjects. Subjects completed a Medical History Form to determine initial qualification.

The informed consent process fully apprised each potential subject of the risks and benefits associated with the research clinical trial and of the confidentiality requirements relating to the subject's clinical trial records. If the potential subject agreed to participate in the research clinical trial, then the potential subject executed the Informed Consent Form (ICF) after which the potential subject entered the clinical trial as a subject. Staff who conducted the informed consent process also executed the form. Each subject received a signed copy of the fully executed ICF. If at any time during the clinical trial the subject had questions, the ICF directed the subject to a Subject Rights Advocate, whose contact information was in the ICF.

Visual Acuity #1 – Normal-straight lens position

Visual acuity was conducted for subjects using the on-line AAPOS (American Association for Pediatric Ophthalmology & Strabismus) eye chart app (https://www.good-lite.com/pages/aapos-app-on-the-istore), that was calibrated to display on an iPad with a 10.2" (diagonal) screen.

Subjects were asked to sit in a chair at a table. An iPad with a 10.2" (diagonal) screen was positioned approximately 16" in front of each subject. The iPad was leaning at an approximate 60-degree angle on the table.

Subjects were provided with the test material to wear on their face, maintained in the normal-straight lenses position.

Subjects looked downward through the lenses, as done when reading, and read aloud the lines of the on-line AAPOS eye chart from top to bottom. Each line had a vision measurement on the right side of the screen.

Line 1 – 20/63
Line 2 – 20/50
Line 3 – 20/40
Line 4 – 20/32
Line 5 – 20/25
Line 6 – 20/20
Line 7 – 20/16

Methodology (continued):

Subjects that read down to Line 6 (20/20) or Line 7 (20/16) were disqualified.

Normal tilt visual acuity scores for each subject were documented by Testing Facility Staff.

Visual Acuity #2 – Tilted lens position

Qualified subjects were instructed to slowly tilt the lens frame forward while looking through the lenses at the chart, by gently grasping the two temple sides with their pointing fingers (top) and thumbs at bottom of lens. Either one hand or both hands were used.

Subjects GENTLY and SLOWLY tilted the lens frame part forward, away from the base frame, while looking in a straight-downward (as though reading on their cellular phone), or outward/downward (as though looking at papers or laptop on a desk in front of them or on their lap).

Subjects continued to SLOWLY tilt the lenses, as far as a 45-degree angle down, to as much as an 80-degree angle down. Subjects stopped at the angle they felt provided the clearest, sharpest view. While the periphery view may have become distorted, subjects focused on viewing/reading objects in the center of their view.

The on-line eye chart was refreshed by Testing Facility staff, reflecting different letters.

While looking through the tilted lenses and without adjusting, subjects read aloud the lines of the on-line AAPOS eye chart from top to bottom. Subjects were asked to try reading to the lowest visible line possible.

Post-Test Questionnaire

Subjects were administered a Sponsor-supplied questionnaire after completion of the second visual acuity capture. Questionnaires were reviewed for completeness prior to subjects' dismissal from the trial.

Deviations: There were no deviations.

Adverse Events: There were no adverse events.

Amendments: There were no amendments.

Statistical Analysis (Per-Protocol Analysis):

Statistical analysis was conducted on the visual acuity assessment. For both the normal straight lens and tilted lens assessments, acuity scores were calculated as the furthest line read by a subject. In addition to providing descriptive statistics of the acuity scores (including proportions of subjects showing improvement/worsening), the differences in scores between the two types of assessments were also statistically compared. Prior to performing the analysis, diagnostic tests on the data were performed to determine whether normality and/or homogeneity of variances of the data were maintained. If the above conditions were maintained, a parametric Student's t-Test or Analysis of Variance was performed. If any of the above conditions were not maintained, a non-parametric equivalent to the above statistical tests was utilized.

Statistical analysis was also conducted on the questionnaire responses. Responses to each question were divided into two categories, "successes" and "failures." Responses indicating the subject agreed with a positive statement about the test material were considered "successes." Responses indicating the subject disagreed with a positive statement about the test material were considered "failures." For any midpoint responses, (neither agree nor disagree), half of the midpoint responses were counted as "successes" and half were counted as "failures." If there was an odd number of midpoint responses, the "successes" category received the extra midpoint response. The proportions of "successes" and "failures" for each question were determined by dividing the number of "successes" and "failures" by the total number of responses. These proportions were compared, and statistically significant differences were identified using a proportion z-Test for each question.

For all of the above analyses, statistical significance was achieved at the 95% confidence level ($p < 0.050$).

Results: Subject demographics are presented in Table 1.

Visual Acuity scores and statistical analysis are presented in Table 2.

Questionnaire tallies and analyses (z-Test) are presented in Table 3.

Results (continued):

For 9 out of the 12 questions answered, a statistically significantly greater number of subjects rated a positive / favorable response when compared to those subjects rating a negative / unfavorable response.

When compared to the normal-straight lens acuity scores, subjects using the tilted lens experienced a statistically significant increase in visual acuity scores.

Summary:

Under the conditions of this trial, use of test material, Pantoscopic Flat-Fold Readers, resulted in a statistically significantly greater number of subjects with positive consumer perception for the majority of the statements in the questionnaire. In addition, subjects using the test material experienced a statistically significant improvement in visual acuity.

Table 1

Subject Demographics

Subject Number	ID#	Age	Sex
1	4792	54	F
2	3096	60	F
3	25664	56	M
4	80803	59	M
5	89104	51	F
6	56003	61	F
7	84011	68	M
8	80497	62	F
9	14341	73	F
10	79764	66	F
11	31098	62	M
12	20004	52	F
13	91535	58	F
14	39759	64	F
15	72425	66	F
16	44968	63	F
17	6733	60	F

Table 2

Visual Acuity - Normal-Straight and Tilted Lens Positions

1. Do the readers properly fit the subject?

Subject #	ID #	Yes	No	Visual Acuity #1 Normal-straight lens position		Visual Acuity #2 Tilted lens Position	
1	4792	X		20	32	20	25-2
2	3096	X		20	32	20	25
3	25664	X		20	40	20	32
4	80803	X		20	25	20	25
5	89104	X		20	50	20	40
6	56003	X		20	50-1	20	50
7	84011	X		20	40	20	32
8	80497	X		20	63	20	50-2
9	14341	X		20	32	20	40-1
10	79764	X		20	40-1	20	32
11	31098	X		20	40	20	40
12	20004	X		20	25	20	25
13	91535	X		20	32	20	40
14	39759	X		20	63	20	50
15	72425	X		20	40	20	32-2
16	44968	X		20	32	20	25-2
17	6733	X		20	50	20	40-2

2. Does the subject qualify for the trial?

Subject #	Yes	No
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	

3. Did the subject tilt the lens until it reached the angle they feel provided the clearest, sharpest view?

Subject #	Yes	No
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	

Table 2
(continued)

Visual Acuity - Normal-Straight and Tilted Lens Positions

Test Material .01 = Pantoscopic Flat-Fold Readers

	Normal-Straight Lens		*Tilted Lens*		**Acuity Score Difference**
Subject #	**20/x Score**	**Acuity Score***	**20/x Score**	**Acuity Score***	**Between Groups**
1	32	4	25-2	5	1
2	32	4	25	5	1
3	40	3	32	4	1
4	25	5	25	5	0
5	50	2	40	3	1
6	50-1	2	50	2	0
7	40	3	32	4	1
8	63	1	50-2	2	1
9	32	4	40-1	3	-1
10	40-1	3	32	4	1
11	40	3	40	3	0
12	25	5	25	5	0
13	32	4	40	3	-1
14	63	1	50	2	1
15	40	3	32-2	4	1
16	32	4	25-2	5	1
17	50	2	40-2	3	1
Mean =		**3.1**		**3.6**	**0.5**
Median =		**3.0**		**4.0**	**1.0**
Standard Deviation =		**1.2**		**1.1**	**0.7**
Maximum =		**5**		**5**	**1**
Minimum =		**1**		**2**	**-1**

* = Acuity score was calculated as the furthest line read by a subject (see evaluation scale below). Subjects were allowed to incorrectly read up to 2 letters while still qualifying as having read a line.

Evaluation Scale

1 = 20/63
2 = 20/50
3 = 20/40
4 = 20/32
5 = 20/25
6 = 20/20
7 = 20/16

Tallies & Percentages	
Total	17
Improvement	11
Worsening	2
No Change	4
Improvement	64.7%
Worsening	11.8%
No Change	23.5%

Table 2
(continued)

Statistical Analysis of Visual Acuity Scores

Test Material .01 = Pantoscopic Flat-Fold Readers

Normal-Straight Lens VS. Tilted Lens

Parameter	Normality Test*	Test Type	P-value	Significance	Improvement
Visual Acuity	< 0.050	Non-Parametric	**0.027**	**Yes**	**Yes**

* = Shapiro Wilk's W Test For Normality (and the Brown-Forsythe Equal Variance Test, where applicable) were performed to check the underlying statistical assumptions of normally distributed data with equal population variances. The results from these tests determined whether a parametric test (if $p > 0.050$) or a non-parametric equivalent (if $p < 0.050$) was utilized. The results also determined the type of statistical test utilized if multiple comparisons were required.

Summary:
When compared to the normal-straight lens scores, subjects using the test material, Pantoscopic Flat-Fold Readers, experienced a statistically significant improvement in visual acuity (i.e., further lines read on the AAPOS eye chart).

Table 3

Final Questionnaire Tallies

	Yes	No
1. I normally wear readers glasses for reading small print, such as using them to read my phone, books, or letters.	17	0

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
2. With help of these or any pair of readers glasses with a 1.75 magnification, I can see and read fine print better than without wearing glasses.	8	6	2	1	0
3. When I tilt the lenses downward, my reading ability is enhanced.	6	7	3	1	0
4. When I tilt the lenses downward, I have the ability to read on an eye chart an additional one or two lines further down in comparison to reading with my prior pair of readers glasses.	3	6	4	4	0
5. When I put these glasses on and proceed to look down and read the eye chart in front of me, as I grasp the lenses with my fingertips and slowly tilt the rotatable lenses downward, the images on the eye chart are becoming increasingly clear and sharp.	4	9	4	0	0
6. When the lenses are tilted forward, I can see the textures and lines in my skin and feel as though I can do tasks such as threading a needle or reading very fine print on a pill bottle.	3	9	4	1	0
7. I believe these readers glasses could actually expand my visual reading, overall comfort, and increase the duration of time before eye fatigue and bleeriness sets in.	6	7	4	0	0
8. I have found that if I just tilt my ordinary readers glasses downward on my face, I can see what I am reading (i.e., newspaper or book) much more clearly.	0	6	7	4	0

Table 3
(continued)

Final Questionnaire Tallies

	Strongly Agree	Agree/Yes	Neither Agree nor Disagree	Disagree/No	Strongly Disagree
9. The flat fold feature of these readers glasses, without having to compress them into a storage case, will make it easier and more convenient for me to just 'slip' the glasses in and out of a shirt pocket.	3	10	4	0	0
10. I would be willing to purchase these readers glasses at a store like Walgreens, Target, CVS or Walmart because it's competitively priced ($29.95 to $39.95), simple, and a small price to pay for substantial vision comfort.	5	8	3	1	0

11. Would the following marketing slogans and names for these readers glasses be appropriate?

	Yes	No
Re-Envisioning Magnifiers	9	8
The First Ever 'Text-Sharpening' Readers	14	3

Table 3
(continued)

Final Questionnaire

z-Test on Questionnaire Responses
Tallies and Percentages: Successes vs. Failures

Test Material .01 = Pantoscopic Flat-Fold Readers

	Question 1		Question 2		Question 3		Question 4	
	I normally wear readers glasses for reading small print, such as using them to read my phone, books, or letters.		With the help of these or any pair of readers glasses with a 1.75 magnification, I can see and read fine print better than without wearing glasses.		When I tilt the lenses downward, my reading ability is enhanced.		When I tilt the lenses downward, I have the ability to read on an eye chart an additional one or two lines further down in comparison to reading with my prior pair of readers glasses.	
Successes	**17**	**100.0%**	**15**	**88.2%**	**15**	**88.2%**	11	64.7%
Failures	0	0.0%	2	11.8%	2	11.8%	6	35.3%
Total Trials	17		17		17		17	
P Value	**< 0.001**		**< 0.001**		**< 0.001**		0.086	
Significance	**YES**		**YES**		**YES**		NO	

	Question 5		Question 6		Question 7		Question 8	
	When I put these glasses on and proceed to look down and read the eye chart in front of me, as I grasp the lenses with my fingertips and slowly tilt the rotatable lenses downward, the images on the eye chart are becoming increasingly clear and sharp.		When the lenses are tilted forward, I can see the textures and lines in my skin and feel as though I can do tasks such as threading a needle or reading very fine print on a pill bottle.		I believe these readers glasses could actually expand my visual reading, overall comfort, and increase the duration of time before eye fatigue and bleariness sets in.		I have found that if I just tilt my ordinary readers glasses downward on my face, I can see what I am reading (i.e., newspaper or book) much more clearly.	
Successes	**15**	**88.2%**	**14**	**82.4%**	**15**	**88.2%**	10	58.8%
Failures	2	11.8%	3	17.6%	2	11.8%	7	41.2%
Total Trials	17		17		17		17	
P Value	**< 0.001**		**< 0.001**		**< 0.001**		0.303	
Significance	**YES**		**YES**		**YES**		NO	

Significance observed at $P < 0.050$. z-Test performed using SigmaPlot 14.5 for Windows.

The responses were pooled into two categories:
1) Successes, subjects who selected "Strongly Agree," "Agree," or "Yes" for the test material attribute.
2) Failures, subjects who selected "Strongly Disagree," "Disagree," or "No" for the test material attribute.

Subjects who selected "Neither Agree Nor Disagree" were divided evenly between the two categories (half in the Successes and half in the Failures). If there was an uneven distribution of undecided responses, the Successes category received the extra-undecided response.

Table 3
(continued)

Final Questionnaire (cont.)

z-Test on Questionnaire Responses
Tallies and Percentages: Successes vs. Failures

Test Material .01 = Pantoscopic Flat-Fold Readers

	Question 9		Question 10		Question 11a		Question 11b	
	The flat fold feature of these readers glasses, without having to compress them into a storage case, will make it easier and more convenient for me to just 'slip' the glasses in and out of a shirt pocket.		I would be willing to purchase these readers glasses at a store like Walgreens, Target, CVS, or Walmart because it's competitively priced ($29.95 to $39.95), simple, and a small price to pay for substantial vision comfort.		Would the following marketing slogans and names for these readers glasses be appropriate? Re-Envisioning Magnifiers		Would the following marketing slogans and names for these readers glasses be appropriate? The First Ever 'Text-Sharpening' Readers	
Successes	**15**	**88.2%**	**15**	**88.2%**	9	52.9%	**14**	**82.4%**
Failures	2	11.8%	2	11.8%	8	47.1%	3	17.6%
Total Trials	17		17		17		17	
P Value	**< 0.001**		**< 0.001**		0.732		**< 0.001**	
Significance	**YES**		**YES**		NO		**YES**	

Significance observed at $P < 0.050$. z-Test performed using SigmaPlot 14.5 for Windows.

The responses were pooled into two categories:
1) Successes, subjects who selected "Strongly Agree," "Agree," or "Yes" for the test material attribute.
2) Failures, subjects who selected "Strongly Disagree," "Disagree," or "No" for the test material attribute.

Subjects who selected "Neither Agree Nor Disagree" were divided evenly between the two categories (half in the Successes and half in the Failures). If there was an uneven distribution of undecided responses, the Successes category received the extra-undecided response.