Federal Aviation Administration

DOT/FAA/AM-09/13
Office of Aerospace Medicine
Washington, DC 20591

Evaluation of Next-Generation Vision Testers for Aeromedical Certification of Aviation Personnel

Van B. Nakagawara
Ron W. Montgomery
Kathryn J. Wood

Civil Aerospace Medical Institute
Federal Aviation Administration
Oklahoma City, OK 73125

July 2009

Final Report

OK-09-0434-JAH

NOTICE

This publication and all Office of Aerospace Medicine technical reports are available in full-text from the Civil Aerospace Medical Institute's publications Web site:
www.faa.gov/library/reports/medical/oamtechreports

Technical Report Documentation Page

1. Report No.	2. Government Accession No.	3. Recipient's Catalog No.
DOT/FAA/AM-09/13		

4. Title and Subtitle	5. Report Date
Evaluation of Next-Generation Vision Testers for Aeromedical Certification of Aviation Personnel	July 2009
	6. Performing Organization Code

7. Author(s)	8. Performing Organization Report No.
Nakagawara VB, Montgomery RW, Wood KJ	

9. Performing Organization Name and Address	10. Work Unit No. (TRAIS)
FAA Civil Aerospace Medical Institute P.O. Box 25082 Oklahoma City, OK 73125	11. Contract or Grant No. 07-CRDA-0231, 07-CRDA-0232

12. Sponsoring Agency name and Address	13. Type of Report and Period Covered
Office of Aerospace Medicine Federal Aviation Administration 800 Independence Ave, S.W. Washington, D.C. 20591	14. Sponsoring Agency Code

15. Supplemental Notes

16. Abstract

Introduction. The Federal Aviation Administration (FAA) allows the use of a variety of vision screening devices to evaluate a pilot applicant's vision performance for medical certification purposes. This study compares human subject test scores obtained using two new vision testing instruments (Optec 5000 and Titmus i400) with those from previously approved counterparts (Optec 2000 and Titmus 2A), which have been discontinued by their manufacturers. **Method.** Testing included near, intermediate, and distant visual acuity, when appropriate, as well as heterophoria and color perception. Aside from color vision deficiencies, visual performance for all subjects was within the minimum Federal Aviation Regulations (FAR) vision requirements for Class II airmen. The test subject population included 36 individuals who ranged in age from 18 to 66 (34.4 ± 14.2). Six subjects were 50 years of age or over, requiring intermediate vision testing and 12 were color deficient. Analysis was designed to detect statistically significant differences between the test scores obtained with the new instruments vs. the older models. **Results.** The results of this study indicate that both new instruments provided visual acuity and heterophoria scores that are statistically equivalent to the older models. Color vision test scores for the Titmus i400 were found to be statistically equivalent to those of the Titmus 2A, with little or no change in failure rate. Although the color vision scores of the Optec 5000 were statistically equivalent to those of the Optec 2000, it failed 50% of the color normal subjects in the study. **Conclusion.** FAA approval is recommended for the Titmus i400 for use in all applicable aviation vision tests. Conditional approval is recommended for the Optec 5000, provided the Aviation Medical Examiner has an appropriate alternate color vision test should individuals be identified as color deficient during the certification exam.

17. Key Words	18. Distribution Statement
Vision, Aeromedical Certification, Vision Tester, Color Vision, Aviation	Document is available to the public through the Defense Technical Information Service Center, Ft. Belvoir, VA 22060; and the National Technical Information Services. Springfield, VA 22161

19. Security Classif. (of this report)	20. Security Classif. (of this page)	21. No. of Pages	22. Price
Unclassified	Unclassified	27	

Form DOT F 1700.7 (8-72) Reproduction of completed page authorized

ACKNOWLEDGMENTS

This research was conducted under a Cooperative Research and Development Agreement (CRDA) established between the FAA and the CRDA partners. The FAA Grants and Cooperative Agreements Center at the William J. Hughes Technical Center acted as the coordinating office for the CRDA.

CONTENTS

Evaluation of Next-Generation Vision Testers for Aeromedical Certification of Aviation Personnel

BACKGROUND

The Federal Aviation Administration (FAA) currently allows Aviation Medical Examiners (AMEs) to use a variety of vision testing devices to evaluate a pilot applicant's vision performance for medical certification purposes. Two of these approved devices are the Optec 2000 vision tester and the Titmus 2A vision screener, both of which have been discontinued by their manufacturers (Stereo Optical Company, Inc., and Titmus Optical Co.). The Optec 5000 vision tester and Titmus i400 vision screener are currently marketed as replacements. The manufacturers of these new instruments have requested FAA approval for use by an AME performing aeromedical certification exams on pilot applicants.

Changes include cosmetic redesigns for both new testers and the use of light-emitting diodes (LEDs) and fluorescent lamps, rather than incandescent light bulbs to illuminate the test slides, for the Optec 5000 and Titmus i400, respectively. All test slides and testing procedures for both instruments remain the same as those for the discontinued devices. This study compares human subject test scores obtained using the two new vision testing instruments with those from the respective discontinued models. Instrument testing included near, intermediate, and distant visual acuity tests, as well as heterophoria and color vision tests.

METHODOLOGY

All testing was performed at the Civil Aerospace Medical Institute, Aerospace Medical Research Division, in Oklahoma City, OK, by the Vision Research Team. All subjects read a full description of the evaluation and testing procedures and signed a release/consent form prior to participating in the study. Test subjects were assigned a subject number for identification purposes, which was used for the duration of the study to ensure confidentially. Prescreen tests included traditional Snellen visual acuity (near, intermediate, and distant), color vision (Dvorine, 2nd Edition, Pseudo-isochromatic Plate [PIP] Test, and Farnsworth Dichotomous Test), and heterophoria evaluation (Maddox rod with Risley prisms) to ensure that the subject's overall vision performance was within the testing limits of the instruments being evaluated. When necessary, test subjects wore their own refractive correction. Subjects with a medical history that would preclude them from receiving a pilot medical certificate or taking medication that could affect visual performance were excluded from the study. Aside from color vision deficiencies, visual performance for all subjects was within the minimum vision requirements for Class II airmen in Title 14 of the Code of Federal Regulations (CFR) Part 67, §67.203 (c) (see Table 1).

Table 1: 14 CFR 67.103(b), §67.203(c), §67.303 (d) Vision Standards (1)

Certificate Class Flight Category	First Class Air Transport	Second Class Commercial	Third Class Private
Distant Vision	20/20 or better in each eye separately, with or without correction		20/40 or better in each eye separately, with or without correction
Intermediate Vision	20/40 or better in each eye separately (Snellen equivalent), with or without correction at age 50 and over, as measured at 32 inches		No Requirement
Near Vision	20/40 or better in each eye separately (Snellen equivalent), with or without correction, as measured at 16 inches		
Color Vision	Ability to perceive those colors necessary for safe performance of airman duties		
Hyperphoria	Maximum of 1 diopter		No Standard
Esophoria & Exophoria	Maximum of 6 diopters of esophoria or exophoria		No Standard

The test subject population included 36 individuals (8 females and 28 males) that ranged in age from 18 to 66 (average = 34.4 ± 14.2). Six subjects were 50 years of age or over, requiring intermediate vision testing. A total of 28 subjects required refractive correction, and two had prior laser refractive surgery. Those who used ophthalmic devices included 18 subjects with spectacle correction (8 single vision, 3 bifocal, 1 trifocal, 4 half-eye readers, and 2 progressive addition lenses) and 10 who used contact lenses to correct their distant vision. Three subjects were eliminated from the study due to inadequate/inappropriate refractive correction (i.e., dark tinted lenses), the use of medication that could bias testing (i.e., depression and pain), and an inability to adequately complete all prescreening tests (i.e., fusion problems due to prior injury).

To compensate for any memorization due to the similarities between the tests, subjects where randomly assigned to one of four groups. The order of testing was divided such that 25% of the subjects (e.g., Group 1) were tested on the Optec 2000 instrument initially, followed by the Titmus i400, the Optec 5000, and then the Titmus 2A, with 10-minute rest intervals between each instrument. The order of testing for subjects in Group 2, Group 3, and Group 4 were similarly alternated so the effects of memorization would not favor any particular instrument. In addition, the left- and right-eye monocular tests were alternated from instrument to instrument, as was the direction (i.e., left to right, or right to left) in which the subjects were asked to read the lines of optotype. Table 2 summarizes the testing sequence for the four groups of nine subjects each.

Near, distant, and intermediate visual acuity scores were converted from Snellen notation to decimal equivalent and then to logMAR values for statistical analysis. Color vision performance was measured by adding the number of digits correctly identified out of the 8 digits and calculating the percentage of correct responses. The response order for the 6 pseudo-isochromatic plates was randomized in an effort to minimize memorization. Lateral phoria (distant) scores were recorded in 15 steps of 1 prism diopter (pd) each, from -7 (esophoria) to +7 (exophoria). Vertical phoria (distant) scores were recorded in 7 steps of one-half pd each, from -1.5 (left hyperphoria) to +1.5 (right hyperphoria).

The instruments used for the testing procedures were provided by Stereo Optical (i.e., refurbished Optec 2000 and new Optec 5000 vision testers) and Titmus Optical (i.e., refurbished Titmus 2A and new Titmus i400 vision screeners). The specifications for both Optec vision testers (2000 and 5000) are provided in Appendix A, and specifications for both Titmus vision screeners (2A and i400) are provided in Appendix B.

Tests on all subjects included:

- Visual Acuity (monocular and binocular)
- Distant
- Near
- Intermediate (Subjects ≥ 50 years of age)
- Color Perception (Binocular) - Distant
- Pseudo-isochromatic Plates
- Heterophoria - Distant
- Lateral Phoria (Esophoria & Exophoria)
- Vertical Phoria (Right & Left Hyperphoria)

Test scores from each of the vision testers were collated and analyzed. Analysis was designed to detect whether a statistically significant difference exists between the acuity scores obtained with the new versus the discontinued vision testers for each company. The Two-Factor (i.e., groups and devices) Analysis of Variance (ANOVA) with Replication was applied to the difference in logMAR acuity scores for (monocular and binocular) near, distant, and intermediate visual acuity tests. The null hypothesis states that the mean acuity scores for the two instruments are equal (H_o: $\mu_1 = \mu_2$). A statistically significant difference between the mean test scores is indicated by a probability value of less than 0.05 ($p \leq 0.05$). The (paired) Student T-test was performed to determine if the differences in the mean color vision test scores were statistically significant ($p \leq 0.05$). Lateral and vertical phoria scores were analyzed using the Spearman's Rank-Order Correlation

Table 2: Summary of Testing Sequences by Subject Groups

	TEST 1	TEST 2	TEST 3	TEST 4
GROUP 1	Optec 2000	Titmus i400	Optec 5000	Titmus 2A
GROUP 2	Titmus i400	Optec 5000	Titmus 2A	Optec 2000
GROUP 3	Optec 5000	Titmus 2A	Optec 2000	Titmus i400
GROUP 4	Titmus 2A	Optec 2000	Titmus i400	Optec 5000

Test for non-parametric data. A Spearman's coefficient (r_s) greater than $r_{critical}$ (where $r_{critical} = 0.33$ and df = n - 2 = 34) suggests a significant correlation may exist ($p \leq 0.05$) between test scores for the old and new instruments.

RESULTS

In the descriptions that follow, the average acuity scores and standard deviations (sd) for the various tests are provided in Snellen decimal form, as well as Snellen fraction notation (in parenthesis), with their corresponding sd converted to the approximate number of optotype. Figure 1 presents the average distant, near, and intermediate (monocular and binocular) visual acuity scores for the two Titmus vision screeners. Average acuity scores for the Titmus 2A ranged from 0.708 (20/28.2) to 0.963 (20/20.8); total average = 0.862 ± 0.095 (20/23.2 ± 1.43 optotype). Average acuity scores for the Titmus i400 ranged from 0.793 (20/25.2) to 0.985 (20/20.3); total average = 0.898 ± 0.064 (20/22.3 ± 0.96 optotype).

Table 3 presents the results of the statistical analysis performed on the (logMAR) visual acuity scores for the two Titmus vision screeners. Included in Table 3 are the average differences in acuity scores for the old and new instruments, standard deviations, 95% confidence intervals, and the probability statistics for all possible sources of variation (i.e., devices, groups, and between-subject by within-subject interactions). The difference in average acuity scores between the Titmus 2A and Titmus i400 ranged from -0.020 (~0.56 optotype) to 0.059 (~1.68 optotype); total average = 0.019 ± 0.025 (~0.55 ± 0.72 optotype). Statistical analysis determined there was no significant overall difference in average acuity scores between the old and new Titmus devices ($p > 0.05$). However, there were significant differences between the intermediate test scores for the two groups of older (≥ 50 years of age) subjects for

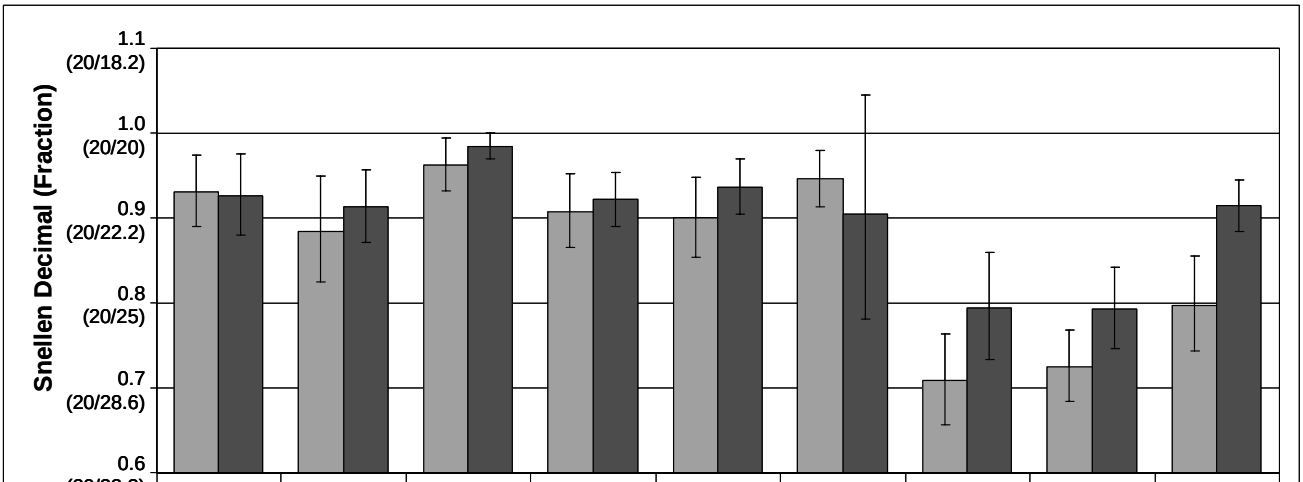


Figure 1: Average acuity scores and 95% confidence intervals for the Titmus vision screeners

Table 3: Titmus Visual Acuity Statistical Analysis (logMAR)

VISION TEST	EYE	Avg Diff	Std Dev	Conf Int	p(device) [df]	p(group) [df]	P(inter) [df]
Distant (N = 36)	Right	-0.002	0.066	0.022	0.905 [1]	0.124 [3]	0.800 [3]
	Left	0.014	0.074	0.024	0.479 [1]	0.563 [3]	0.890 [3]
	Both	0.010	0.047	0.015	0.217 [1]	0.159 [3]	0.803 [3]
Near (N = 36)	Right	0.006	0.067	0.022	0.630 [1]	0.323 [3]	0.940 [3]
	Left	0.017	0.046	0.015	0.248 [1]	0.975 [3]	0.839 [3]
	Both	-0.020	0.196	0.064	0.556 [1]	0.314 [3]	0.526 [3]
Intermediate (N = 6)	Right	0.050	0.077	0.062	0.352 [1]	**0.017 [1]**	0.928 [1]
	Left	0.039	0.111	0.089	0.422 [1]	0.092 [1]	0.648 [1]
	Both	0.059	0.111	0.089	0.136 [1]	0.136 [1]	**0.045 [1]**

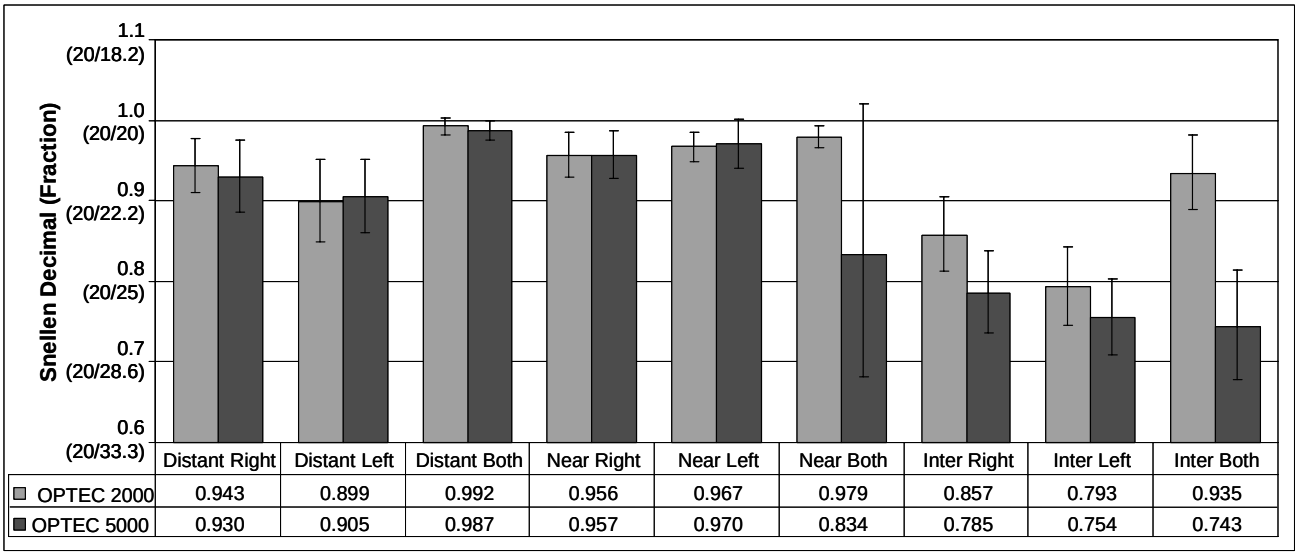


Figure 2: Average acuity scores and 95% confidence intervals for the Optec vision testers

Table 4: Optec Acuity Statistics (logMAR)

VISION TEST	EYE	Avg Diff	Std Dev	Conf Int	P(device) [df]	p(group) [df]	p(inter) [df]
Distant (N = 36)	Right	-0.006	0.043	0.014	0.985 [1]	0.337 [3]	0.745 [3]
	Left	0.003	0.035	0.011	0.862 [1]	0.623 [3]	0.840 [3]
	Both	-0.002	0.014	0.005	0.131 [1]	0.456 [3]	0.564 [3]
Near (N = 36)	Right	0.000	0.029	0.009	0.630 [1]	0.323 [3]	0.940 [3]
	Left	0.001	0.047	0.015	0.248 [1]	0.975 [3]	0.839 [3]
	Both	-0.070	0.273	0.089	0.556 [1]	0.314 [3]	0.526 [3]
Intermediate (N = 6)	Right	-0.039	0.050	0.040	0.242 [1]	**0.003 [1]**	0.420 [1]
	Left	-0.022	0.095	0.076	0.596 [1]	**0.026 [1]**	0.195 [1]
	Both	-0.100	0.140	0.112	0.169 [1]	0.393 [1]	0.991 [1]

the right-eye (F [1, 6] = 8.92, p = 0.017) and a significant (between-subject [group] by within-subject [device]) interaction for the binocular intermediate test scores (F [1, 6] = 5.62, p = 0.045) of these subjects.

Figure 2 presents the average distant, near, and intermediate (monocular and binocular) visual acuity scores for the two Optec vision testers. Average acuity scores for the Optec 2000 ranged from 0.793 (20/25.2) to 0.992 (20/20.2); total average = 0.925 ± 0.065 (20/21.6 ± 0.97 optotype). Average acuity scores for the Optec 5000 ranged from 0.743 (20/26.9) to 0.987 (20/20.3); total average = 0.874 ± 0.096 (20/22.9 ± 1.44 optotype).

Table 4 provides the results of the statistical analysis performed on the (logMAR) visual acuity scores for the two Optec vision testers. Included in Table 4 are the average differences in acuity scores between the old and new instruments, standard deviations, 95% confidence intervals, and the probability statistics for all possible sources of variation (i.e., devices, groups, and between-subject by within-subject interactions). The difference in average acuity scores between the Optec 2000 and Optec 5000 ranged from -0.10 (~2.83 optotype) to 0.003 (~0.08 optotype); total average = -0.026 ± 0.037 (~0.74 ± 1.04 optotype). Statistical analysis determined there was no significant difference in average acuity scores between the old and new Optec devices (p > 0.05). However, there were significant differences between the intermediate test scores for the two groups of older (≥50 years of age) subjects for both the right (F [1, 6] = 18.76, p = 0.003) and left (F [1, 6] = 7.84, p = 0.026) eyes.

Figures 3 and 4 present the results of the lateral and vertical (distant) phoria tests in prism diopters for the Titmus 2A and i400 vision screeners. Lateral phoria scores for the Titmus 2A ranged from -4 to 5.5 pd and averaged -0.014 ± 1.90 pd. Lateral phoria scores for the Titmus i400 ranged from -5 to 5 pd and averaged 0.236 ± 1.69 pd. Vertical phoria scores for the Titmus 2A ranged from -1 to 1 pd and averaged 0.042 ± 0.403 pd. Vertical phoria scores for the Titmus i400 ranged from -1 to 1.5 pd and averaged -0.194 ± 0.482 pd.

Table 5 presents the average difference in heterophoria scores (in prism diopters) for the Titmus 2A and i400 vision screeners, as well as standard deviations and 95%

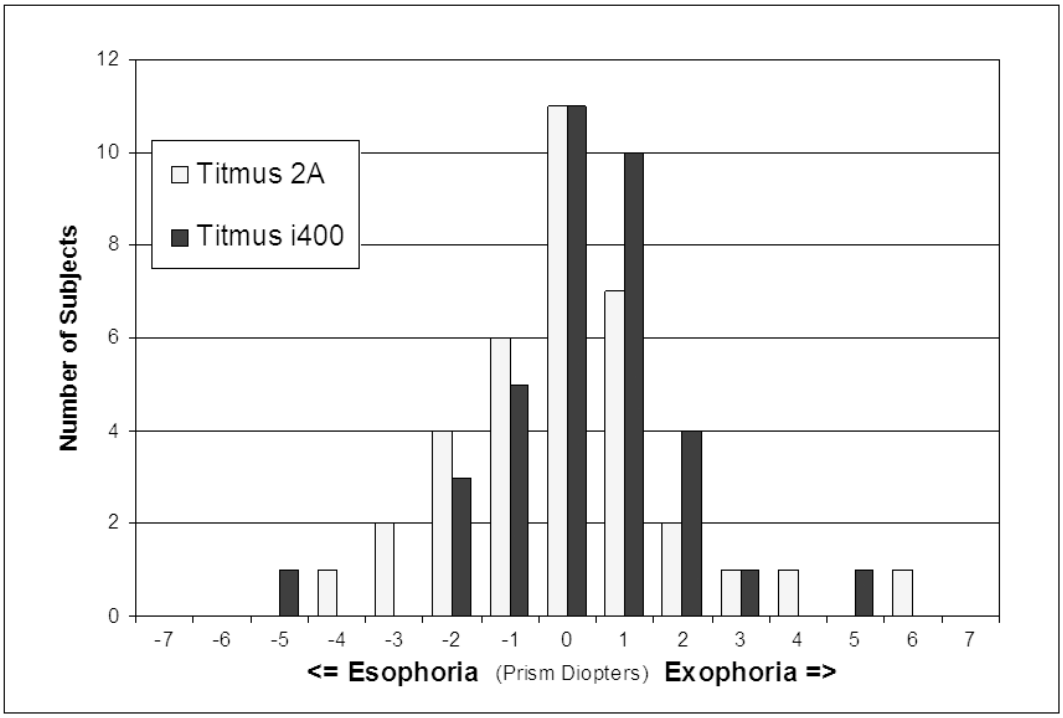


Figure 3: Lateral phoria scores for the Titmus vision screeners (greater or less than ± 6 pd fails)

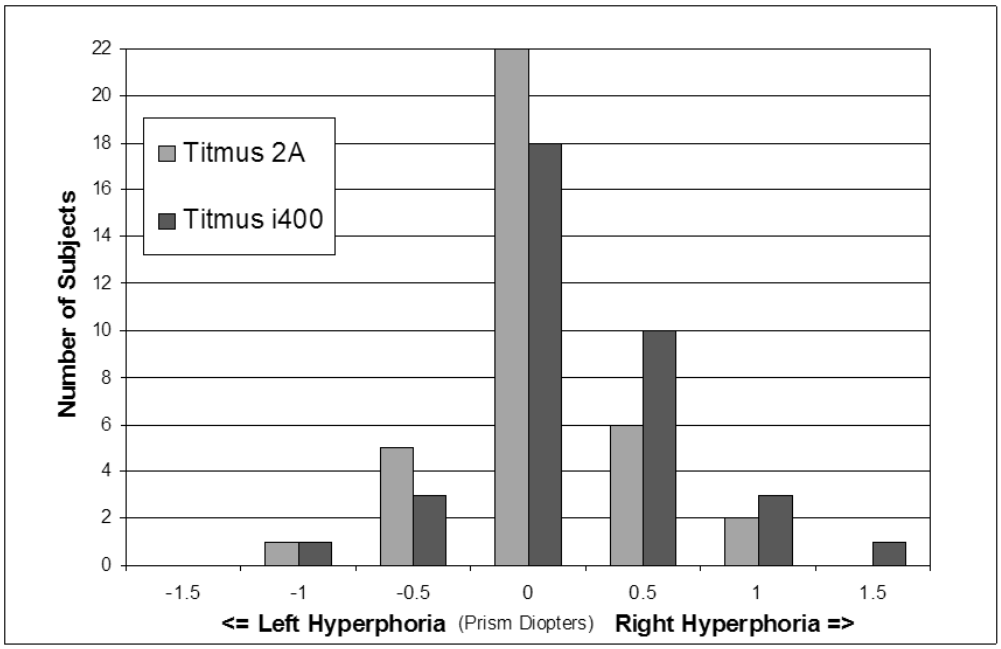


Figure 4: Vertical phoria scores for the Titmus vision screeners (greater or less than ± 1 pd fails)

Table 5: Titmus Heterophoria Statistics

PHORIA TEST	Avg Diff	Std Dev	95% Confidence Interval	r_S	r_S^2	t	P(t)
LATERAL	-0.250	0.952	-0.572 < -0.250 < 0.072	0.856	0.732	9.63	$< 1X10^{-6}$
VERTICAL	-0.153	0.334	-0.266 < -0.153 < -0.040	0.754	0.569	6.70	$< 1X10^{-6}$

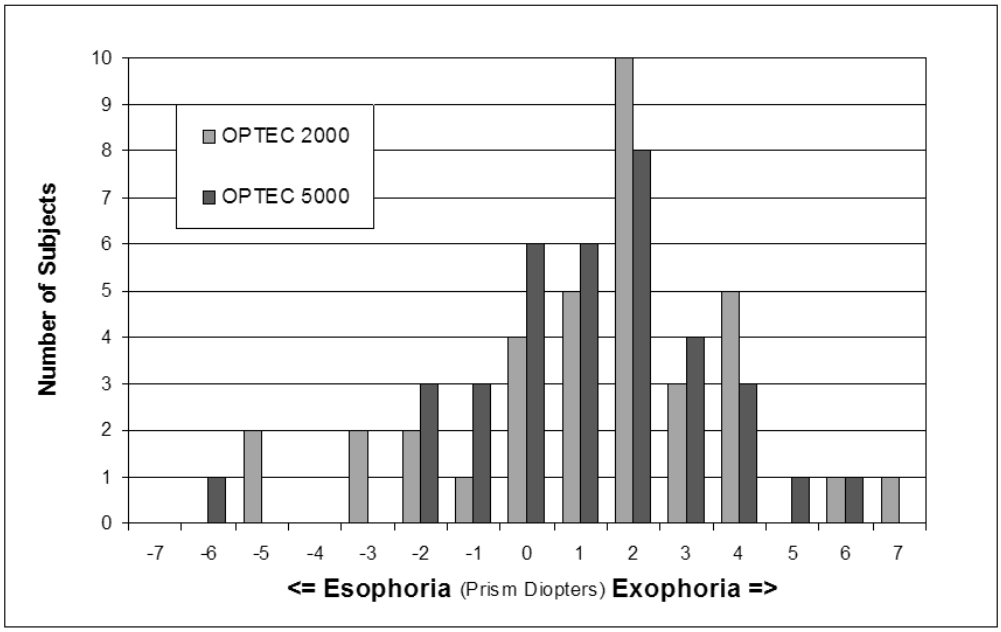


Figure 5: Lateral phoria scores for the Optec vision testers (greater or less than ± 6 pd fails)

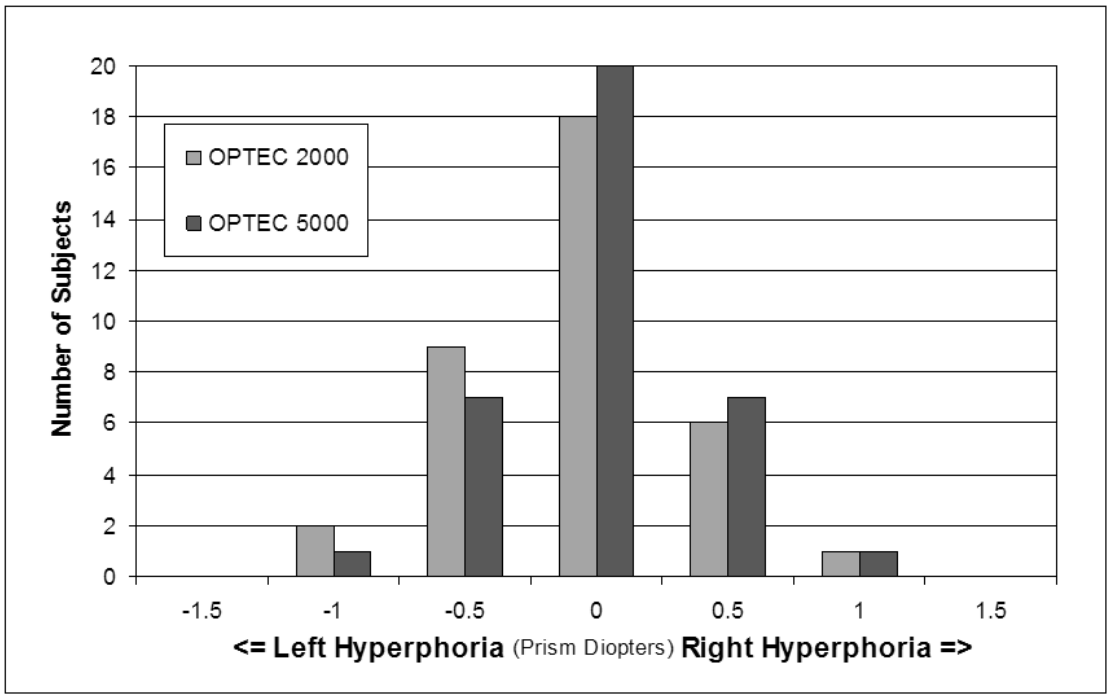


Figure 6: Vertical phoria scores for the Optec vision testers (greater or less than ± 1 pd fails)

confidence intervals. Also provided are the Spearman coefficients (r_s and r_s^2), approximated t-statistic, and probability values for the Titmus (distant) heterophoria scores. The average difference in the (lateral and vertical) phoria scores for the two instruments was relatively small (– 0.3 pd), but lateral phoria scores exhibited greater variability. Both Spearman's coefficients (r_s) were positive and greater than $r_{critical} = 0.33$ (df = 34), indicative of significant correlations between test scores. Both lateral and vertical p-values were considerably less than 0.05, indicating strong ($r_s > 0.67$), positive correlations between the phoria scores for the old and new Titmus instruments.

Figures 5 and 6 present the results of the lateral and vertical (distant) phoria tests in prism diopters for the Optec 2000 and 5000 vision testers. Lateral phoria scores for the Optec 2000 ranged from -5 to 7 pd and averaged -1.25 ±

Table 6: Optec Heterophoria Statistics

PHORIA TEST	Avg Diff	Std Dev	95% Confidence Interval	r_S	r_S^2	t	P(t)
LATERAL	0.083	1.279	-0.349 < 0.083 < 0.516	0.888	0.790	11.31	$< 1X10^{-6}$
VERTICAL	-0.063	0.183	-0.124 < -0.063 < -0.001	0.902	0.814	12.21	$< 1X10^{-6}$

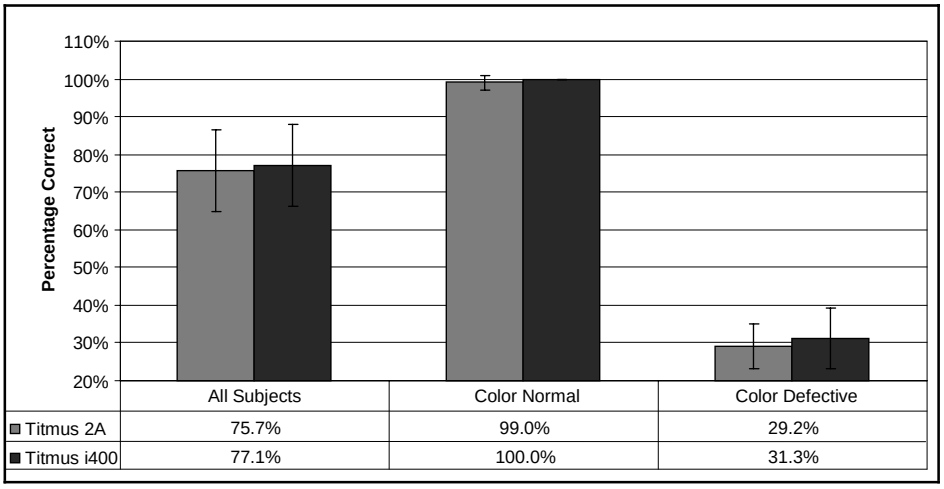


Figure 7: Average color vision scores and 95% confidence intervals for the Titmus vision screeners (< 100% fails for pilot certification purposes)

2.71 pd. Lateral phoria scores for the Optec 5000 ranged from -6 to 6 pd and averaged 1.17 ± 2.30 pd. Vertical phoria scores for the Optec 2000 ranged from -1 to 1 pd and averaged -0.069 ± 0.43 pd. Vertical phoria scores for the Optec 5000 ranged from -1.25 to 1 pd and averaged -0.007 ± 0.42 pd.

Table 6 presents the average difference in heterophoria scores (in prism diopters) for the Optec 2000 and 5000, as well as standard deviations and 95% confidence intervals of the difference in Optec (lateral and vertical) phoria scores in prism diopters. Also provided are the Spearman Coefficients (r_s and r_s^2), approximated t-statistic, and probability values for the Optec (distant) heterophoria scores. The average difference in the (lateral and vertical) phoria scores for the two instruments was relatively small (< ± 0.1 pd), but lateral phoria scores exhibited greater variability. Both Spearman coefficients (r_s) were positive and greater than $r_{critical} = 0.33$ (df = 34), indicative of significant correlations between test scores. Both lateral and vertical p-values were considerably less than 0.05, indicating strong ($r_s > 0.67$) positive correlations between the phoria scores for the old and new Optec instruments.

Figure 7 presents color vision test scores as the percent of correctly identified digits (out of 8 possible) for the Titmus instruments. Note that the average color vision scores were marginally higher from the new Titmus device for both color defective and color normal test subjects.

Table 7 presents the average, standard deviations, 95% confidence intervals of the differences in color vision scores for the Titmus instruments, and the probability values, as determined by the (paired) Student T-test. The number of subjects to pass or fail the Titmus 2A and i400 color vision tests are also presented by subject population. Only one color normal subject failed the Titmus 2A color vision test, while none failed on the Titmus i400 and both devices failed all color defective subjects. All probability values indicate the differences in average color vision test scores for the two instruments are not statistically significant ($p > 0.05$).

Color vision test scores for the Optec instruments are presented in Figure 8. Note that the average color vision scores from the old Optec device were higher for color normal test subjects.

Table 8 presents the average, standard deviations, 95% confidence intervals of the differences in color vision scores for the Optec instruments, and the probability values, as determined by the (paired) Student T-test. The number of subjects to pass or fail the Optec 2000 and 5000 color vision tests are also presented by subject population. The color vision scores for color normal subjects were significantly ($p < 0.05$) higher using the

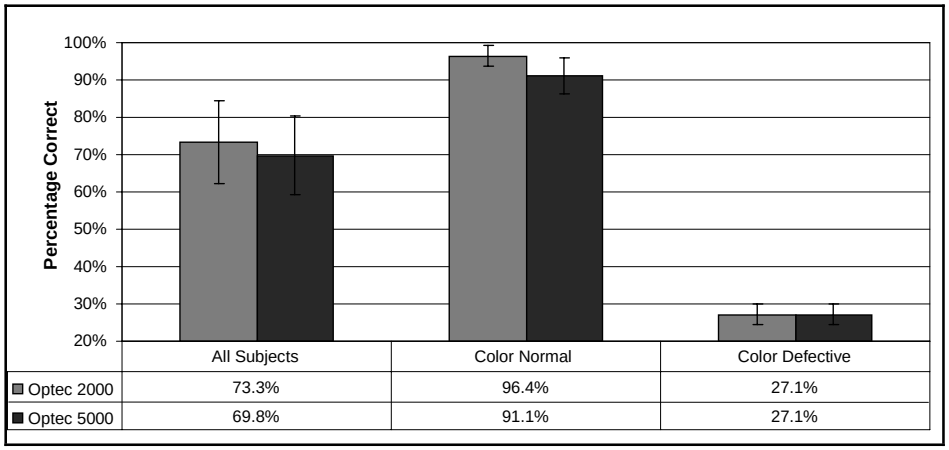


Figure 8: Average color vision scores and 95% confidence intervals for the Optec vision testers (< 100% fails for pilot certification purposes)

Table 7: Titmus Color Vision Statistics

Subject Population	Avg Diff	Std Dev	CI (+/-)	p(t)	Pass	Fail
					2A / i400	2A / i400
All Subjects (n=36)	-1.39%	5.73%	1.87%	0.160	23 / 24	13 / 12
Color Normal (n=24)	-1.04%	5.00%	2.00%	0.328	23 / 24	1 / 0
Color Defective (n=12)	-2.08%	6.91%	3.91%	0.339	0 / 0	12 / 12

Optec 2000 than those obtained with the Optec 5000 vision tester. Six color normal subjects failed at least one response on the Optec 2000, while 12 failed at least one response on the Optec 5000 instrument.

DISCUSSION

Since November 1985, the Titmus 2A vision screener and Optec 2000 vision tester have been approved for use by AMEs to test the visual performance qualifications of applicants seeking an airman medical certificate (see Appendices C and D). Approval for both devices was based on the manufacturers' success in meeting FDA requirements and FAA assessment that the newer vision testers were "substantially equivalent" to the previously approved Titmus OV7-M. How this equivalence was determined is not known, as there is no documentation to indicate that independent testing was performed. FAA approval for intermediate visual acuity testing of subjects 50 years of age and older, in accordance with the revised medical standard, was granted for the Titmus 2A and earlier models of that series in May 1996 (see Appendix E). No evidence of a similar approval for the Optec devices was found. Although a 1990 study performed for the military by McAlister and Peters found the Titmus II's acuity and color vision test scores to be statistically equivalent when compared to clinical test scores, similar comparison found a significant difference in heterophoria scores (2).

To ensure the validity and repeatability of test results, recommended standards for vision testing are put forth by several esteemed organizations. A number of these standards are widely accepted and generally adhered to in clinical testing and in the development of vision testers. Examples of these recommendations include: standards

Table 8: Optec Color Vision Statistics

Subject Population	Avg Diff	Std Dev	CI (+/-)	p(t)	Pass	Fail
					2000 / 5000	2000 / 5000
All Subjects (n=36)	3.47%	7.68%	2.51%	0.010	18 / 12	18 / 24
Color Normal (n=24)	5.21%	8.17%	3.27%	0.005	18 / 12	6 / 12
Color Defective (n=12)	0.00%	5.33%	3.02%	1.00	0 / 0	12 / 12

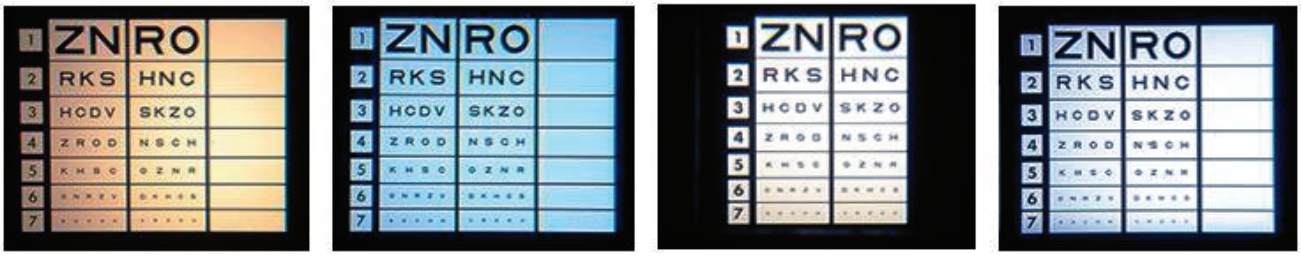


Figure 9: Photos of target slides taken through the optics of each device with a Nikon E8700 digital camera. From left to right: Optec 2000, Optec 5000, Titmus 2A, and Titmus i400. (Note: These images are to demonstrate color differential, not to accurately depict the subject's view of the test slides.)

for eye chart luminance (avg. = 160 cd/m^2 – range: 80 - 320 cd/m^2), color temperature (between 2500K and 7000K), characteristics of target letters (National Research Council, 1980) (3), and letter contrast (ISO 8596 [1994], ANSI Z80.21-1992 [R2004]) (4,5). Visual acuity test slides generally conform to these recommended standards and have remained unchanged for all Titmus and Stereo Optical instruments. All instruments utilize slides that are photographic reproductions of Snellen eye charts to measure distant, intermediate, and near acuity. The slides are essentially abbreviated versions of the Early Treatment for Diabetic Retinopathy Study (ETDRS) (6). Figure 9 provides a subject's view of the (left monocular) distant acuity test slide for each of the four instruments.

Several of the recommended standards for vision testers post-date the initial FAA approval of the older devices; therefore, they were not required to meet those standards. Similarly, the determination of substantial equivalence does not require the new devices to conform to current recommended standards for vision testing. However, luminance, target contrast, and optotype were evaluated for both new instruments and found to be within minimum tolerances. The color temperature and color rendering of the light sources could not be measured with the equipment available.

A standard illuminant C source has a color temperature of 6700K that is considered ideal for color vision testing (7). Illuminant C is a bluish-white light corresponding to the north sky on an overcast day in the northern hemisphere (8). As Figure 9 illustrates, the incandescent lighting of the older devices appears warmer compared to the cooler, bluish lighting (fluorescent and LED) of the new models.

The average visual acuity scores of the new devices compared favorably with those of the older models. However, 7 subjects (5 subjects ≥ 50 years of age) experienced difficulty in maintaining fusion when binocular near and intermediate testing was performed with the new devices (i.e., 6 subjects on the Optec 5000; 1 subject on both the Optec 5000 and Titmus i400). Only 2 of these individuals could not achieve adequate fusion to complete the near visual acuity test (i.e., 1 subject on the Optec 5000 and the other on both the Optec 5000 and Titmus i400). This fusion problem may be due to induced prism effects from the instruments' lenses.

It should be noted that these results would not have medically disqualified these subjects for aeromedical certification of pilots, since all subjects met the FAA standard for monocular intermediate and near vision. These subjects had no fusion problems during prescreening or when tested on the older vision screening devices. Even with these anomalies, statistical analysis indicated non-significant ($p > 0.05$) differences in average acuity scores between the old and new instruments.

There were significant differences between the group acuity scores for the Titmus monocular (right-eye) intermediate test ($F [1, 6] = 8.92$, $p = 0.017$) and significant between-subject and within-subject interactions ($F [1, 6] = 5.62$, $p = 0.045$) for the binocular intermediate test (Table 3). Similarly, there were significant differences between the group scores in the monocular (right- and left-eye) intermediate tests ($F [1, 6] = 18.76$, $p = 0.003$ and $F [1, 6] = 7.84$, $p = 0.026$, respectively) for the Optec units (Table 4). These findings may be the result of practice effects (or memorization) introduced due to the small number of subjects requiring intermediate vision testing ($n = 6$), which did not allow for an even distribution of subjects between the 4 test groups. However, follow-up analysis using the paired Student T-test confirmed the non-significant findings of the ANOVA tests for the difference between the intermediate acuity scores for the old and new instruments of both manufacturers.

Phoria tests measure the latent or relative deviation between the eyes that occurs when fusion is interrupted. It is often described as the resting position of the eyes. A phoria does not exclusively apply to one eye or the other and may be lateral (esophoria for "in," or exophoria for "out") and/or vertical ("right" or "left" hyperphoria). First- and Second-Class pilot applicants for aeromedical certification with more than 1 pd of hyperphoria and/or 6 pd of esophoria or exophoria are not disqualified but would be referred to an eyecare specialist for further testing to determine if there is bifoveal fixation and an adequate vergence-phoria relationship. While all subjects passed the prescreening (Maddox rod) phoria test, two individuals did not meet the certification standard when tested on these instruments. One subject's score was greater than 1 pd of right hyperphoria (1.5 pd) on the Titmus i400 and another subject scored greater than 6 pd of exophoria (+ 7 pd) on the Optec 2000. However, statistically, the (lateral and vertical) phoria scores for the old and new devices compared favorably, according to the Spearman Test. All four Spearman's coefficients (r_s) were greater than $r_{critical} = 0.33$, indicative of significant ($p < 0.05$) correlations between test scores for the old and new Titmus and Optec instruments.

The CFR state that pilot applicants must demonstrate the "ability to perceive those colors necessary for the safe performance of airman duties" (9). AMEs must administer color vision screening tests as part of the certification exam to identify those that may not meet this requirement. Defective color vision is characterized by abnormal color matching and a loss of color discrimination. Dichromats are color defectives that lack one of the three photopigments responsible for color discrimination normally found in the cone receptors of the retina. Anomalous trichromats have all three photopigments, but one is abnormal. Color deficiencies can be further categorized as follows: protans either have a loss of the long wavelength-sensitive cones (protanope) or have long wavelength-sensitive cones whose spectral response is shifted towards the middle wavelength-sensitive cones (protanomalous); deutans either have a loss of the middle wavelength-sensitive cones (deuteranope) or have middle wavelength-sensitive cones whose spectral response is shifted towards the long wavelength-sensitive cones (deuteranomalous); and tritans either lack the short wavelength-sensitive cones (tritanope) or have only a limited number of short wavelength-sensitive cones responding (tritanomalous). Most color vision tests cannot distinguish between the dichromats and anomalous trichromats, so the terms protan, deutan, and tritan deficiency are used. A range of severity is found in each type of deficiency (8).

Prescreening color vision tests included the Dvorine PIP (plates 1-15) and the Farnsworth Panel D-15. The Dvorine test is widely used as a screening test for congenital red-green deficiency. Accuracy for identifying color-deficient individuals is reportedly about 95% (10). The FAA standard for the Dvorine PIP test requires the subject to correctly identify at least 8 of the 15 plates to qualify for certification. All 24 subjects that claimed to have normal color vision easily met the FAA standard; however, 1 subject misidentified 3 plates and would have been considered mildly color deficient based on the Dvorine test criteria (i.e., 0 to 2 plates missed) (11). The first plate is for demonstration and is recognized by all subjects. The two most common types of color deficits are detected with plates 6 and 7 (i.e., protan and deutan, respectively). However, there is some thought that these plates have a low efficiency rate (10). In this study, the Dvorine PIP test correctly identified the 12 color-defective (CD) subjects, classifying 3 as severely defective and 9 as moderately defective. Of the 12 CD subjects, 5 were categorized with both red and green (protan/deutan) deficits, 6 with green (deutan), and 1 could not be categorized with the Dvorine PIP test.

The D-15 test is not used to qualify pilot applicants for aeromedical certification. Scoring is designed to differentiate between subjects with moderate-to-severe color deficiencies and those with normal color vision (12). The D-15 requires the subject to arrange 15 colored caps, or

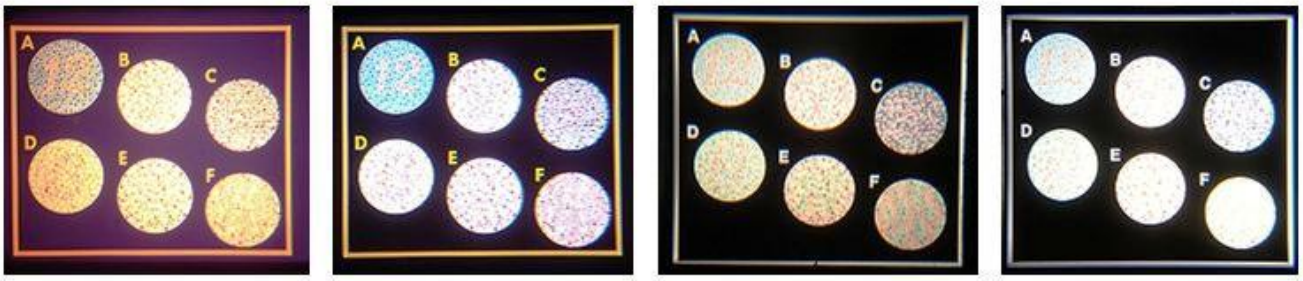


Figure 10: Photos of color vision test slides taken through the optics of each device with a Nikon E8700 digital camera. From left to right: Optec 2000, Optec 5000, Titmus 2A, and Titmus i400. (Note: These images are to demonstrate color differential, not to accurately depict the subject's view of the test slides.)

"buttons," in order according to their hue. An observer scores the results using numbers on the bottom of the caps to trace a circular diagram that should correspond to a steady stepwise progression in hue. If isochromatic errors are made by the test subject, they give rise to lines that cross the diagram where buttons belonging to the opposite side of the hue circle were incorrectly placed next to each other. The degree of deficiency is determined by the number of isochromatic confusions made by the subject's arrangement of the buttons (10). Two or more errors results in a test failure. All 24 subjects that claimed to have normal color vision correctly positioned the 15 colored caps. Of the 12 CD subjects, 10 failed the D-15 test and 2 passed, indicating mild-to-moderate color deficiency. Of the 10 subjects that failed, the Dvorine classified 4 subjects as being both deutans and protans, while the D-15 classified them as 3 protans and 1 deutan. Agreement between the two tests was found for 5 of the 10 subjects (all classified as deutans), with the 1 remaining subject classified as a deutan by the Dvorine and as an anomalous trichromat by the D-15. These results suggest that the classification of color deficiency can vary between the Dvorine and D-15 test.

According to the instructions for the Optec and Titmus instruments, both classify the correct identification of all 8 digits on the 6 PIPs (A – F) as normal color vision (see Figure 10), while correctly reading at least 5 digits indicates a reading 4 or fewer digits correctly results in test failure. For the purpose of aeromedical certification of pilots, an error on any of the 8 digits results in failure on any of the instruments under evaluation. Although one color normal (CN) subject failed to correctly identify 2 digits on the Titmus 2A color vision test, statistical analysis found no significant differences ($p > 0.05$) between the average scores of the old and new Titmus instruments for both the CN and CD subjects. Both old and new Optec instruments correctly identified all 12 CD subjects; however, the Optec 2000 failed 6 of the 24 CN subjects (25% failure rate), and the Optec 5000 failed 5 of those 6 subjects, as well as an additional 7 CN subjects, for a total of 12 (50% failure rate). While the findings for the Optec 2000 were not totally unexpected, given its high rate of false positives documented in previous FAA reports (13,14), the 50% false-positive rate exhibited by the Optec 5000 was troubling. Analysis indicated that the color vision test scores for CN subjects provided by the Optec 5000 were significantly ($p = 0.005$) poorer than those obtained with the Optec 2000. This does not, however, indicate that the instruments are not equivalent based on the pass/fail criteria of the manufacturer, since all CN subjects who failed would be considered only mildly color deficient (i.e., 7 to 5 correct responses). Overall, color vision test scores provided by the old and new Optec devices demonstrated a strong positive correlation using the Spearman Test ($rs = 0.88$) when CN and CD scores were analyzed together.

All 13 CN subjects who failed the color vision test on 1 of the 3 devices had passed both prescreening color vision tests, but 3 of these subjects incorrectly identified 1 to as many as 3 digits on the Dvorine PIP test. These 13 CN subjects had an average age of 41.7 (std dev ± 18 years, range: 20 to 66 years of age). While 11 CN subjects missed only 1 digit on any one instrument, 2 subjects missed 2 digits on the Optec 5000. Digits were most frequently missed on the D plate, followed by the "diagnostic" C plate. The diagnostic C plate results categorized 3 of the CN subjects as being green (deutan) color deficient, 2 red (protan), and 2 green/red (deutan/protan). The remaining 6 CN subjects could only be categorized as mildly color deficient.

While vision testers can make the task of examining patients more convenient, the examiner must be well acquainted with the instrument and its limitations. The following are general recommendations that could be helpful when using such instruments.

1. When setting up a new instrument, perform all test procedures to verify the instrument is working correctly.
2. Confirm that the lenses for intermediate visual acuity testing are of the correct power.

3. Instrument should be placed in an area where lighting can be controlled (e.g., dimming overhead lights during testing).
4. Some instruments require a period to warm up for correct illumination before use.
5. If corrective lenses are to be worn during testing, check them for cleanliness and that the subject can position their head comfortably in the instrument with the spectacles on.
6. Subjects should be seated comfortably with forehead firmly against the headrest (instrument, seat, or table may have to be adjusted up or down). Some instruments require that the forehead be pressed firmly against the headrest to turn on the illumination system. Others require that forehead be lightly touching the headrest so that lights on the side of the instrument can detect that the subject's head is correctly positioned. Proper positioning of the head is critical for binocular near and intermediate vision tests.
7. While performing distant visual acuity, have the subject read letters in the far right column for the right eye, those in the far left column for left eye, and the middle column for binocular testing. If the subject reports that visual acuity charts are not clear while performing binocular testing, first check to see that you have the correct chart selected. If the subject still has difficulty, reposition subject's head and try again. Finally, suggest the subject close both eyes, open one, and then open the other eye, as this may help in fusion of the binocular charts.
8. While performing near testing, some instruments require the subject to look downward to see near acuity charts. Those wearing bifocal correction should position themselves to access the bifocal portion of their lenses.
9. If the subject requires intermediate visual acuity testing, the instrument must be set for distant vision, and intermediate lenses must be placed in a slot on top of the instrument. Those wearing intermediate correction should position themselves to access the appropriate portion of their lenses.
10. While testing color vision, the subject should be made aware that numbers may not be present on all test plates. Seeing no digits on a color plate is an acceptable response.
11. For lateral and vertical phoria testing, the instructions may suggest switching "on" the right eye first and having the subject report how many notes are visible. Then, after switching "on" the left eye, the subject reports to which note the arrow points or which note the red line intersects. Other instruments require that both right and left eye be switched "on" simultaneously. To assist the subject if he or she reports that the arrow or line appears to move, switch "off" left eye (i.e., arrow/red line will disappear). When the left eye is switched back "on," have subject identify to which note the arrow or red line first points.
12. At the end of each day, clean instrument viewing lenses carefully, cover the instrument to keep dust from collecting, and clean and store intermediate lenses.
13. When the illumination lights require replacement, check the instruction manual for the correct replacement procedure.

CONCLUSIONS

The results of this study indicate that, although fusion problems were encountered in the binocular near and intermediate visual acuity tests on the new models, both new instruments provided visual acuity and heterophoria scores that are statistically equivalent to those of their predecessors. Color vision scores for the new Titmus i400 were found to be statistically equivalent to those provided by the discontinued Titmus 2A. Therefore, FAA approval is recommended for Titmus i400 for testing visual acuity, heterophoria, and color vision requirements of pilot applicants seeking aeromedical certification. Although the Optec 5000 met the criterion for both visual acuity and heterophoria testing, it did not demonstrate statistical equivalence with the earlier model for color vision testing. Based on the FAA criteria for pass/fail on the color vision test, the Optec 2000 vision tester failed 25% of the CN subjects tested, while the Optec 5000 failed 50%. The reasons for these high failure rates are unclear. However, possible causes include inaccurate photographic reproduction of PIP test slides, combined with the poor color rendering of the LED light source (8,15). Reproduction of test slides using an imprecise color gamut that differs significantly from that of the original PIP could affect the accuracy and consistency of test results. In addition, inappropriate lighting could be a confounding influence by introducing variations in luminance, color temperature, and color rendering that may result in test patterns appearing less recognizable to color normal subjects. Based on these findings, conditional FAA approval is recommended for the Optec 5000, provided the AME has an alternate color vision test available (e.g., Dvorine PIP), should individuals be identified as color deficient during the certification exam.

Note: The most recent version of the "Guide for Aviation Medical Examiners" lists the Titmus i400 as an approved vision tester for visual acuity, heterophoria

and color vision testing. The Optec 5000 is listed as an approved vision tester for visual acuity and heterophoria testing, but it is listed as an unapproved instrument for color vision testing (9).

REFERENCES

1. Code of Federal Regulations. Title 14 of the Code of Federal Regulations (CFR) Part 67, §67.103(b), §67.203(c), §67.303(d). Washington, DC: U.S. Government Printing Office, Jan. 1, 2008.
2. McAlister WH, Peters JK. The validity of the Titmus vision testing results. *Military Medicine.* 1990 Sep; 155(9):396.
3. Recommended standard procedures for the clinical measurement and specification of visual acuity. Report of working group 39. Committee on Vision. Assembly of Behavioral and Social Sciences, National Research Council, National Academy of Sciences, Washington, DC. *Adv Ophthalmol* 1980; 41:103–48.
4. ISO 8596:1994, Ophthalmic optics -- Visual acuity testing -- Standard optotype and its presentation. International Organization for Standardization / 01-Feb-1994 / 4 pages. Available at URL: http://webstore.ansi.org/RecordDetail.aspx?Sku=ISO%208596:1994&PageType=0 (Accessed: 20 Jan. 2009).
5. ANSI Z80.21 – 1992 [R2004] Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts. American National Standards Institute. Available at URL: http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI+Z80.21-1992+(R2004) (Accessed: 20 Jan. 2009).
6. Ferris FL, Kassoff A, Bresnick GH, and Bailey IL. New visual acuity charts for clinical research. *Am J Ophthalmol* 1982 Jul; 94(1), 91-6.
7. CIE (1932). Commission internationale de l'Eclairage proceedings, 1931. Cambridge: Cambridge University Press.
8. Birch J. Diagnosis of defective colour vision. In: Birch J. Diagnosis of defective colour vision 2nd Ed. London: Butterworth-Heineman; 2001:5-29.
9. Examination Techniques Item 52. Color Vision. The Guide for Aviation Medical Examiners. www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/ (Accessed: 11 Apr. 2008).
10. Birch J. Tests for defective colour vision. In: Birch J. Diagnosis of defective colour vision 2nd Ed. London: Butterworth-Heineman; 2001:61-2.
11. Devorine I. Estimating the degree of color vision defect: Quantification classification table. Dvorine Pseudo-Isochromatic Plates 2nd Ed. New York, NY: The Psychological Corporation, 1953.
12. Farnsworth D. The Farnsworth Dichotomous test for color blindness. New York, NY: The Psychological Corporation, 1947.
13. Mertens HW. Evaluation of functional color vision requirements and current color vision screening tests for air traffic control specialists. Washington, DC: Department of Transportation/Federal Aviation Administration: 1990. Report No. DOT/FAA/AM-90/9.
14. Mertens HW, Milburn NJ. Validity of clinical color vision tests for air traffic control specialists. Washington, DC: Department of Transportation/Federal Aviation Administration: 1992. Report No. DOT/FAA/AM-92/29.
15. Hashimoto K, Yano T, Shimizu M, Nayatani Y. New method for specifying color-rendering properties of light sources based on feeling of contrast. C*olor Res Appl* 2007 Aug; 32(5):361-71.

APPENDIX A

SPECIFICATIONS FOR OPTEC 2000

1. **EXTERNAL DESIGN:**
   a. Occupy two square feet of space.
   b. Use on table or counter top.
   c. Lightweight and transportable (15 lbs.) with slides.
   d. Convenient built in handle.
   e. The housing is flame retardant, non-conductive material. Made from high-impact ABS plastic, which can be cleaned with mild soap and water.
   f. Dimensions: 15-1/2”-H, Base 9-1/2”-W x 14-1/4”-L.

2. **ELECTRICAL:**
   a. 120 VAC or 220 VAC configuration. 0.2 AMPS/24 WATTS
   b. Push button switch controls.
   c. Headrest switch activates internal lighting when subject’s head is in proper position.
   d. Non-Perimeter model is UL Listed. Ref. UL No. E95176 (N).

3. **DESIGN FEATURES**:
   a. Near point test allows the patient to use normal bifocal lens without having to move their head.
   b. Observation windows on both the right and left sides of instrument enables test administrator easy access to point at tests for clarification when needed.
   c. Bulbs replaced easily by field personnel.
   d. No gears in unit.
   e. Confidential testing. Only subject and administrator can observe test and results.
   f. Evenly distributed illumination over entire test pattern. Color corrected light source.
   g. Positive occlusion of right or left eye independently of each other by electronic control.
   h. Lens system capable of Far Point, Near Point and Intermediate Point testing.
   i. Disposable headrest tissues for maximum hygienic conditions.
   j. Faceplate will accommodate contemporary eyeglasses and bifocal frames.
   k. Locking adjustment for height positioning.

4. **TEST:**
   a. Capable of presenting up to 12 tests on a rotating drum.
   b. Field personnel can make installation or replacement of slides quickly and easily.
   c. Slides are manufactured from high quality, photographic film. Sealed between two glass plates protecting it from moisture and dust.
   d. Slides are easily cleaned with glass cleaner.
   e. Photographically reproduced tests are transilluminated rather than using reflective light,eliminating any possible surface glare.
   f. Slides to test the following functions can be supplied: Monocular Acuity, Binocular Acuity, Color, Perception, Depth Perception and Muscle Balance, and Near and Far Point positions.

SPECIFICATIONS FOR OPTEC 5000

1. **EXTERNAL DESIGN:**
   a. Occupy 2 square feet of space.
   b. Use on table or counter top.
   c. Lightweight and transportable (15 lbs.) with slides.
   d. Convenient built in handle.
   e. The housing is flame retardant, non-conductive material, molded from high impact ABS plastic, which can be cleaned with mild soap and water.
   f. Dimensions: 18”-H, Base 11”-W x 15-1/2”-L.

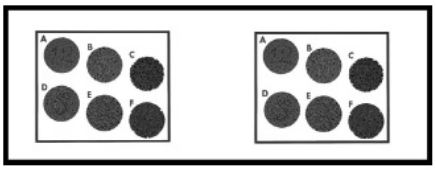
2. **ELECTRICAL:**
   a. Input:100-240V ~ 1.6A Max, 50-60Hz
   b. Output: +24V ⎓ 2.1A
   c. Output Power: 50W MAX.
   d. UL 60601-1/CAN/CSS C22.2 NO. 601.1
   e. Push button switch controls.
   f. Headrest switch activates internal lighting when subject’s head is in proper position.

3. **DESIGN FEATURES**:
   a. Near point test allows the patient to use normal bifocal lens without having to move their head.
   b. Observation windows on both the right and left sides of instrument enables test administrator easy access to point at tests for clarification when needed.
   c. LED Illumination – no bulb replacement necessary.
   d. No gears in unit.
   e. Confidential testing. Only subject and administrator can observe test and results.
   f. Evenly distributed illumination over entire test pattern. Color corrected light source.
   g. Positive occlusion of right or left eye independently of each other by electronic control.
   h. Lens system capable of Far Point, Near Point and Intermediate Point testing.
   i. Disposable headrest tissues for maximum hygienic conditions.
   j. Faceplate will accommodate contemporary eyeglasses and bifocal frames.
   k. Locking adjustment for height positioning.

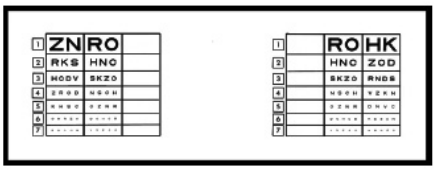
4. **TEST:**
   a. Capable of presenting up to 12 tests on a rotating drum.
   b. Field personnel can make installation or replacement of slides quickly and easily.
   c. Slides are manufactured from high quality, photographic film, sealed between two glass plates, protecting them from moisture and dust.
   d. Slides are easily cleaned with glass cleaner.
   e. Photographically reproduced tests are transilluminated rather than using reflective light, eliminating possible surface glare.
   f. Slides to test the following functions can be supplied: Monocular Acuity, Binocular Acuity, Color Perception, Depth Perception and Muscle Balance, and Near and Far Point positions.

5. **WARRANTY:**
   a. Two years parts and labor.

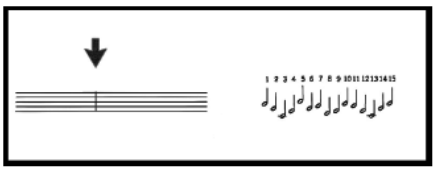
AEROMEDICAL SLIDE PACKAGE



Slide #1 (2000-010)
FAR Point Color Perception

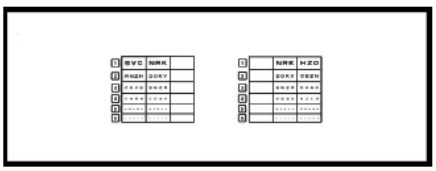


Slide #2 (2000-003)
FAR Point Acuity Right Eye, Left Eye
Both Eyes(20/200-20/20)



Slide #3 (2000-012)
FAR Point Lateral Phoria
(1 Diopter Increments)

Slide #4 (2000-025)
FAR Point Vertical Phoria
(1/2 Diopter Increments)



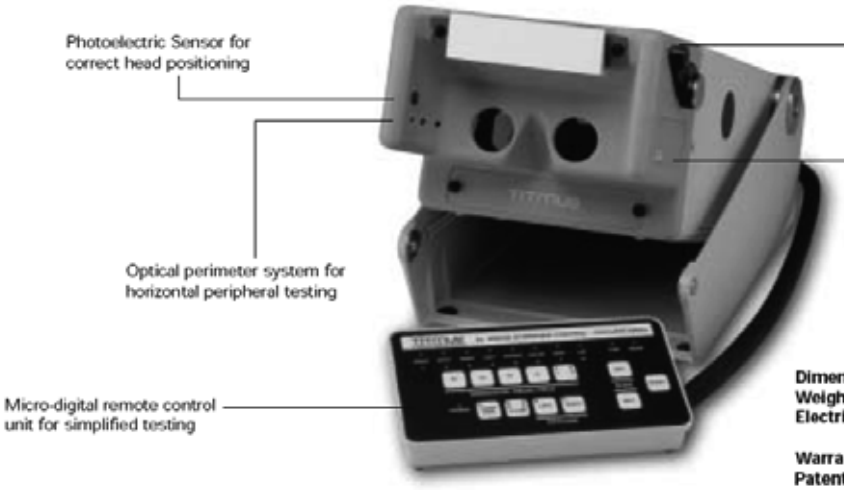
Slide #5 (2000-007)
NEAR Point Acuity Right Eye, Left Eye
Both Eyes(20/100-20/20)

APPENDIX B

SPECIFICATIONS FOR TITMUS 2A

TITMUS 2a VISION SCREENER
MEDICAL MODELS
Professional, Aeromedical, Pediatric

The Titmus Vision Screener is the preferred vision screening instrument of professionals who demand reliable performance. In less than 10 minutes, the Titmus 2a Vision Screener can screen for various visual functions like visual acuity (far and near), binocularity, muscle balance, color perception, three dimensional perception, and peripheral vision. Various test slides are available that meet the requirements of testing as per FAA, DOT and AAP Standards.



Dimensions: *10" W x 18" L x 6.5" H (closed)*
Weight: *11 lbs.*
Electrical: *90-240 VAC, 50-60 Hz*
CE, UL, & CSA Approved
Warranty: *3 years*
Patent Numbers: *4740072, 6505937 B1*

TECHNICAL SUPERIORITY

❶ A remote control panel with state-of-the-art tactile dome switches puts complete command of all test operations at your fingertips. The control panel is connected to the instrument by a coiled cable, providing location flexibility.

❷ A non-contact photoelectric sensor ensures correct head positioning. Test slides will illuminate only when this sensor is activated.

❸ The test slides are manufactured from high quality photographic film, sealed between two optical quality glass plates. The bottom glass is translucent to provide even light diffusion. A special filter simulates daylight viewing conditions.

OPTIONS AVAILABLE

Instrument with Perimeter: A unique optical perimeter system provides for peripheral vision testing in the horizontal plane at angles - 85˚, 70˚, 55˚ and 45˚ (nasal).

Intermediate Lens/Plus Lens: Five different intermediate lenses offer the best means of identifying vision problems at distances of 19, 22, 26, 32 and 40 inches. Plus lenses of values +1.00, +1.50, +1.75 and +2.25 are available for testing children's vision. A set of prism lenses is included with the Aeromedical Model to test for false answers.

STANDARD ACCESSORIES

Eight Test Slides
Training Manual
Dust Cover
Accessory Case
Pointer
Lens Cleaning Towelettes
100 Record Forms
500 Head Rest Tissues
2 Replacement Bulbs

Aeromedical Model: 2 Prism Lens Units
Professional Model: 5 packs of Allen Preschool Test Training Cards, +1.75 Lens Unit
Pediatric Model: 5 packs of Michigan Preschool Test Training Cards, +1.75 Lens Unit

SPECIFICATIONS FOR TITMUS i400

Warranty, Accessories, Standards and Technical Data

Warranty

The TITMUSi400 has a warranty for a period of three (3) years against defects in materials and workmanship from date of purchase. Warranty includes the light module.

Standard Accessories

- 8 Test Slides made from high grade photographic film sealed between optical-quality glass
- Training Manual (technical support available via the internet)
- Record Forms - pad of 100 forms to record test results
- 10 Lens Cleaning Wipes
- Package of 3 Fog Eliminator Cloths
- Accessory Case for storing lens cleaning wipes, fog eliminator cloths, and lenses
- Dust Cover for instrument storage

Optional Accessories

- Carrying Case - soft-sided, ergonomically designed with wheels, for easy transport of vision screener
- Intermediate Lenses - 19, 22, 26, 32 and 40 inches (50, 57, 67, 80 and 100 cm)
- Plus Lenses with values of +1.00, +1.50, +1.75 and +2.25 are available for testing children's vision

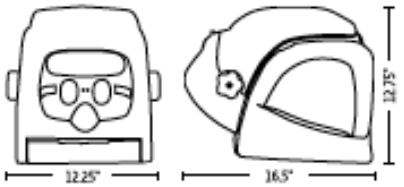
Electrical Standards

The TITMUSi400 meets the CE, UL, and CSA Standards

Europe:	EN 55011 Group 1, Class A
	EN 60601-2
	IEC 601-1-2
USA:	UL 2601-1, 1st Ed. Category 355
Canada:	CSA-C22.2, No. 601.1-M90, Category 245
	Class 1 Device

Technical Data

Power Supply:	110-240 VAC, 0.4-0.2 A, 50/60 Hz
Fuse Rating:	2 A, 250 V
Illumination:	As per ISO 8596 and ANSI Z80.21 Standards
Dimensions:	W X L X H units
	12.25 X 16.5 X 12.75 inches (closed condition)
	31 X 42 X 32 cm (closed condition)
Weight:	18 lbs/ 8.5 kg
Temperature:	+50°F to +100°F (+10°C to +40°C)
Humidity:	30% to 75%



TITMUSiSeries Model Comparison

Model Features	i500	i400	i250	i200
Touch-Screen Control Panel with Software	•			
Membrane Control Panel		•		
Built-In Membrane Switches			•	•
Natural Line of Sight Testing	•	•		
Ergonomics (TitmusComfort™ Height Adjustment)	•	•	•	•
New Fluorescent Light Source	•	•	•	•
Portability	•	•	•	•
Soft Foam Headrest	•	•	•	•
Head Positioning Sensor	•	•		
Peripheral Vision Testing	•	•	•	
Test Slide Advance/Reverse	automatic	automatic	manual	manual
Night Vision Testing	•	•		
Carrying Case (soft-sided)	optional	optional	optional	optional
Standard Accessories	•	•	•	•

INL0601
Q1.000.3.06WHA

TITMUS®
An ISO 9001: 2000 Company

3911 Corporate Drive, Petersburg, VA 23805
800-446-1802 P
804-861-3957 F
info@titmus.com Email

www.titmusiseries.com

Distributed by:

Bacou-Dalloz

Warranty, Accessories, Standards and Technical Data

Warranty

The TITMUSi400 has a warranty for a period of three (3) years against defects in materials and workmanship from date of purchase. Warranty includes the light module.

Standard Accessories

- 8 Test Slides made from high grade photographic film sealed between optical-quality glass
- Training Manual (technical support available via the internet)
- Record Forms - pad of 100 forms to record test results
- 10 Lens Cleaning Wipes
- Package of 3 Fog Eliminator Cloths
- Accessory Case for storing lens cleaning wipes, fog eliminator cloths, and lenses
- Dust Cover for instrument storage

Optional Accessories

- Carrying Case - soft-sided, ergonomically designed with wheels, for easy transport of vision screener
- Intermediate Lenses - 19, 22, 26, 32 and 40 inches (50, 57, 67, 80 and 100 cm)
- Plus Lenses with values of +1.00, +1.50, +1.75 and +2.25 are available for testing children's vision

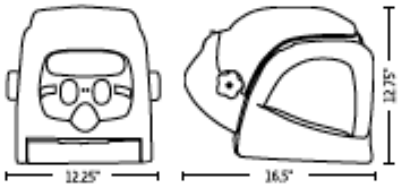
Electrical Standards

The TITMUSi400 meets the CE, UL, and CSA Standards

Europe:	EN 55011 Group 1, Class A
	EN 60601-2
	IEC 601-1-2
USA:	UL 2601-1, 1st Ed. Category 355
Canada:	CSA-C22.2, No. 601.1-M90, Category 245
	Class 1 Device

Technical Data

Power Supply:	110-240 VAC, 0.4-0.2 A, 50/60 Hz
Fuse Rating:	2 A, 250 V
Illumination:	As per ISO 8596 and ANSI Z80.21 Standards
Dimensions:	W X L X H units
	12.25 X 16.5 X 12.75 inches (closed condition)
	31 X 42 X 32 cm (closed condition)
Weight:	18 lbs/ 8.5 kg
Temperature:	+50°F to +100°F (+10°C to +40°C)
Humidity:	30% to 75%



TITMUSiSeries Model Comparison

Model Features	i500	i400	i250	i200
Touch-Screen Control Panel with Software	•			
Membrane Control Panel		•		
Built-In Membrane Switches			•	•
Natural Line of Sight Testing	•	•		
Ergonomics (TitmusComfort™ Height Adjustment)	•	•	•	•
New Fluorescent Light Source	•	•	•	•
Portability	•	•	•	•
Soft Foam Headrest	•	•	•	•
Head Positioning Sensor	•	•		
Peripheral Vision Testing	•	•	•	
Test Slide Advance/Reverse	automatic	automatic	manual	manual
Night Vision Testing	•	•		
Carrying Case (soft-sided)	optional	optional	optional	optional
Standard Accessories	•	•	•	•

1NL0601
Q10003.06WHA

TITMUS®
An ISO 9001: 2000 Company

3811 Corporate Drive, Petersburg, VA 23805
800-446-1802 P
804-861-3957 F
info@titmus.com Email
www.titmusiseries.com

Distributed by:

Bacou-Dalloz

APPENDIX C

U.S. Department
of Transportation
**Federal Aviation
Administration**

800 Independence Ave., S.W.
Washington, D.C. 20591

NOV 19 1985

Mr. Joseph Andera
President
3539 North Kenton Avenue
Chicago, Illinois 60641

Dear Mr. Andera:

Thank you for your letter of November 7 and for the additional material concerning the OPTEC 2000 vision tester. You included copies of your notification to the Food and Drug Administration, as required, of your intent to market the device.

We are satisfied that the OPTEC 2000 vision tester is substantially equivalent to the Titmus OV7-M, used for many years, with our approval, by Aviation Medical Examiners (AME). We have determined, therefore, that the OPTEC 2000 is satisfactory for use by designated Federal Aviation Administration AME's in performing the pertinent parts of the medical examination for airman medical certification (distant and near visual acuity, heterophoria, and color vision).

Your cooperation was appreciated.

Sincerely,

Frank H. Austin, Jr., M.D.
Federal Air Surgeon

APPENDIX D

U.S. Department
of Transportation
**Federal Aviation
Administration**

800 Independence Ave., S.W.
Washington, D.C. 20591

NOV 0 4 1985

Mr. Anthony G. Gates
Technical Manager/Marketing
Titmus Optical Incorporated
Petersburg, Virginia 23804-0191

Dear Mr. Gates:

Thank you for the additional material regarding the Titmus II Vision Tester and your notification to the Food and Drug Administration, as required, of intent to market the device. You had previously submitted the test data from Mr. Marvin Efron of the University of South Carolina.

We are satisfied that the Titmus II Vision Tester is substantially equivalent to your earlier version. We have determined, therefore, that the Titmus II Vision Tester is satisfactory for use by designated Federal Aviation Administration Aviation Medical Examiners in performing the pertinent parts of the medical examination for airman medical certification (distant and near visual acuity, heterophoria, and color vision).

Your cooperation was appreciated.

Sincerely,

Frank H. Austin, Jr., M.D.
Federal Air Surgeon

APPENDIX E

U.S. Department of Transportation
Federal Aviation Administration

Office of the Federal Air Surgeon

800 Independence Ave., SW.
Washington, DC 20591

MAY 31 1996

Mr. William A. Broach, Jr.
Titmus Optical, Inc.
1015 Commerce Street
Petersburg, Virginia 23803

Dear Mr. Broach:

I understand that your company's vision screeners, Models T2A, T2S, TII, and TIIS, have an available intermediate vision lens unit with an effective distance of 31.48 inches. You asked if this lens unit meets the Federal Aviation Administration's new requirement for the testing of intermediate vision (at 32") in applicants for first- and second-class airman medical certification who are 50 years of age or older. This testing requirement begins on September 16, 1996.

Our review of the issue finds no significant concerns. Accordingly, I consider Titmus vision screeners, fitted with the Titmus 31.48" lens unit, to be fully acceptable for use by designated aviation medical examiners to determine visual acuity at 32" as required by the medical standards of revised part 67 of the Federal Aviation Regulations.

Thank you for your company's support of our medical certification program.

Sincerely,

Jon L. Jordan, M.D.
Federal Air Surgeon