

# ***Factors contributing to the inaccuracy and lack of repeatability with the traditional subjective heterophoria measurements.***

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## **Background**

Clear and single binocular vision is critical for normal visual behavior. Our eyes focus (accommodation) and align (vergence) to the object of interest in the real world thereby maintaining clear and single binocular vision. Any inaccuracies in the alignment would lead to eye deviations which can be broadly classified into three types: heterophoria, fixation disparity and heterotropia (strabismus). Heterophoria is the relative misalignment of the eyes in the absence of fusion. In other words, it is the eye misalignment measured under dissociated conditions. It can be horizontal, vertical, cyclo deviated or any combination of the above and is typically compensated by the eye's fusional vergence in the presence of fusion. An inability to compensate this eye misalignment would lead to a manifest deviation called heterotropia or strabismus. Fixation disparity, on the other hand, is the relative misalignment of the eyes in the presence of fusion. This deviation is typically less than the Panum's fusional area therefore objects in space do not appear double. Conditions related to phoria or fixation disparity are clinically referred to as non-strabismic binocular vision disorders.

Traditionally, a diagnostic vision testing routine involves determination of uncorrected refractive errors which are corrected using lenses that provide the best possible vision. However, comprehensive vision care cannot just be limited to the best monocular and binocular visual acuity that can be provided. In the natural world, our eyes work together to focus and align objects to achieve a clear and single binocular vision. Therefore, to provide the best vision care, it is important to also evaluate how well our patients' eyes work together. This is especially critical in this modern day and age where we see an increasing trend in our near vision demand associated with viewing digital devices including phones, tablets and computers. This increasing near visual demand increases the load on the accommodation and vergence mechanisms to constantly focus and align objects at closer distances. Recent reports show that, on average, American children and adults spend about 7.5 to 9.7 hours/day on digital platforms with about 40-80% of them reporting one or more Digital Vision Syndrome (DVS) symptoms such as tired eyes, eye strain and discomfort or dry eyes (Rosenfield, 2016). Therefore, it is important to evaluate the binocular vision mechanism in these patients and treat them accordingly.

To evaluate the binocular vision mechanism, clinicians measure the magnitude and the direction of the phoria at distance (6m) and near (40cms). Tests such as cover-uncover, Von Graefe or modified Thorington are typically used to measure phoria. A comprehensive way to measure binocular vision would include testing the limits (NPA/NPC), amplitudes (NFV/PFV, NRA/PRA), accuracy (phoria/fixation disparity, lag/lead of accommodation) and the dynamics (vergence and accommodation facility) of both accommodation and vergence. Prism bars, flippers, RAF rulers, Maddox rods, retinoscopes and phoropters are employed to obtain this information about these two motor mechanisms. Given the unique cross-coupled behavior of the accommodation and vergence mechanism, another important measure would be to determine the strength of the cross-links between the two systems typically quantified as accommodative vergence response (AC/A ratio) and vergence accommodation response (CA/C ratio). CA/C is not commonly measured in a clinical setting. Individual clinical practices typically measure only phoria and limits (NPA/NPC). If the patient with phoria is symptomatic, treatment options aimed at reducing the phoria are traditionally recommended. Currently, several treatment options including lenses, prisms and vision therapy are available and often prescribed based on the information obtained from the above-mentioned tests (Scheiman & Wick, 2014). Given how important it is to evaluate binocular vision in this digital world, it is crucial that we test this mechanism both comprehensively and accurately; however, the current testing routine involved for phoria estimations is not ideal and has several sources that could potentially cause errors in estimating the binocular function. These sources include the subjective nature of testing, inter-examiner repeatability and the variability and complexity involved in the tests and procedures.

## Sources of Error

### *Subjective nature of the tests*

Most clinical testing routines for evaluating binocular vision are subjective, depending on either the patient's attentive response or the clinician's level of expertise. This subjectivity could cause inaccurate estimates of the phoric posture with poor repeatability. Furthermore, given the subjective nature of testing, these tests will not be suitable for testing young children or individuals that are differently abled where it is difficult to obtain an accurate verbal response.

### *Inter-examiner repeatability*

Most clinical tests, given their subjective nature, are dependent on the clinicians' ability to perform the test accurately. Although several studies have reported that the level of expertise does not lead to clinically significant differences in phoria estimations, these studies do show that the variability in the estimation is larger with novice examiners (Hrynychak et al., 2010). Another potential source for inter-examiner repeatability would be the difference in the neutralization criterion employed by the clinician. For example, when performing subjective prism cover test, some examiners choose the prism value which neutralizes the eye movement as their end point while others choose the prism which creates an opposite movement of the eye or the point of reversal. Given the steps of prism changes seen in a prism bar, this could potentially lead to a variability of about 2-4PD. A study with a small sample also reported that the smallest phoria value that can be detected by clinicians with varying levels of expertise is about 2-3PD (Fogt et al., 2000). This would mean that any misalignments less than this value would not be detected and may potentially lead to inaccuracies. Finally, while performing tests that depend on the placement of prisms, such as prism cover test or fusional vergence testing, the distance between the prism and eye can impact prism effectivity and can lead to spurious or less reliable estimations.

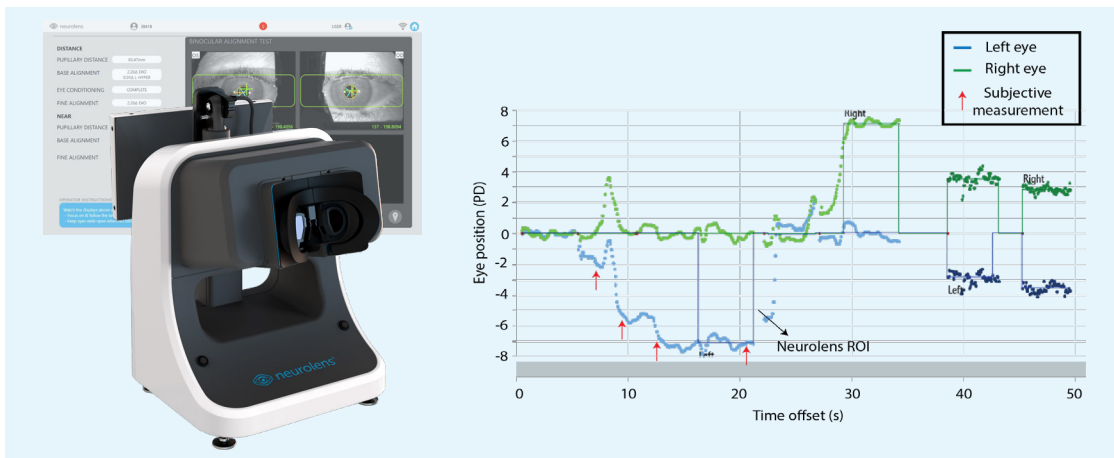
### *Tests and procedures*

Another crucial aspect to consider is what measurements should be used to calculate the prismatic correction that could be prescribed to your patient. Should you decide the prism value based on dissociated phoria, fixation disparity or both? Is one more effective than the other? Although most clinicians in North America typically prescribe prisms based on the dissociated phoria, there is evidence that fixation disparity could be a better predictor and should be employed for estimating the prism value. These studies argue that fixation disparity tests provide a more natural viewing condition with both eyes viewing similar content which could be fused (Yekta et al., 1989). Others have pointed out that neither of these alignment tests really provide any natural cues with measurements since the subjects view targets in an artificial or abnormal viewing conditions. Previous studies suggested that the practitioners could recommend prisms that make their patients feel most comfortable while viewing objects in real world (Otto et al., 2008). There is also disagreement on effectivity of prism corrections estimated based on either dissociated or associated phoria values (reviewed in Otto et al., 2008).

As mentioned before, several tests including Thorington, cover test and Von Graefe are used to measure phoria. Several studies have reported a significant difference in measured estimates between the tests with a standard deviation of about 4-5PD. One would reasonably expect to see differences between the tests given the difference in the testing procedure, stimuli used, influence of proximal convergence, ability to control accommodation and the nature of subjectivity involved in the test. For example, does the subjective test involve a patient's response compared to a clinician's judgement of the deviation? A study looking at the inter-examiner repeatability of different tests reported that only tests such as the Thorington have high inter-examiner repeatability while commonly employed tests such as the Von Graefe have a very low repeatability with differences as large as 3-5PD (Rainey et al., 1998; reviewed in Goss et al., 2010).

Another important difference that could lead to the lack of repeatability and inaccuracies in the estimate is the amount of the time used to dissociate the eyes before taking a measurement. Previous research had reported a dissociation time as long as 5-25 min would be necessary to minimize the influence of vergence adaptation so a more accurate estimate of heterophoria could be obtained (Rosenfield et al., 1997). Unfortunately, this is not possible in a clinical setting and, given the limited ability of an unaided eye to identify and track very small and slow eye motion, it is difficult to say if measurements are indeed obtained after the eye stabilizes in a certain phoric posture under dissociated conditions. This, again, would potentially cause errors in the estimation. Finally, a major complexity associated with binocular vision testing is that the clinician must typically perform a battery of tests to decide on type and magnitude of the corrective option. This is especially challenging in busy individual practices to invest a significant amount of time into performing a battery of tests to estimate an accurate prism correction that can effectively relieve symptoms.

### Neurolens Measurement Device, Gen 2 (NMD2)



**Figure 1:** An illustration of the Neurolens Measurement Device, Gen 2. An example data trace of a subject's left eye (blue) under dissociated conditions. Eye position, in prism diopters (PD), is plotted as a function of time offset. After dissociation, the left eye slowly drifts towards the phoric position. Neurolens measurement algorithm measures the phoria position once the dissociated eye stabilizes, defined as the Neurolens region of interest (ROI). However, when a clinician subjectively measures phoria or even when a patient subjectively responds, depending on the time of measurement, indicated approximately with red arrows, the amount of phoria value can vary anywhere from 2-7 PD. That is approximately a 5PD variability that can be induced depending on the time of the measurement. This could be one of the potential causes of variability with the traditional clinical methods that measure eye alignment.

The Neurolens Measurement Device, Gen 2 (NMD2) is a diagnostic tool that measures binocular vision. It is an objective, efficient, patient-friendly, accurate, precise and simple way to measure eye alignment along with the inter-pupillary distance and AC/A measurements. The NMD2 does not rely on subjective responses, therefore eliminating both clinician and patients' biases or variabilities. The objective measuring aspect of the NMD2 is achieved by employing an eye tracking system which robustly tracks patients' eyes in a continuous fashion while the eyes are dissociated. This allows the system to measure the phoria once the eye stabilizes under dissociated conditions leading to an accurate and repeatable estimate of the phoria (Figure 1). The system can identify phoria smaller than 1PD and can detect changes as small as 0.01PD. An internal clinical study done using three different systems on 15 subjects with and without non-strabismic disorders found that the repeatability of the NMD2 was 0.53PD for distance and 0.86PD for near phoria measurements which is significantly lower than 2.5-5PD reported with the traditional methods such as Von Graefe and Thorington. Furthermore, the examiner's level of expertise or the patient's responsiveness do not affect the NMD2 measurements. The NMD2 continuously monitors the eye movement and measures both dissociated phoria and fixation disparity at distance and near. To ensure accurate estimates were obtained and the eye movement data was not corrupted with large eye/head movements, the NMD2 also provides a measurement quality index (MQI) which informs the examiner about the quality of measurement obtained (MQI > 0.7 is considered a good measurement with the eye movement having been neutralized within 0.25PD).

The NMD2 is simple in the sense that it employs an iterative procedure which takes the misalignment measurements into account and provides a final Neurolens prism correction (Neurolens value), in units of PD, which the clinicians can readily use to treat their patients. Unlike prescribing guidelines like Sheard's Criterion, Percival's Rule or the 1:1 rule, the Neurolens value utilizes a proprietary algorithm that was developed based on patient outcomes across hundreds of thousands of measurements and outcomes. The NMD2 is efficient in that it finishes the basic binocular vision testing, including phoria/fixation disparity and AC/A, and provides a Neurolens correction value within 180 seconds; and, it can be performed by a clinical technician. Finally, it also provides a visual representation of the patient's misalignment which can be used to explain the problem causing the symptoms along with the solution being recommended to the patient.

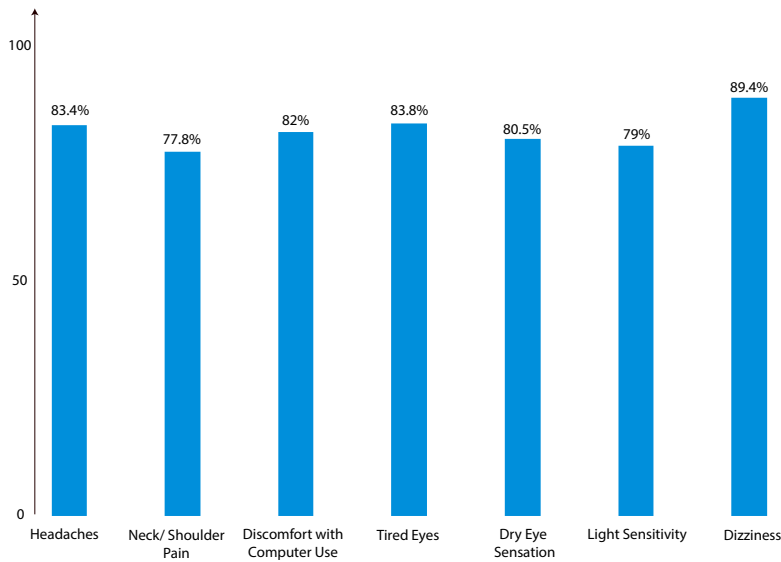


Figure 2: Proportion of individuals that reported symptom relief after wearing Neurolens correction for 60 days.

As shown in figure 2, Neurolens correction prescribed based on the Neurolens prism value has proven very successful delivering a very high level of symptom relief for patients with various DVS related symptoms such as headaches, neck pain, discomfort with computer use, etc. Unlike a regular prism, Neurolenses incorporate a contoured prism design which allows clinicians to provide different amounts of prism at distance and near. Overall, approximately 83% of Neurolens wearers reported improvement in the typically reported DVS symptoms including discomfort with computer use (82%), tired eyes (83.8%) and headaches (83.4%). After a 60-day wear of Neurolenses, prescribed based on the neurolens prism value reported by the NMD2, approximately 80% of the symptomatic patients reported that they are willing to recommend Neurolens to their friends and family.

## Conclusion

An average American spends about 7-10 hours/day on digital devices of which approximately 40-80% individuals experience some sort of DVS related symptoms including headaches, neck pain and tired eyes. Furthermore, individuals with traumatic brain injury (TBI), post LASIK surgery or young adults with myopia have also been reported to be strongly associated with non-strabismic disorders. It is therefore critical that these individuals are provided with the best possible comprehensive vision care, including an accurate and efficient binocular vision evaluation. The Neurolens Measurement Device, Gen 2 (NMD2) is an accurate, efficient, precise, objective and simple way to diagnose these patients and provide a treatment option (Neurolenses with contoured prism) that can relieve their symptoms, ultimately helping them to lead a symptom-free digital life.

**Table 1:** Summary of the differences between the traditional subjective methods used to estimate eye misalignment and NMD2.

Source of Error		Traditional Methods	NMD2
Subjective nature		Clinicians' expertise or patient responsiveness	Objective and can be operated by a technician
Inter-examiner repeatability	Variability with clinical expertise	Yes	No
	Neutralization criterion	Yes. Does the examiner choose a prism neutralization that induces no eye movement or opposite eye movement (reversal)?	No. The algorithm measures deviation when the eyes stabilize
	Accuracy of the end point	Depending on the test (prism bar) employed, can vary between 2-4 PD	Measurement Quality Index (MQI) > 0.7 would indicate that the end point is within 0.25PD
	Smallest phoria that can be identified	~2-3PD	Misalignment less than 0.01PD would be detected
	Prism effectivity	Depending on where the prisms have been placed relative to the patient's eyes, prism effectivity can be different	Vertex distance is always kept constant
Tests and Procedures	Should you decide the prism value based on the dissociated phoria, fixation disparity or both?	Clinicians typically use dissociated phoria	NMD2 utilizes a proprietary algorithm which takes both dissociated and associated phoria into account
	Repeatability	Depending on the test employed, it can be anywhere between 3-5PD	0.53PD for distance and 0.86PD for near measures
	Dissociation time	Variable depending on the test and is limited by the unaided eye's ability to track very small and slow eye movements	Eye trackers can accurately track the eye during dissociation and association measures

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