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Problem Being Addressed

- According to the Defense and Veterans Brain Injury Center, there were 361,092 brain injuries recorded in the US Military between 2000 and 2016¹
- It is difficult, with presently available methods, to image every soldier or athlete who experiences a potential brain injury and, damage to delicate brain tissues is frequently undetectable by conventional imaging, including CT and MRI scanning.
- In mild to moderate TBI, symptoms are difficult to quantify, particularly with existing cognitive tests like SCAT, MACE, or King-Devick.

Background on VEP Testing

- In a Visually Evoked Potential (VEP) test, the shape and latency of the electrical response at the occipital cortex from a visual stimulus is measured.
- This “can provide a sensitive indication of visual pathway disturbances as they traverse through the parietal and temporal lobes to their final destination in the occipital lobes”².
- Intracranial Pressure (ICP), an accepted marker of TBI, has been shown to have a positive correlation to VEP latency and can also serve as a marker of brain injury^{3,4}.
- Current VEP equipment generally uses a large computer monitor and sensitive recording equipment.

Our Approach

- The Portable Multi-Modal TBI (PMT) monitor will implement multiple tests
- Initial PMT does Visually Evoked Potential (VEP) testing in a head-worn, portable device

Human Subjects Testing

- Local IRB approval obtained under Non-Significant Risk determination
- Initial pilot cohort of 10 healthy subjects were tested by PMT and approved Nicolet Viking System and previously reported
- Data presented here are from a second cohort of 30 subjects, including 10 subjects with prior concussion, taken after system upgrades.

Data Presentation

- Subjects were tested at 1 Hz, 2 Hz and 4 Hz repetition rates; Only the 2 Hz repetition data is shown in comparison graphs here.
- VEP response graphs show good agreement for non-concussion subjects
- With some concussion subjects, both systems show very weak response, dominated by noise.



Fig. 1 – VEP data for non-concussion Subject 27. PMT 2 Hz data (left) and Nicolet-Viking data (right) show good correspondence of the response graph

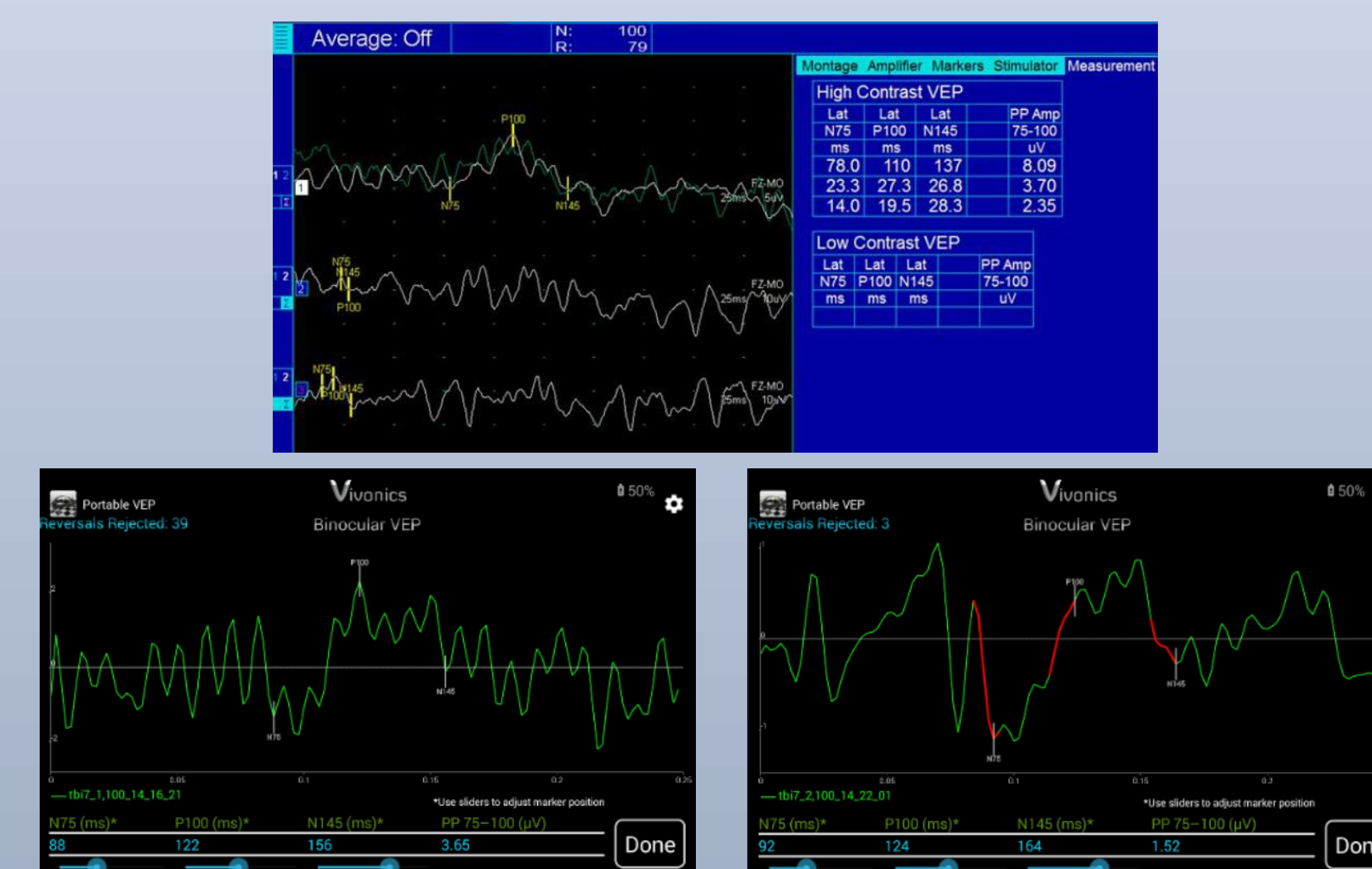


Fig. 2 – VEP data for concussion/TBI Subject 7. Top shows Nicolet at 1, 2, and 4 Hz reversal rates. Bottom shows PMT displays for 1 Hz (left) and 2 Hz (right). Patterns are weaker and not as clear as for non-concussion subjects.

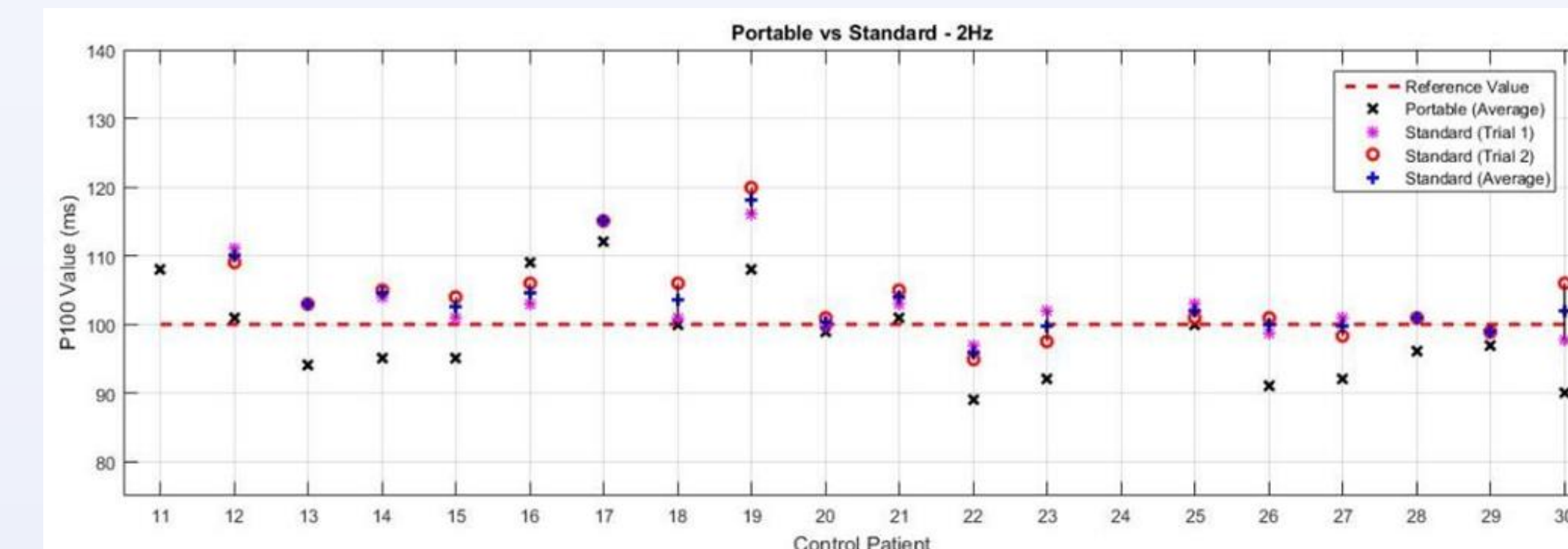


Fig. 3 - 2Hz, P100 non-concussion subject graph
 (Note: subject 24 withdrew from study)

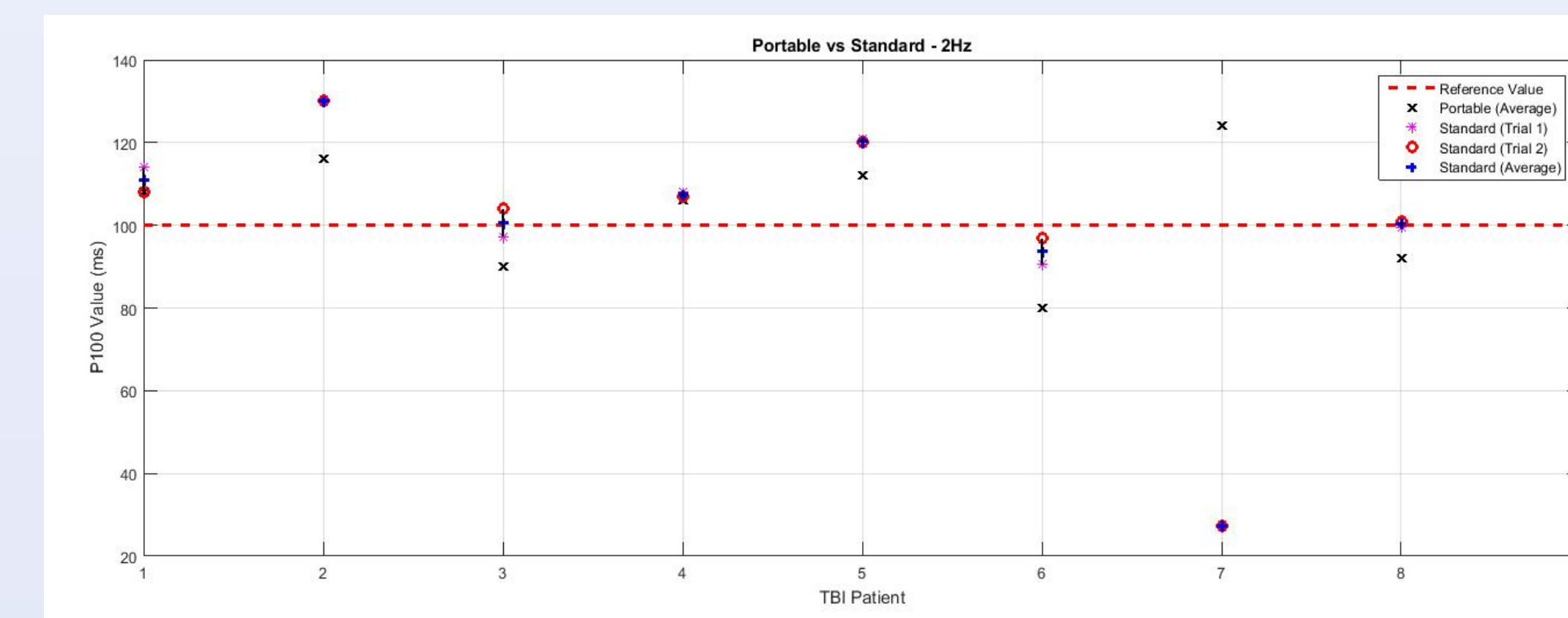


Fig. 4 - 2Hz, P100 concussion/TBI subject graph
 (Note: subject 7 had visual convergence difficulty)

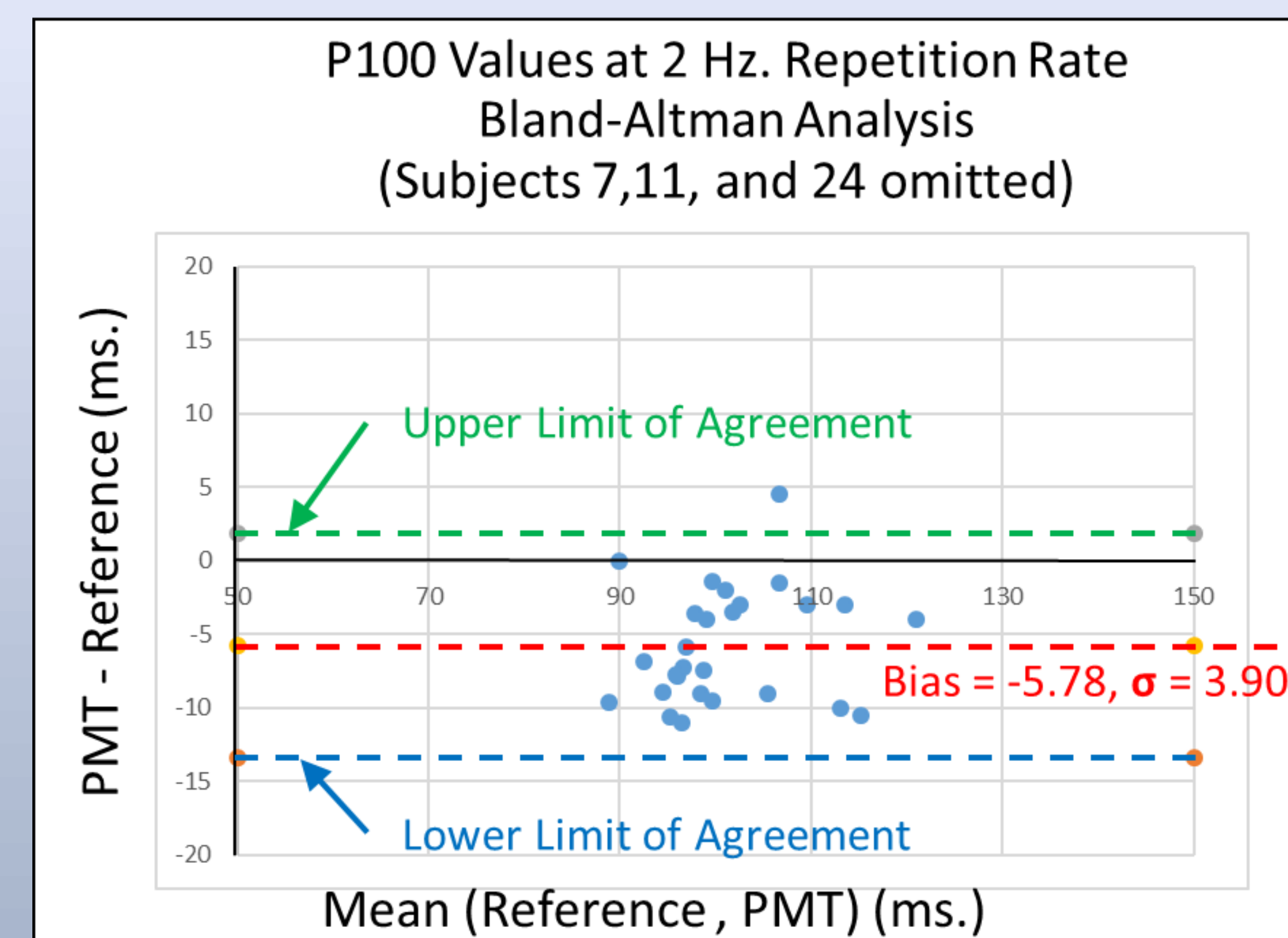


Fig. 5 - Bland-Altman plot of 2Hz data across all 27 of the 30 subjects with complete data shows PMT values biased below corresponding Reference values, but bias appears consistent across the range of values (simple offset error)

Data Analysis / Conclusions

- Comparative data between the PMT and the reference Nicolet-Viking system are shown for the non-concussion group and the concussion/TBI group separately.
- Bland Altman analysis includes both groups Data shows that the PMT system reports slightly lower P100 values on a fairly consistent basis
- This is confirmed by the Bland-Altman analysis which shows a bias in the data for 5.78 lower for the PMT.
- The bias appears to be predominantly a simple offset, not highly dependent on the reading.
- Additional system analysis may determine a cause for the offset, but this is easily corrected for in the system or data interpretation.
- PMT may be more demanding on visual convergence, which can be impaired from TBI

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