ETF$^{128®}$/ETF^{Mx} **Clinical White Paper/FAQ**

The 128 Hz tuning fork has long been used by a variety of medical professionals for the assessment of vibratory sensation. Although the tuning fork has proven its utility over time, little has been done to improve its design since being introduced into clinical medicine in the 19th century. Given this background, O'Brien Medical envisioned a 21st century version of this venerable instrument taking advantage of advances in modern electrical design techniques. Our four year research and development effort has culminated in the first medical-grade 128Hz electronic tuning fork, the ***ETF^{128}***. Further refinements and customer feedback has resulted in an enhanced version of the product, the ***ETF^{Mx}.*** This version of the product extends the capabilities of the base unit by providing two additional frequencies, 64 and 256 Hz.

The ***ETF*** recreates the amplitude, frequency and decay rate of the traditional tuning fork. This new electronic configuration provides a standardized output between users and patients. Additionally, the integrated timer now allows users to perform accurate timed vibration tests which have been shown to be a reliable method of assessing large fiber nerve function (1,2). Four additional output modes have been included for clinicians and researchers to use as desired.

1. **Output Modes**

- **64, 128, 256 Hz Descending**: This mode creates the same output as the traditional tuning fork. Vibrational output amplitude starts out high and tapers to zero over a 25 second period. In clinical use, patients will tell providers when they can no longer feel the vibrations. This point is known as vibration perception threshold (VPT) disappearance.
- **64, 128, 256 Hz Ascending**: Vibrational output amplitude in this mode is the reverse of the traditional tuning fork. Amplitude starts at zero and progresses to its highest point over a 25 second period. The point at which patients start to feel the vibrations is known as VPT appearance. It is possible that some patients may find it easier to identify when this point appears as opposed to VPT disappearance (3).
- **64, 128, 256 Hz Constant**: This mode provides constant vibrational output amplitude set to the equivalent of the 25v level in a traditional biothesiometer. This allows users to quickly assess patients for the presence or absence of neuropathy using this established reference standard (4). It should be noted that 9 seconds in the Descending and Ascending Modes is also equivalent the 25v biothesiometer output. Additionally, some users may prefer this mode for testing by the On-Off method (3).
- **128 Hz Fx Test:** This mode provides a constant maximum output of vibrations at 128Hz for as long as the user holds down the Run button. Users hold the contact tip on suspected fracture or stress fracture sites and see if a pain response is elicited. Traditional tuning forks have been used for this purpose to screen for potential fractures for many decades (5,6).
- **128 Hz Averaging**: This mode combines the descending and ascending modes into a two-step test. The user interface will take clinicians and patients through descending and ascending tests. The resulting "Vibroception Average" is then displayed. Some researchers suggest this averaging technique may be more representative of a patient's vibratory sensation than VPT appearance or disappearance alone. (7)

2. **Where does the Timed Vibration Test (TVT) Score come from? What does it mean?** The cutoff values were derived from a 2012 study done utilizing a proof-of-concept prototype ***ETF***. This study, which was published in the ***Journal of the American Podiatric Medical Association***, postulated cutoff values in seconds through correlation with 10 gm monofilament and biothesiometer testing (8). The score, although derived independently, is in approximate agreement with another researcher's suggestions for diabetic ulcer risk assessment using the TVT (9). The current scoring system is an initial attempt at providing clinicians with a semi-quantitative method of stratifying diabetic peripheral neuropathy. This system may be refined by further research.

3. **What type of nerve function is assessed by the *ETF*?**
   Vibration testing has traditionally been used for assessment of large fiber nerve function. Large fiber nerves are known to register vibration, light touch, and position sense. Damage to these nerves results in a general sense of numbness which can potentially lead to diabetic foot complications.
   The vibrations created by the ***ETF*** primarily stimulate Pacinian corpuscles which are most sensitive in the 60-400 Hz range. Periosteum, known to be rich in these receptors, makes boney prominences excellent sites for vibration testing. Meissner's corpuscles (20-50 Hz) and Merkel disk receptors (5-15 Hz) found mostly in the dermis are also stimulated to a lesser degree. Action potentials generated by these three mechanoreceptors are transmitted to the posterior column of the spinal cord through large and medium myelinated nerve afferents and then to the brain where they are perceived.
4. **What anatomic locations can be tested?**
   As with the traditional tuning fork, any body site can be tested. The first studies with the ***ETF*** have focused on vibration testing at the dorsal aspect of the hallux. This is the most commonly noted site for vibration testing in diabetic patients. Some researchers advocate testing the plantar aspect of the distal hallux (i.e. the pulp of the hallux). It is unclear if there is a diagnostically significant disparity between the two sites making this a potential area of future research.
   It should be noted that the current scoring system is derived from studies on the hallux. Other locations which may be more or less sensitive than the hallux will require further research to delineate site-specific scoring. For example, a recent study with the ***ETF*** revealed relative sensory sparing at the 5^{th} metatarsal head compared to the hallux in diabetic patients with neuropathy (10).
5. **Does age affect vibratory sensation? Does this affect the TVT Score?**
   Yes, there is an age-related decline in vibratory sensation. One study found that many otherwise healthy participants over 70 years of age had lost varying degrees of vibration sense (11). Although this "senescent neuropathy" may be common, it still represents a deficit. Given the importance of proprioception, this could make the ***ETF*** a particularly useful proxy test for assessing balance sense in geriatric patients. Future studies incorporating ***ETF*** testing as part of a fall risk assessment protocol are now being contemplated.
   Anecdotally, many healthy, non-diabetic patients over 70 years of age are scoring in the 7-9 second range. Further studies will be required to provide firmer guidance on this issue.

6. **How do I hold the unit against the patient's skin?**
   The ***ETF*** should be held perpendicularly to the skin during testing. Any off axis positioning may result in less than optimal vibration transmission.

7. **How do I change the batteries?**
   A small flat-head screw driver or finger nail can be used to detach the battery door on the back side of the unit. Three "AAA" batteries are required for operation. Replace batteries when the "Replace Battery" message displays. In order to provide a standardized vibratory output, the unit will stop functioning below a set power level. When the unit reaches this threshold, the batteries must be replaced to resume testing. The unit is expected to perform for 6-8 weeks with moderate use*.

8. **How do I clean the unit?** The unit may be wiped clean with isopropyl alcohol or with soapy water and a damp towel. It is recommended that the contact tip be wiped clean with alcohol before and after each patient use.

*Based on 280 patient tests in TVT 128Hz Descending mode (two individual test sites/patient) over the course of 8 weeks.

References

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