OBRIEN MEDICAL
DESIGN THROUGH EXPERIENCE

# ETF$^{Mx}$

# Instruction Manual


**Model: ETFMx-01-07/2017**
**Frequency Outputs: 64,128, 256 Hz**

# *ETF$^{Mx}$* Instruction Manual

**Introduction**
The ***ETF$^{Mx}$*** has been engineered to be an efficient, point-of-care neurological screening instrument. Basic clinical usage and maintenance are presented in this manual. Users will find more clinically-related information in the ***ETF$^{Mx}$ White Paper/FAQ*** found on our website.

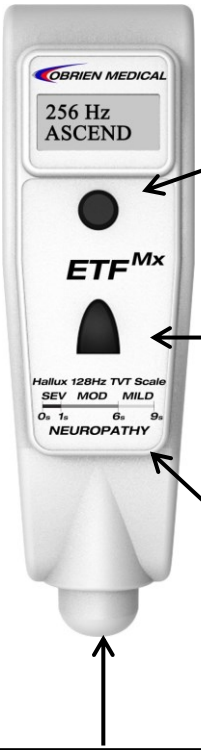
**Intended Use**
The ***ETF$^{Mx}$*** is used by professional healthcare providers to determine the status of vibratory sensation in humans.

**Contraindications**
There are no known contraindications to use of the ***ETF$^{Mx}$***.

**Cautions**

- Avoid immersion.
- Avoid dropping as impact may damage the vibration mechanism.
- Avoid using in temperatures below 60°F (15.5°C) as it may affect the frequency output.
- • WARNING : No modification of this equipment is allowed.
- • WARNING : Do not modify this equipment without authorization of the manufacturer.
- • WARNING : If this equipment is modified , appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

## Directions for Use




**Mode: Push to select mode.**

| | | |
|---|---|---|
| 64 Hz DESCEND | 128 Hz DESCEND | 256 Hz DESCEND |
| 64 Hz ASCEND | 128 Hz ASCEND | 256 Hz ASCEND |
| 64 Hz CONSTANT | 128 Hz CONSTANT | 256 Hz CONSTANT |
| | 128 Hz Fx Test | |
| | 128 Hz VIB AVG | |

**Run: Push to turn on ETF.**

- After a brief calibration period, current testing mode will display.
- Push and hold a second time to start vibration testing.
- Lift thumb to end test, time will display.
- Push to reset if performing sequential testing.

**Hallux Timed Vibration Test Scale (128 Hz Descending Mode only)**

- 6-9 seconds = Mild vibratory sensation deficit
- 1.1-5.9 seconds = Moderate vibratory sensation deficit
- 0-1 second = Severe vibratory sensation deficit

**Contact Tip**

**Clinical Protocol- Timed Vibration Test (TVT) 64, 128, 256 Hz Descending Mode**

1. Touch patient contact tip to the desired anatomical location.
2. Push the ***RUN*** button with thumb. The current output mode will display.
3. Push and hold the ***RUN*** button and ask patient to report when perceived vibrations fade out.
4. When patient indicates that vibrations have faded, lift thumb off the ***RUN*** button.
5. Elapsed time in seconds will display. If testing hallux, the reference scale on front of unit will provide status of vibratory sensation.

**Clinical Protocol- TVT 64, 128, 256 Hz Ascending Mode**

1. Touch patient contact tip to the desired anatomical location.
2. Push the ***RUN*** button with thumb. The current output mode will display.
3. Push and hold the ***RUN*** button and ask patient to report when perceived vibrations begin.
4. When patient indicates that vibrations have begun, lift thumb off the ***RUN*** button.
5. Elapsed time in seconds will display. If testing hallux, the reference scale on the front of unit will provide status of vibratory sensation.

**Clinical Protocol- TVT 64, 128, 256 Hz Constant Mode- for On/Off Testing Method**

1. Touch patient contact tip to the desired anatomical location.
2. Push the ***RUN*** button with thumb. The current output mode will display.
3. Push and hold the ***RUN*** button and ask patient to report if they perceive vibrations.
4. If patient perceives vibration, lift thumb off the ***RUN*** button. Ask patient if they still feel the vibrations.
5. These steps may be repeated to assess patient's ability to perceive vibrations at multiple locations.

**Clinical Protocol-128 Hz Fx Test Mode- fracture/stress fracture test**

1. Touch patient contact tip to the desired anatomical location while in Fx Test Mode.
2. Push and hold the ***RUN*** button and ask patient to report if they perceive increased pain.

**Clinical Protocol- TVT 128Hz Vibroception Averaging Mode**

**Step One**

1. Touch patient contact tip to the desired anatomical location.
2. Push the ***RUN*** button with thumb. The descending output mode will display.
3. Push and hold ***RUN*** button (**STEP ONE VIB AVG** will display) and ask patient to report when perceived vibrations fade out.
4. When patient indicates that vibrations have faded, lift thumb off the ***RUN*** button.

**Step Two**

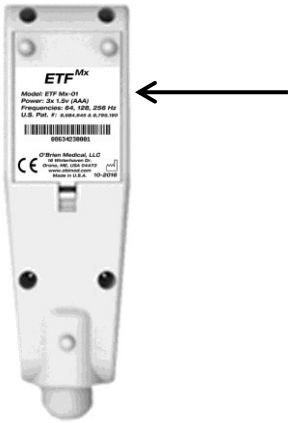
1. Maintaining the unit in the same location push and hold the ***RUN*** button (**STEP TWO VIB AVG** will display) and ask patient to report when perceived vibrations begin.
2. When patient indicates that vibrations have begun, lift thumb off the ***RUN*** button.
3. Average elapsed time in seconds will display. If testing the hallux, the reference scale on the front of the unit will provide status of vibratory sensation.

**Output Modes**

- **Timed Vibration Test (TVT) 64, 128, 256 Hz Descending**: This mode creates approximately 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. The timer counts up from 0 to 25 seconds in this test.
- **TVT 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 (1). The timer counts down from 25 to 0 seconds in this test.
- **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 (2). 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 to see if a pain response is elicited. Traditional tuning forks have been used for this purpose to screen for potential fractures for many decades.
- **TVT 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 (4).

**Maintenance and Care**

- 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.
- 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.
- Three "AAA" batteries are needed to run the unit. It is recommended that users obtain high-quality alkaline batteries. The unit is expected to perform for 6-8 weeks with moderate use*.
- Replace all used batteries in your device at the same time. Insert batteries properly, with the plus (+) and minus (–) terminals aligned correctly.
- Where possible, recycle your batteries where communities offer recycling or collection programs. You can contact your local government for information about the disposal options in your area.




**Battery Door**
Remove battery door to replace three "AAA" alkaline batteries.

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

**Risk Analysis**

**Ultrasound/Infrasound:** The ***ETF$^{Mx}$*** does not emit ultrasound or infrasound. The frequency emitted is 128 Hz.

**Fire Risk:** The components used in this device do not pose a fire risk.

**Software Error:** A "Replace Battery" message will display when the battery power is too low to run the unit. If this occurs, users should replace the three "AAA" batteries as noted above.

**Report Usability:** The ***ETF$^{Mx}$*** is used by professional healthcare providers to determine the status of vibratory sensation in humans. Normal operation presents low risk to patients. The ***ETF$^{Mx}$*** is intended for external use only. Internal use may result in injury.

Please recycle per European Community directive 2012/19/EU on waste electrical and electronic equipment.

**Environmental Requirements:**
Operation Temperature: 15.5°C - 40°C (60°F-104°F)
Storage temperature: -20°C - 55°C (-4°F-131°F)
Ambient Humidity: ≤80%, no condensation in operation
≤93%, no condensation in storage

**Declaration:** The materials which users can come into contact with are non-toxic and comply with ISO13485 standards.

**References**


1. Duke J, McEvoy M, Sibbritt D, Guest M, Smith W, Attia J. Vibrotactile threshold measurement for detecting peripheral neuropathy: defining variability and a normal range for clinical and research use. Diabetologia. 2007; 50: 2305-12.
2. Miranda-Palma B1, Sosenko JM, Bowker JH, Mizel MS, Boulton AJ.A comparison of the monofilament with other testing modalities for foot ulcer susceptibility. Diabetes Res Clin Pract. 2005 Oct;70(1):8-12.
3. Perkins BA, Olaleye D, Zinman B, Bril V. Simple screening tests for peripheral neuropathy in the diabetes clinic. Diabetes Care 2001; 24: 250-256.
4. Martin CL, Waberski BH, Pop-Busui R, Cleary PA, Catton S, Albers JW, Feldman EL, Herman WH. Vibration perception threshold as a measure of distal symmetrical peripheral neuropathy in type 1 diabetes: results from the DCCT/EDIC study. Diabetes Care 2010; 33: 2635-41.


# O'Brien Medical One-Year Limited Warranty

This O'Brien Medical product is warranted to be free from original defects in material and workmanship and to perform in accordance with O'Brien Medical's specifications under normal use. The warranty period begins from the date of purchase from the company or its authorized distributors and continues for a period of one (1) year from this date. The company's obligation is limited to the repair or replacement of components determined by the company to be defective within the warranty period. These warranties extend to the original purchaser and cannot be assigned or transferred to any third party. This warranty shall not apply to any damage or product failure determined by the company to have been caused by misuse, accident (including shipping damage), neglect, improper maintenance, modification, or repair by someone other than the company or one of its authorized service representatives.
These express warranties are in lieu of any and all other warranties, express or implied, including the warranties of merchantability and fitness for a particular purpose, and no other person has been authorized to assume for the company any other liability in connection

with the sale of the product. The company shall not be liable for any loss or damages, whether direct, incidental, or consequential, resulting from the breach of any express warranty, except as set forth herein.



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