Mechanical and Environmental Test Spec – 090414 Preliminary Draft

Description: EKG Dongle. Medical device used indoors and out, in all weather conditions; on emergency vehicles police, fire, medi-vac; medical treatment and care facilities; public spaces such as stadiums; public transportation buses, trains, aircraft. Can be used in working environments, offices, industrial and factory spaces; and private homes.

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| **Environmental** | | | | |
| Item | Test | Parameter | Standard(s) Not all standards that may apply have been identified | Duration of testing |
| 1 | Temperature, Operating | 0° to 50° C | EN 1789 | 4 hrs |
| 2 | Temperature, Non-operating | -40° to 70° C | EN 1789 | 1 week |
| 3 | Humidity, Non-condensing | 5 to 95% | AAMI EC11 | High humidity and temp exposure is required for some testing |
| 4 | Altitude Operating | -1253 to +15,000ft | AAMI EC11 | Must meet all operating requirements when in this range |
| 5 | Dust/Liquid Ingress | IP64  (category 2 for dust) | IEC standard 60529 | Unit must perform after exposure, in worst case of proper use and transport |
| **Mechanical** | | | | |
| 6 | Vibration, Operating | Category TBD | MIL-STD-810F (Ground vehicle) | Unit must be completely operational and undamaged |
| 7 | Vibration, Non-operating, transport of unit | Category 20, random vibration | MIL-STD-810F | Ground vehicles, air planes. Helicopters TBD |
| 8 | Shock | TBD |  |  |
| 9 | Drop | EN 1789 | 30” Drop on to all sides. 6 drops total Contact surface TBD (steel, concrete?) |  |
| 10 | Drop Tests Package Unit | ISTA Procedure 2A | Drop and Vibration |  |
| 11 | Mechanical Strength | EN/IEC 60601-1 | Inward force 10.26 lbs applied over 1 inch square area anywhere on the device | This requirement needs some review. Force may not be realistic for this product |
| 12 | Cleaning | AAMI TBD | Cleaned 15 times with the following chemicals:   1. Isopropyl alcohol 2. Hydrogen peroxide (3% solution) 3. Quaternary ammonium compound | Procedure TBD |