EKG Module Mechanical and Environmental Test Spec – 091814 Draft

Description/useage: EKG ~~Dongle~~ Module. 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)** | **Notes:**  “Functions normally” means unit performs all functions within specifications. |
| 1 | Temperature, Operating | 0°C (32°F) to 40° C (105°F) | EN 1789-2007 | Unit functions normally through-out temperature range |
| 2 | Storage temperature, non-operating, unpackaged | -30° (-22°F) to 70° C (158°F) | EN 1789-2007 | Unit functions normally after stabilization at 20°C for 30 minutes after removal from unpackaged storage temperatures. |
| 3 | Humidity, Non-condensing | 5%-95% | ~~AAMI EC11~~ | Unit functions normally during testing  The effects of temp/humidity |
| 4 | Altitude Operating | -1253 to +15,000ft | ~~AAMI EC11~~ | Unit functions normally during testing through-out the range |
| 5 | Dust/Liquid Ingress | IP64  (category 2 for dust) | IEC standard 60529 | Unit functions normally after testing |
| **Mechanical** | | | | |
| 6 | Vibration and shock Test | See section 6.4.1 of std. | EN1789-2007 | Unit functions normally during testing |
| 9 | Drop | 30” Drop on to all sides. 6 drops to concrete surface | EN 1789-2007 | Unit functions normally after testing |
| 10 | Drop Tests Package Unit | Drop and Vibration | ISTA Procedure 2A |  |
| 12 | Cleaning | Cleaned 15 times with the following   1. Isopropyl alcohol 2. Hydrogen peroxide (3% solution) 3. Quaternary ammonium compound |  | Procedure TBD |