Senior Design 2018/2019

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Technical Interface Standards 05/27/2019



- 1. Bluetooth: The Muscle Guide will be equipped with Bluetooth Low Energy (BLE) Connectivity compliant with Bluetooth 4.2. BLE is a low-power wireless standard defined by the Bluetooth Special Interest Group (SIG) for short-range communication. By using the PSOC6 BLE, the MCU utilizes BLE 4.2 radio and a protocol stack with enhance security, privacy, and throughput compliant with the BLE 5.0 specification. Most importantly, the PSOC 6 BLE incorporates Bluetooth Smart subsystem that implements the BLE link layer and physical later as specified in the Bluetooth specification 4.2, called the BLESS, a subsystem that supports all Bluetooth SIGG adopted BLE profiles and Bluetooth 4.2 compliant. The physical layer consists of a digital PHY and RF receiver compliant with the Bluetooth 4.2 specification. In the case of the Muscle Guide, the data will be received by the transmitter as a uint-8 and sent to the receiver as a unit-8.
- 2. FDA: The Food and Drug Administration (FDA) is a guidance association that the Muscle Guide abides with. A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. The Muscle Guide device is designed to be standard-compliant with the Food and Drug Administration's (FDA) 501(k) review process for marketing clearance.
- **3. Battery Safety:** The Muscle Guides' standard applies to battery operated appliances as such (UL2595). This compliance applies to devices comprising of detachable, integral and separable battery packs. These requirements address the safety of battery systems during storage and use including discharge and charge. These requirements are only considered to be supplementary requirements with respect to the risk of fire and electric shock in battery chargers (UL2595). Battery packs for appliances covered under this standard intended to be charged by a non-isolated charger are to be evaluated by this standard and the requirements for protection against electric shock of the end-product standard.
- 4. Water/Dust: It is imperative that the device is water resistant, as to the safety of the user and the longevity of the product itself. Our product will likely encounter vast amounts of water and sweat. Given that it will be used in the field repetitively, the device must not be altered by this magnitude of exposure. Because of this, the device is intended to be compliant with IEC IP56. Where the (Ingress Protection) rating 56 relates to how dust and waterproof we intend the product to be.