Guidance on Wireless Medical Devices

The FDA has issued a draft guidance to assist DTB and their customers with the development of radio-frequency (RF) wireless technology in medical devices. This guidance addresses issues related to the safe and effective use of RF technology in medical equipment. It emphasizes the need to address wireless coexistence, performance, data integrity, security, and electromagnetic compatibility (EMC).

Because these issues affect all stage of a product's life cycle, the FDA recommends that each of these issues be considered during the identification, documentation, and implementation of product design requirements as well as during design verification and validation and during risk management processes.

Essentially, the FDA believes that the more critical the medical device function and information passed via RF technology, the more important it is that the wireless connection be robust. To protect against electromagnetic interference to other medical devices, the FDA is recommending that wireless medical devices limit their RF output to the lowest power necessary to reliably accomplish their intended function.

FDA recommends that device manufacturers describe in their pre-market submissions and in their labeling the wireless technology and RF specifications, the testing performed, and the testing results demonstrating that the wireless functions will operate safely and effectively in the intended environment.

The guidance document notes that IEC 60601-1-2:2001, the EMC standard for medical equipment, is exempt from immunity provisions in the pass-band and therefore is currently inadequate to assess whether a wireless link will operate in the presence of in-band electromagnetic disturbance. For example, recent surveys have shown that perimeter surveillance equipment, electronic article surveillance systems, and RFID readers can generate magnetic fields in excess of the levels set in the existing non-medical and medical EMC standards.