Electromagnetic Compatibility (EMC)

Electromagnetic compatibility, or EMC means that a device is compatible with (i.e., no interference is caused by) its electromagnetic (EM) environment and it does not emit levels of EM energy that cause electromagnetic interference (EMI) in other devices in the vicinity. A medical device can be vulnerable to EMI if the levels of EM energy in its environment exceed the EM immunity (resistance) to which the device was designed and tested. The different forms of EM energy that can cause EMI are conducted, radiated, and electrostatic discharge (ESD). EMI problems with medical devices can be very complex, not only from the technical standpoint but also from the view of public health issues and solutions.

The Center for Devices and Radiological Health (CDRH) has regulatory authority over several thousand different kinds of medical devices, with thousands of manufacturers and variations of devices. Because of its concern for the public health and safety, the CDRH part of FDA has been in the vanguard of examining medical device EMI (electromagnetic interference) and providing solutions. Extensive laboratory testing by CDRH, and others, has revealed that many devices can be susceptible to problems caused by EMI. Indeed, CDRH has been investigating incidents of device EMI, and working on solutions (e.g. the 1979 draft EMC standard for medical devices), since the late 1960s, when there was concern for EMI with cardiac pacemakers.

Related Links

- Electromagnetic Compatibility (EMC) of Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices)
- Wireless Medical Devices (/wireless-medical-devices)
- Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff (/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff)
- Recommendations for EMC/EMI in Healthcare Facilities (/radiation-emitting-products/electromagnetic-compatibilityemc/fdacdrh-recommendations-emcemi-healthcare-facilities)
- Coordination with FCC (/medical-devices/digital-health-center-excellence/wireless-medical-devices)
- Electromagnetic Compatibility - Documents Available to Help Resolve Medical Device EMC Problems (http://wayback.archive-it.org/7993/20180725165316/https://www.fda.gov/RadiationEmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116592.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Electromagnetic Compatibility - EMC Working Group (/radiation-emitting-products/electromagnetic-compatibilityemc/electromagnetic-compatibility-emc-working-group)
- Medical Devices and EMI: The FDA Perspective (https://wayback.archive-it.org/7993/20171101212817/https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106367.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices - Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices)
- Labeling for Electronic Anti-Theft Systems - Guidance for Industry (/regulatory-information/search-fda-guidance-documents/labeling-electronic-anti-theft-systems)