Electromagnetic compatibility (EMC) and radio regulatory requirements for medical devices

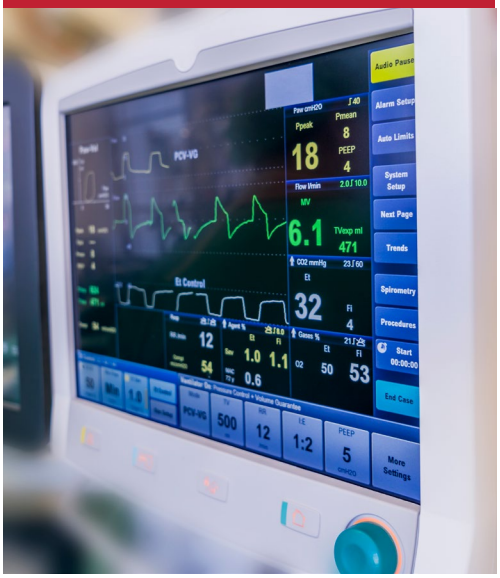
UL can help you to efficiently meet regulatory requirements for medical devices and increase global market access.

Summary

EMC, radio performance, radio frequency (RF) exposure and safety requirements are mandatory in most markets. For medical products, IEC 60601-1-2 fourth edition, has significant changes that impact both testing and risk management related to basic safety and essential performance. On Dec. 31, 2018, this standard became mandatory for new product submittals to the U.S. Food and Drug Administration and medical products entering the European Union. It is now required that risks resulting from reasonably foreseeable electromagnetic disturbance be taken into account in the risk management process and references ISO 14971, Medical Devices – Application of Risk Management to Medical Devices.

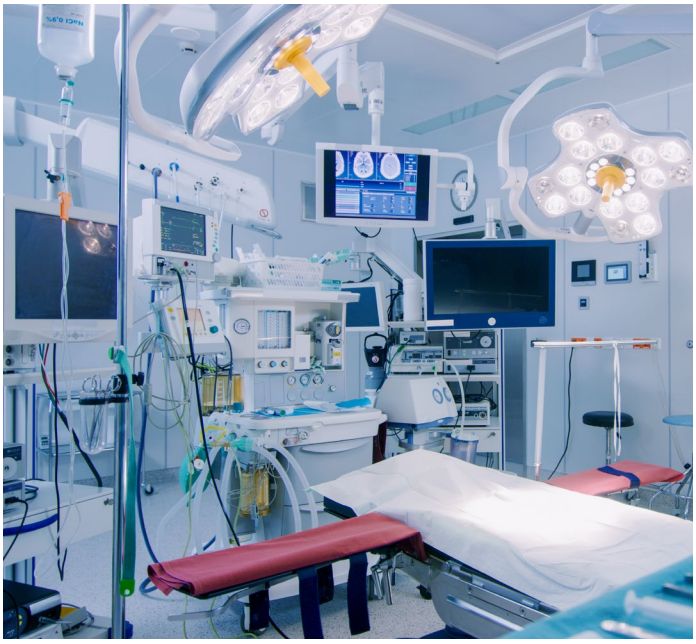
Around the globe, we help companies navigate market complexity and innovate with confidence. Whether you are interested in demonstrating compliance, managing transparency, evaluating a product for potential risks, or looking for a trusted adviser to create a certification strategy, we can help.

As a medical equipment manufacturer, are you prepared to demonstrate you have addressed the risk?



Full compliance testing to global EMC and wireless requirements

- EMC risk management evaluation to IEC 60601-1-2 fourth edition
- IECEE CB Scheme to IEC EMC and safety standards
- Pre-compliance services that include risk management, test plans, and instruction for use review as part of full IEC 60601-1-2 fourth edition projects
- EMC Pre-compliace testing services
- Technical assistance program – spend time with one of our experts
- Telecommunication Certification Body (TCB) for the U.S. Federal Communications Commission (FCC)
- Foreign Certification Body (FCB) for Canada
- Conformity assessment body (CAB) – Notified Body for the European Union for EMC Directive and RED Directive
- SAR (specific absorption rate) testing for human exposure to electromagnetic fields requirements
- Wireless Global Market Access (GMA) services



Meet the right standards, fast

A full suite of automated test platforms allows us to operate efficiently and price competitively, while reducing your time to market.

Knowledge of global standards and regulatory requirements

UL has helped to set more than 1,600 standards defining safety, security, quality and sustainability.

Total solution provider

By combining EMC and Wireless testing services with safety certification and our Global Market Access expertise, UL can guide you through every step of the compliance process.

To learn more about EMC, visit UL.com/services/electromagnetic-compatibility-emc-testing-medical-devices.

Empowering Trust®