## Medical Devices

RN Electronics offers comprehensive EMC testing of devices intended for the medical market.

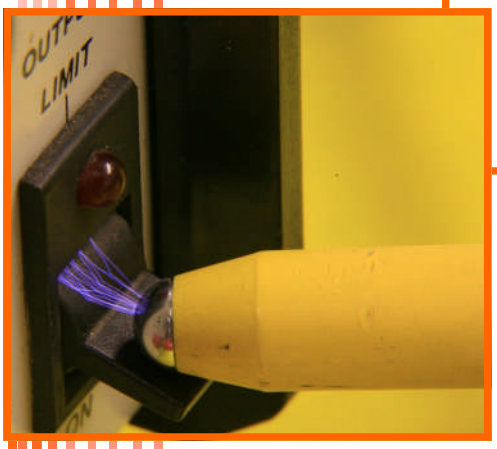
Electrical and electronic medical devices can be vulnerable to electromagnetic interference (EMI), if the levels of electromagnetic energy in its environment exceed the EM immunity (resistance) to which the device was designed. This can cause inconvenience, and even life threatening situations. For these high risk devices a more rigorous approach to EMC testing is required and RN Electronics is well equipped to perform such tests.

CE marking is a legal requirement for medical devices intended for sale in Europe, the directives that specifically apply to medical device manufacturers are:

- The Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC - applies to all active medical devices and related accessories intended to be permanently implanted in humans.
- The In-Vitro Diagnostic Medical Devices Directive (IVDMDD) 98/79/EEC - applies to all medical devices and kits used for examining substances taken away from the patient (in-vitro literally means in a test tube) to make a diagnosis of patient medical conditions.
- The Medical Devices Directive (MDD) 93/42/EEC - applies to all other medical devices

A 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.




RN Electronics can assist with the planning and execution of medical device testing, which is required to be integrated into the risk management process. We are a UKAS accredited testing laboratory no. 2360, incorporating the latest medical devices specifications (EN 60601-1-2 and EN 61326-2-6) called up by the European Union.

RN Electonics is also experienced in medical device testing for the US market. The US Food and Drug Administration (FDA) adopted the international version of 60601-1-2 from IEC edition 2.1, which means both sets of tests can be conducted simultaneously.

For further information contact RN Electronics, a professionally recognised laboratory with expertise in EMC and the risk based approach required for medical devices.

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