

IEC 60601-1-2 Medical Devices

Top 16 FAQs

1. What does the term "Essential Performance" mean?

It is quite literally referring to which functions of the product are considered essential. According to IEC 60601-1, performance of a certain function, other than non-essential SAFETY CRITICAL, where failure or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable level of hazard, then ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in unacceptable risk.

2. Does using either 2nd or 2nd edition would any device face risk? Are there any benefits to 2nd compared to 2nd?

The 2nd and 2nd editions required by both the 2nd and 2nd editions of IEC 60601-1-2 are the same. The changes included a revision and rewording of clauses in alignment with the 2000 edition of IEC 60601-1 and other IEC/ISO safety standards. The main change was in clause 4, where 2nd edition mandates that IEC 60601-1:2000 implements a risk management process.

For the reason, while the 2nd and 2nd editions are the same, the objective of the meeting and what is being considered may be different in a 2nd and 2nd edition test report. It can be shown that the 2nd edition testing covered all aspects of basic safety and essential performance described in the 2nd edition risk management file. Even the 2nd edition report can be used to prove compliance with the 2nd edition requirements on that topic. Actual device safety will vary from device to device and will depend on how robust the risk management file is in regards to EMC phenomena.

3. For devices approved in 2000 with 2000-1 do we have to test for item 3 in the 2000-1-2 PDA with other measures like in Europe? When would be the new 2 requirements at present for devices released in 2000?

Devices approved in the 2000-1-2 period by the transition date are grandfathered in until the manufacturer further testing to the updated requirements unless they are changed in a way which requires a follow up submission to the FDA. In Europe, devices placed on the market after the transition date must meet the new requirements. Currently the 2nd edition of the IEC 60601-1-2 applies in the EU until December 31, 2016. IEC 60601-1-2:2015 edition will be required.

4. For IEC 60601-1-2, are all EMC and 2nd or 2 applicable to all MDR or only MDR that includes a transmitter?

The IEC 60601-1-2 is generally tested from 100 wireless communications equipment test at clause 4.10 of IEC 60601-1-2:2015 edition applies to all devices, not just those which contain a transmitter.

5. Is the 2000 "new" method suitable to fulfill parts of immunity that may carry a change post marketing of the device? Like the 2000-1-2?

No, it is intended only to indicate (IC) some where the gaps have not been tested, when they cannot comply, the tested device being used occasionally. This does not mean removed from the 2nd edition of IEC 60601-1-2.

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Iec 60601 1 2 Medical Devices Intertek:

EDN, Electrical Design News ,1998 **Headquarters USA** ,2003 *Amendment 1 to ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment, Part 1: General Requirements for Safety. 2. Collateral Standard* American National Standards Institute, Association for the Advancement of Medical Instrumentation, 2004-01-01 **Medical Electrical Equipment - Part 1** ,2002 **Medical Electrical Equipment** Malaysia. Jabatan Standard, 2007 BS EN IEC 60601-2-64 AMD 1. Medical Electrical Equipment British Standards Institution, 2023 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ,2006 *Medical Electrical Equipment. Guidance and Interpretation. Considerations of Unaddressed Safety Aspects in the Third Edition of IEC 60601-1 and Proposals for New Requirements* British Standards Institute Staff, 1915-04-30 Medical equipment Electrical medical equipment Electrical equipment Electronic equipment and components Safety engineering Electrical safety Safety measures Defibrillators Medical instruments Cardiology Heart Monitors **Nederlandse Norm NEN-EN-IEC 60601-1:2006 en** ,2006 **BS EN IEC 60601-2-33. Medical Electrical Equipment** British Standards Institution, 2020 **BS EN IEC 60601-2-46. Medical Electrical Equipment** British Standards Institution, 2021 *Medical Electrical Equipment* South African Bureau of Standards, 2024 BS EN IEC 60601-2-83 AMD1. Medical Electrical Equipment British Standards Institution, 2021 **Medical Electrical Equipment - Part 1** ,2006 **Considerations of Unaddressed Safety Aspects in the 2nd Edition of Iec 60601-1 and Proposals for New Requirements** British Standards Institute Staff, 2003-09 Safety measures Electrical medical equipment Electrical safety Hazards Protected electrical equipment Radiation hazards Fire risks Electrical protection equipment Type testing Electrical testing Environmental testing Environment working Test equipment *Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design* ,2008 **BS EN IEC 60601-2-2 AMD1. Medical Electrical Equipment** British Standards Institution, 2021 Medical Electrical Equipment Part 2-11 ,2006 BS EN IEC 60601-2-93. Medical Electrical Equipment British Standards Institution, 2023 **Medical Electrical Equipment** Asociación Española de Normalización y Certificación, 2015

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