

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 critical function, other than non-related to EMC/RFI/EMF, where failure or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable risk. It is very clear, EMF/RFI/EMC is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

2. Does using either 2nd or 3rd edition standards always lead to better? Are there any benefits to 2nd compared to 3rd?

Two 2nd levels required by both the 2nd and 3rd editions of IEC 60601-1-2 are the same. The changes included a revision and strengthening of clauses in class B with the 2000 edition of IEC 60601-1, and other EMC/RFI/EMF testing requirements. The main change was in clause 4, where 2nd edition introduces the EMC/RFI/EMF risk management process.

For this reason, while the 2nd level and the same the objective of the testing and what is being measured may be different in a 2nd and 3rd edition test report. It can be shown that the 3rd edition testing covered all aspects of basic safety and essential performance specified in the 2nd edition risk management file, then the 2nd edition report can be used to show compliance with the 3rd edition requirements in that file. 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 keep for item 3 in the 2000-1 PDA until either (assumed) the 1st Europe? When would the 2nd or 3rd requirements at present for devices released in 2000?

Devices approved in the 1st stage by the transition clause are grandfathered in and do not require further testing to the updated requirements unless they are changed in a way which requires a follow-up evaluation by the FDA. In Europe, devices placed on the market after the transition date must meet the new requirements. Countries that 2nd edition of the 2000-1-2 is applied in the 2nd time December 31, 2010, IEC 60601-1-2 2nd edition will be required.

4. For IEC 60601-1-2, and all EMC and RFI or if applicable to all EMC or only EMC that facilities a transition?

The 2000-1-2 is currently listed from the wireless communications equipment test in clause 4.10 of IEC 60601-1-2 2nd edition applies to all devices, not just those which contain a transmitter.

5. Is the 2000-1-2 essential suitable to include parts of country that may carry a change point monitoring of the device? Is the 2000-1-2?

No, it is intended only to indicate the same where the parts have not been tested, when they cannot comply the tested device having been approved. This may be done removed from the 2nd edition of IEC 60601-1-2.

Iec 60601 1 2 Medical Devices Intertek

Raffaella Di Napoli



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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 *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 *BS EN IEC 60601-2-64 AMD 1. Medical Electrical Equipment* British Standards Institution, 2023 **BS EN IEC 60601-2-3 AMD2. Medical Electrical Equipment** British Standards Institution, 2021 **Medical Electrical Equipment** ,2015 BS EN IEC 60601-2-33. Medical Electrical Equipment British Standards Institution, 2020 *Nederlandse Norm NEN-EN-IEC 60601-1:2006 en* ,2006

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