

# 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 alignment 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 is not as obvious that the 3rd edition testing covered all aspects of basic safety and essential performance specified in the 2nd edition risk management file, that the 2nd edition report can be used to prove compliance with the 3rd edition requirements in that regard. Actual device safety will vary from device to device and will depend on how robust the risk management filing is relative to EMC phenomena.

**3. For devices approved in 2000 with 2000-1, do we have to keep for item 2 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 PDA. In Europe, devices placed on the market after the transition date must meet the new requirements. Countries that 2nd edition of the EMC/RFI/EMF 1-2 applies in the EU after December 31, 2016, 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 EMC/RFI/EMF is currently tested 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 "new" 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 IEC compliance. The parts have not been tested, which they would normally be tested due to being used accessories. This may have been removed from the 2nd edition of IEC 60601-1-2.

# Iec 60601 1 2 Medical Devices Intertek

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## **Table of Contents Iec 60601 1 2 Medical Devices Intertek**

1. Understanding the eBook Iec 60601 1 2 Medical Devices Intertek
  - The Rise of Digital Reading Iec 60601 1 2 Medical Devices Intertek
  - Advantages of eBooks Over Traditional Books
2. Identifying Iec 60601 1 2 Medical Devices Intertek
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Iec 60601 1 2 Medical Devices Intertek
  - User-Friendly Interface
4. Exploring eBook Recommendations from Iec 60601 1 2 Medical Devices Intertek
  - Personalized Recommendations
  - Iec 60601 1 2 Medical Devices Intertek User Reviews and Ratings
  - Iec 60601 1 2 Medical Devices Intertek and Bestseller Lists
5. Accessing Iec 60601 1 2 Medical Devices Intertek Free and Paid eBooks
  - Iec 60601 1 2 Medical Devices Intertek Public Domain eBooks
  - Iec 60601 1 2 Medical Devices Intertek eBook Subscription Services
  - Iec 60601 1 2 Medical Devices Intertek Budget-Friendly Options

6. Navigating Iec 60601 1 2 Medical Devices Intertek eBook Formats
  - ePub, PDF, MOBI, and More
  - Iec 60601 1 2 Medical Devices Intertek Compatibility with Devices
  - Iec 60601 1 2 Medical Devices Intertek Enhanced eBook Features
7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Iec 60601 1 2 Medical Devices Intertek
  - Highlighting and Note-Taking Iec 60601 1 2 Medical Devices Intertek
  - Interactive Elements Iec 60601 1 2 Medical Devices Intertek
8. Staying Engaged with Iec 60601 1 2 Medical Devices Intertek
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Iec 60601 1 2 Medical Devices Intertek
9. Balancing eBooks and Physical Books Iec 60601 1 2 Medical Devices Intertek
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Iec 60601 1 2 Medical Devices Intertek
10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
11. Cultivating a Reading Routine Iec 60601 1 2 Medical Devices Intertek
  - Setting Reading Goals Iec 60601 1 2 Medical Devices Intertek
  - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Iec 60601 1 2 Medical Devices Intertek
  - Fact-Checking eBook Content of Iec 60601 1 2 Medical Devices Intertek
  - Distinguishing Credible Sources
13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
  - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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