Transitioning to IEC 60601-1 Amendment 2

Understand what is required of your products so you can get compliant medical products to market

What is IEC 60601?

IEC 60601 is a widely accepted series of standards for the basic safety and essential performance of medical electrical equipment and systems. The growing complexity of medical devices requires more advanced testing and certification to evaluate compliance to safety and performance requirements, especially since noncompliant equipment can pose a significant risk to patients.

Regulatory bodies in key markets in U.S., Europe and Asia require medical devices comply to the standard before manufacturers can launch these products in their markets. And now, with the publication of IEC 60601-1 Amendment 2 in August 2020, navigating the requirements across different markets is even more complicated due to the varying regulatory transition periods worldwide.

What is changing?

While many of the updates to the base standard consist of corrections or clarifications to existing requirements, some of the updates require effort on the part of manufacturers to upgrade from the previous version. This includes updates to:

- Risk management standard: Amendment 2 refers to an updated version of risk management standard ISO 14971
- Collaterals aligned with Amendment 2 have significant changes:
  - IEC 60601-1-6
  - IEC 60601-1-8
  - IEC 60601-1-10
  - IEC 60601-1-11
- IEC 60601-1 base standard has many changes including:
  - Risk management standard ISO 14971:2019
  - Additional testing requirements for SIP/SOP connections
  - Use of connected equipment certified to IEC 62368-1

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What do manufacturers need to know?

To help avoid regulatory delays due to noncompliance to the updates, medical device manufacturers should seek advice from trusted third-party experts before trying to navigate Amendment 2 updates. They should fully understand what is required of their products, when the updates will be required in various markets around the world, as well as the different development and publication dates of particular standards and how they relate to the Amendment 2 base standard.

Pathways to certification and regulatory approval

To help launch their products without delay, medical device manufacturers should actively engage with a trusted third-party product certification body such as UL Solutions to help evaluate compliance with the most recent updates to the standards.

The cadence of publications of standards, followed by country or regional standards and then regulatory requirements are giving a clear picture of the urgency needed to transition to the updated standards. We have local experts in key markets around the world who are knowledgeable about the changes to the standard as well as regional deadlines and regulations.

The current edition of the applicable requirements used for CB Scheme includes U.S. and Canadian National Differences. The previous version of the standard did include country deviations for the U.K., Israel, Japan and South Korea. We anticipate that these national differences are forthcoming during the next several months.

Why choose UL Solutions?

Since the publication of the IEC versions of 60601-1 in late 2020, our main testing laboratories across the U.S., Europe and Asia have achieved Certified Body Testing Laboratory (CBTL) status, and national differences will be applied as soon as available and as needed by manufacturers.

Dedicated to healthcare industry innovation, UL Solutions leverages decades of technical, regulatory and market access expertise to help you manage regulatory challenges and bring compliant products to market. Our testing and compliance engineers participate on and work closely with standards committees to stay up to date on all the new amendments and upcoming changes. These committees include the American National Standards Institute (ANSI), the Association for the Advancement of Medical Instrumentation (AAMI) and the International Electrotechnical Commission (IEC). We also have many IECEE CB Scheme, NRTL and U.S. FDA ASCA-accredited testing laboratories across the U.S., Europe and Asia.

Do you have any IEC 60601 reports that need to be transferred over during this update?
Is your EMC up to date to the latest 60601-1-2 4.1?
Get in touch with our experts at www.UL.com/contact-us or visit us at www.UL.com/60601

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