



Add value.
Inspire trust.

IEC 60601-1 (Edition 3.1)

Make a smooth transition with
reduced cost and complexity.

Your challenges

With the publication of IEC 60601-1:2005 + A1:2012, otherwise known as IEC 60601-1 (Edition 3.1), medical device manufacturers must be aware of the varying regulatory transition periods worldwide. Some countries and regions are changing over to accept medical electrical equipment that complies with edition 3.1, while other markets will continue to recognise one of the previous editions, i.e. IEC 60601-1:1988+A1:1991+A2:1995 (Edition 2.2) or IEC 60601-1:2005 (Edition 3.0), for a limited time.

IEC 60601-1:2005 contains nearly 700 entirely new or more stringent requirements compared to the prior edition (Edition 2.2), and risk management has become a crucial requirement. Manufacturers must now estimate for each applicable risk, the probability of occurrence and the severity of that risk both before and after risk mitigation measures have been applied. This must be in conformance to ISO 14971 – Application of Risk Management to Medical Devices, and these estimates may be challenged at each approval level or destination

market. Taken together, all these requirements increase the complexity and associated costs of transition to the new edition.

What is IEC 60601-1 (Edition 3.1)?

IEC 60601 is a series of technical standards that ensure the safety of medical electrical equipment. IEC 60601-1 (Edition 3.1) deals with the basic safety and essential performance requirements of medical electrical equipment, and serves to ensure that no single electrical, mechanical or functional failure shall pose an unacceptable risk to patients and/or operators. Public health authorities in many countries recognise IEC 60601-1 (Edition 3.1) as a pre-requisite for the commercialisation of electrical medical equipment. IEC 60601-1 (Edition 3.1) is the newest published general standard with around 1500 single specific requirements. The requirements are often recognised as State-Of-The-Art (SOTA), and are required to be met in different markets around the globe.



Why is IEC 60601-1 (Edition 3.1) important for your business?

IEC 60601-1 (Edition 3.1) is a widely accepted standard in the U.S., Canada, the EU, Japan, Brazil, Russia and Australia. Some major import countries for such equipment have started to enforce the implementation of the third edition as early as January 2014. To avoid being denied entry into these and other markets, manufacturers should ensure that their products comply with both the second and third editions of the standard.

IEC 60601-1 (Edition 3.1) expertise from TÜV SÜD

Our experts actively participate in international advisory bodies and standardisation committees. This industry-leading expertise underpins the wide public awareness and first-class international reputation of the TÜV SÜD brand.

Our IEC 60601-1 (Edition 3.1) services

TÜV SÜD offers a full suite of testing and certification services for this standard that can be provided at our state-of-the-art facilities or on-site at your premises.

▪ Product testing

We operate some of the world's most sophisticated test laboratories, which are capable of testing products to various electromagnetic compatibility, environmental and electrical safety and performance standards.

▪ Certification

TÜV SÜD provides certification to safety standards and international standards (e.g. CB scheme and NRTL certification) to assist you in gaining market access for your products.

Your business benefits

- **Save time and money** – by ensuring your product is compliant to both editions in your first prototype, thereby avoiding costly delays in redesign.
- **Minimise risk** – with redesign development right from the beginning.
- **Benefit from global support** – with engineers in your local markets that speak your language and are capable of conducting tests and audits.
- **Work with a single-source partner** – that is an internationally recognised testing body with a strong presence in all major markets worldwide.

Why choose TÜV SÜD?

With over 400 dedicated medical health and services experts situated in major markets worldwide, TÜV SÜD is one of the largest Notified Bodies in the world and the only one to have its own clinical expert team. We also have a dedicated Regulatory Foreign Affairs & Clinical Department to monitor developments in regulations for medical health services and devices globally.

With the widest range of accreditations, we possess an in-depth understanding of international standards and the medical health services sector. In addition to regulatory and quality assurance expertise, TÜV SÜD's experts are also skilled in advanced medical device assessments for functional and software safety, especially related to essential performance.

Add value. Inspire trust.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certifications. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Assessments of clinical evaluations
- Expertise in high-risk medical devices
- Functional safety for medical devices – full product testing