IEC/EN 60601-1-2

IMPLICATIONS OF THE 4TH EDITION

Risk Management & Immunity Changes | Time to De - Risk

WHITE PAPER

Your industry, our focus

By: Dr Katie Hodges

E&E International Marketing Manager

Eurofins Consumer Product Testing

www.eurofins.com/ee

April 2018

IEC 60601-1-2:2014/EN 60601-1-2:2015 for Medical Electrical (ME) equipment (medical devices) is now in its 4th edition and supersedes EN 60601-1-2:2007. It is a major update with significant changes and therefore compliance implications. The transition period ends on 30th December 2018, at which point both new and existing products placed on the market will have to be compliant with the new version of the standard.

As EN 60601-1-2 is a collateral standard to the International Medical Safety Standard IEC/EN 60601-1, it has been adopted by many nations. As such, non-compliance removes the ability to place ME equipment on the market in a significant proportion of the globe, substantially reducing a manufacturer's potential return on investment (ROI).

Why the 4th edition?

EN 60601-1-2 defines the basic and essential performance for medical equipment with regard to Electromagnetic (EM) disturbances associated with electromagnetic compatibility (EMC) emissions and immunity which the equipment manufacturer needs to show compliance with. The 2015 version takes into account the changing EM environment and addresses the use of equipment outside of professional healthcare facilities; such as in the home, where there is both reduced control of the EM environment and increased contributors to the EM disturbances – both of which can adversely affect medical devices.

The 4th edition is also aligned with its general safety standard EN 60601-1's emphasis on risk management.

The changes between the 2007 and 2015 version of EN 60601-1-2 therefore have two underlying themes:

1. Increased risk management with the requirement for a Risk Management File (RMF).
2. Increased (more onerous) EM immunity requirements.

These themes are discussed in more detail below.

3rd Edition vs 4th edition overview

There are a number of changes in the 2015 version of EN 60601-1-2 compared to the 2007 version, some of which have far reaching compliance implications. Changes arising from a gap analysis include (but are not limited to):

- The standard's overall philosophy defines tests and limits according to risk and intended use instead of a device type.
- Tests are defined based on where the ME equipment (medical device) is intended to be used:
    1. In a "professional healthcare facility environment" where medical professionals are continually available (e.g. intensive care, dental offices)
    2. "Home healthcare environment" where medical professionals are not continually available
    3. "Special environment" such as; military, heavy industrial, and Medical treatment areas with high-powered medical equipment (e.g. short-wave therapy equipment).
- There are increased requirements for radiated immunity.
- More onerous immunity tests are imposed specifically to improve the safety of medical electrical equipment when portable RF communications are used closer than recommended.
- ME equipment is required to withstand higher levels of electrostatic discharge (ESD).
- When the loss of basic safety or essential performance of a ME equipment system could occur due to non-ME equipment being used in the intended electromagnetic environment, the non-ME equipment must be tested according to the requirements of the standard.
- A test plan is required to be submitted prior to testing as part of the new risk management requirements.
- Radio frequencies (Wifi, LTE, etc.) need to be considered based on the environment and using a risk management approach.

Increased risk management – RMF and test plan

There is an expanded, more rigorous risk management process in the 4th edition of EN 60601-1-2 with guidance in Annex F. The updated standard ensures that electromagnetic disturbances are considered in a manner appropriate to the present-day EM environments. It takes into account basic safety plus essential performance, including when there are special considerations of mitigations or intended use with regard to EM disturbances.

The 3rd edition of EN 60601-1-2 only *implies* that risk analysis and management should appropriately be considered prior to testing. The 4th edition however is much more prescriptive, ensuring that risk management forms a central part of the compliance process.

Example requirements include (but are not limited to):

- The manufacturer's ME equipment Risk Management File (RMF) needs to; show that the functions and essential performance of the equipment are known and understood; and provide a justification for the intended environment(s) chosen
- The RMF shall contain risk analyses, risk management and a test plan; all of which must be submitted to an accredited test laboratory *prior* to testing
- In the RMF, each known EMC phenomena needs to be considered for relevance to the device
- The test plan needs to include the method of monitoring, pass/fail criteria and specify any acceptable degradations in device immunity
- Any test level deviations must be documented and justified in detail in the RMF; a reduction in test levels is only allowed for a special environment
- Operating modes must be based on a risk analysis
- The risk management process needs to specifically show the consideration of a number of other factors including:
  - Minimum separation distances, especially where special environments and intentional RF (radio frequency) devices are involved
  - Whether subsystem testing is permitted
  - That reasonably foreseeable magnetic disturbances have been taken into account as defined in the standard.

EM immunity

A number of changes have been implemented regarding electromagnetic immunity in the 4th edition of EN 60601-1-2 compared to the 3rd, including the implementation of higher immunity levels, harmonisations and changes in procedures, e.g.:

- The range of testing for radiated immunity has been harmonized up to 2.7 GHz.
- Conducted immunity is performed at higher levels in ISM and/or amateur bands at 6V.
- Higher ESD levels are defined ±8 kV for contact and ±15 kV for air.
- Higher magnetic immunity testing is required at 30 A/m.
- A procedure to continue testing a product that has been damaged by an immunity test is defined.
- Immunity levels have been harmonized with IEC 60601-1-11; a collateral standard which refers to homecare as the intended location of use (the environment).
- Immunity to proximity fields from RF wireless communications equipment is required and has a minimum separation distance of 30 cm.

While the immunity level requirements are more onerous for all medical electrical equipment / medical devices, remember that the requirements now also differ based on the environment. For example in the 4th edition of IEC / EN 60601-1-2, the requirements for home healthcare are more stringent and more difficult to meet than those for the professional healthcare environment.

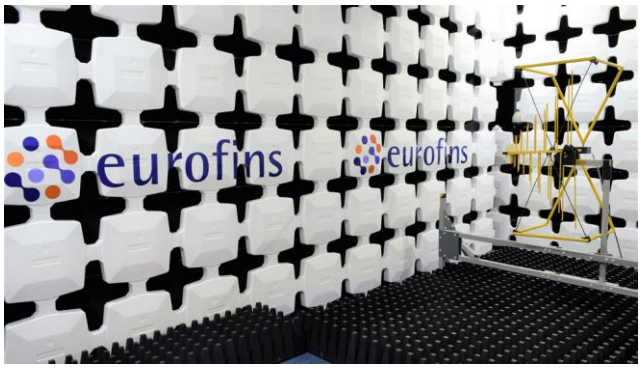
Summary

The latest, 4th edition of the collateral standard IEC / EN 60601-1-2 brings with it far-reaching changes to both the planning and implementation of the compliance process for Medical Electrical Equipment / Medical Devices.

The risk management approach adopted from the general safety standard EN 60601-1 requires the manufacturer's Risk Management File (RMF) to provide evidence that the device, its functionality, intended use and all operational environments are understood and accounted for. The RMF and its accompanying test plan have to be submitted to a Notified Body or accredited test facility *prior* to testing commencing; with defined pass/fail test criteria and any acceptable degradation of use for the intended environment(s).

Electromagnetic (EM) testing and test levels are more onerous than in the third edition of the standard including significantly elevated EM immunity requirements.

The new standard's transition period ends on 30th December 2018, by which time all medical electrical equipment being placed on the market must be compliant with the new edition; whether they were first placed on the market prior to that date or not.



At the time of writing, there is still time for manufacturers to make design changes and ensure compliance with the updated standard without the need to delay launching a product, or temporarily withdrawing one from the market.

Next steps

De-risk your product with pre- or full-compliance testing

At Eurofins, engineers from our Electrical and electronics (E&E) test laboratories are able to work with you to identify the appropriate standards for your medical electrical equipment and to guide you through the testing process, either through a pre-compliance process or full compliance assessment. We offer accredited testing of Medical Electrical Equipment (Medical Devices) for compliance with:

- **IEC / EN 60601-1** | General requirements for basic safety and essential performance.
- **IEC / EN 60601-1-2** | Collateral standard: electromagnetic disturbances (EMC) including both the 4th edition.

For manufacturers with products in development, our pre-compliance testing service can provide an early indication of their level of compliance and allows any necessary changes to be incorporated in a cost effective manner.

So, be ready for the increased test levels and obligatory risk-based management approach in the 4th Edition of IEC / EN 60601-1-2 when it comes into force in 2018. Contact your local Eurofins accredited laboratory where our experienced compliance engineers will be happy to guide you through the testing process.

Notified Body

We operate as a Notified Body (n. 0477) authorised to award EC certification of Medical Devices in accordance with Directive 93/42/EEC.

Need to know more?

Training and specialist advice is available on EMC, Electrical Safety, Radio Equipment and Electromagnetic Fields (EMF). We provide help on aspects of electrical and electronic product and project design as well as achieving and maintaining compliance with global certifications.

For more information visit our E&E website.

Contact your local Eurofins E&E Laboratory

Eurofins Consumer Product Testing Division has a global network of E&E test laboratories offering a wide range of testing and certifications to help you place your Medical Device products on the market in a fast and efficient manner.

Contact our experts at your local Eurofins E&E laboratory:

- E-mail: EE@Eurofins.com
- Send us with your enquiry
- Find your local representative.

eurofins

Your industry, our focus

eurofins | Consumer Product Testing

Your industry, our focus