

EN 60601-1-2:2001

Meanwhile a third edition of 60601-1-2 has been published as an IEC version dated quarter 3-2007. The new version is only an adaption to IEC 60601-1:3rd edition correcting failures.

This Med-Info is addressed to:

- manufacturers of medical electrical devices
- manufacturers of components for medical electrical devices

Background

Since June 1998, all medical electrical devices and/or systems must comply with Medical Device Directive (MDD) 93/42/EEC [1]. Regarding EMC, the protective goals of the directive are demonstrated through the application of the standard EN 60601-2-2. This standard was published in 1993. In the intervening years, the basic standards, i.e. the underlying conditions, have changed decisively. Therefore it became necessary to revise this standard.

The generic standard for electromagnetic compatibility was published in the EU Journal and went into force on 1 November 2004. This Med-Info from TÜV SÜD Product Service is designed to provide information on the standard and give you some tips and hints about how you can prepare for the requirements.

What is the new EMC standard called?

EN 60601-1-2:2001: Medical Electrical Equipment/Part: Medical Products 1–2/General Requirements for Safety
Supplementary Standard: Electromagnetic Compatibility – Requirements and Testing (IEC 60601-1-2:2001)

Which is the current status?

This standard is the second version of the supplementary standard to IEC/EN 60601-1. It went into force as a harmonized European standard on 1 November 2004, replacing IEC/EN 60601-1-2 in the version of 1993. From now on, compliance with the 1993 version does not fulfill the prerequisites for compliance with the requirements of the medical products directive for products marketed after 1 November 2004. All manufacturers of medical products should make a serious effort to bring their products into compliance with the 2001 version. As you all know, the use of a harmonized standard is one way to demonstrate compliance with the essential protective goals of a directive under the "New Approach". Nevertheless, the application of the standard remains a voluntary matter. As a manufacturer, for products marketed after 1 November 2004, you still have the option of demonstrating compliance with legal requirements in another manner. In this case, however, you must carefully observe the changes in the principles in the second version.

What steps are necessary for the changeover?

1. Variance analysis: analysis of the changes of the 2001 version.
2. Risk analysis: The second version permits the use of a risk analysis as basis for the essential features and safety of the medical electrical equipment.
3. Necessary testing: either as an upgrade or as a complete product test.

Which are the essential changes from the first to the second version?

Since the standard covers 105 pages, we cannot cover everything in detail. Here is an overview of the most important changes.

Selection of functions to be tested

The essential features of the devices must provide adequate immunity to electromagnetic interference. The electromagnetic environment of the hospital as described by the testing limits of EN 60601-1-2 is regarded as the normal condition, not as a serious fault situation. The manufacturer must determine or define the essential features. Cooperation between the testing lab and the manufacturer to prepare this summary and to provide monitoring during the tests is usually indispensable.

ESD under EN 61000-4-2	The testing limits have been adapted to Level 3 under EN 61000-4-1. This results in a final testing precision of 8 kV for air discharge, or 6 kV for contact discharge.
Interference immunity against radiated interference under EN 61000-4-3	The frequency range is 80 to 2,500 MHz. The field strength is 3 V/m. The modulation frequency has been defined as 1 kHz or 2 Hz, depending on the device. The testing precision for life-sustaining/supporting devices has been raised to 10 V/m.
BURST under EN 61000-4-4	The basic final testing precision is 2 kV. Data lines longer than 3 m must be tested at 1 kV. Patient cables are excluded.
SURGE under EN 61000-4-5	No changes in the testing precision (1 kV or 2 kV). The test must be conducted with five positive and five negative impulses, each at 0°, 90°, 180°, and 270°. For equipment without a suppressor circuit, it is not necessary to increase the testing precision.

Interference immunity to power-line-based interference under EN 61000-4-6	This test is new for the area of medical equipment, as are the next two tests. Patient cables are excluded. The testing precision is 3 Veff, or, for life-sustaining devices, 10 Veff for the ISM frequencies. The frequency range is 150 kHz to 80 MHz. The test uses AM modulation with 80 % and a modulation frequency of 1 kHz or 2 Hz.
Interference immunity against magnetic fields with power frequency under EN 61000-4-8	The device is exposed to a sustained magnetic field at 3 A/m. The test must be conducted at both 50 Hz and 60 Hz, with the exception that devices designed to work with only one of these frequencies have to be exclusively tested with that frequency.
Voltage dips, short interruptions, and voltage fluctuation/flicker under EN 61000-4-11	The devices are tested with an input power rating of up to 1 kVA. For non-life-sustaining devices with an input power rating of more than 1 kVA (with a nominal current of up to 16 A/phase), it is permissible to deviate from these requirements (compliance criteria) – provided the device remains safe, shows no component failure, and can be returned to the previous state by the user. These three criteria must also be assessed during a 5-second power interruption.

Changes in the requirements

In the area of protection against radio interference, EN 55011 in the most recently published version is still applicable. The requirements for measurement of radio noise voltage on the mains and for measurement of radio noise radiation have not changed compared to EN 60601-1-2:1993. A new aspect of the application area is the measurement of circuit feedback under EN 61000-3-2 (harmonic) and EN 61000-3-3 (flicker).

Interference immunity

In the area of interference immunity, basic adjustments to the standard series EN 61000-4-XX have been made. Some of the basic changes include:

Changes in compliance criteria

Paragraph 36.202.1j describes the compliance criteria as follows: The equipment or system shall be able to provide the essential performance and remain safe. This paragraph of the standard contains a list of impairments that are not allowed. They include component failure, changes in programmable parameters, change of operation mode, false alarm, etc.

Obligation of the manufacturer to inform the user

Paragraph 6.8.201 defines the information that manufacturers must include in the accompanying documentation for their equipment. In addition to any warnings, this includes in particular detailed tables on interference immunity and protection against radio emissions. The standard uses flow charts and examples to provide a detailed description of the information that must be included in these tables. The presentation or justification for the use of lower testing limits is another feature. They are permitted as long as they are based on physical, technological, and/or physiological limitations. Of course, this is allowed only if the deviations are noted and justified in the accompanying documents.

Which is the status outside Europe?

In the United States, the FDA has already replaced the first edition of 1993 with the 2001 version. However, the FDA takes into account that there are devices that are currently being tested under the old version or have been

developed under this 1993 version. For this reason, the FDA accepts declarations of compliance with either the first or the second version for the period from January 14, 2002 to November 30, 2004. After expiration of this transition period, the FDA will only accept declarations of compliance with the second version.

This new version is an international standard and is gradually being recognized by all countries.

Summary

The new, second version of EN 60601-1-2 has now replaced the "outmoded" first version as of 1 November 2004. The new, very extensive publication requires new interference immunity tests and expanded/elevated testing limits. Requirements for accompanying documents as well as the number of functions to be tested are specified. It has become necessary for manufacturers to work even more closely with the testing labs.

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