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Unit 4 - Pressure Equipment, Medical Devices, Metrology

MEDICAL DEVICES : Guidance document

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GUIDELINES RELATING TO THE APPLICATION OF :

THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES

THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

" EMC REQUIREMENTS "

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1. Background

The notified body group recognised the fact that different NB's chose different ways how to check for EMC essential requirements and identified the need for harmonisation of the ongoing practice. It therefore established a task force group which should collect data and work out a proposal for a commonly agreed practice. This group should not perform additional standardising work as it is already done by CENELEC committees but should try to find a solution which is based on the already existing standards.

In its meeting of April, 29-30, 1996 the notified body group agreed on this position paper.

2. Data Collection

With the aid of a questionnaire NB's were asked whether they already apply EN 60601-1-2 as a basis for testing against the essential requirements and how they handle those points of the standard that are not sufficiently specified yet. Until the NB meeting in April 1995, 12 NBs replied and until the beginning of July 1995 the task force group succeeded to get back in total 22 filled out questionnaires and decided to base its recommendations on that quorum. The first draft was discussed at the NB group meeting in September 1995; the comments received until February, 29th were considered in this 2nd revision of the position paper.

The results of the inquiry can be summarised as follows:

1. Almost every NB accepts EN 60601-1-2 as a basis for testing according to the essential requirements.

2. Due to some missing test procedures and limit values several specific clauses are handled quite differently by different NBs. Some of the requirements of the EN 60601-1-2 that are only mentioned by headings are seen quite differently.

3. There is a need for detailed classification rules of devices and for setting limits for various requirements.

3 Recommendations

Although EMC can become an important issue for electromagnetic devices, the discussion at the NB Group meetings so far showed that there is some tendency of overtesting this aspect. On the one hand, in fact, EMC testing cost already amount to 20 - 50 % of the overall testing cost of a medical electrical device. Already IEC 801-1/1984 concludes that asking for highest immunity levels irrespective the intended use and expected electromagnetic environment would lead to unjustifiable loads.

Having assessed and analysed the present practice the EMC task force group would like to make the following suggestions:

As a **basic standard** EN 60601-1-2 should be applied as harmonised standard for EMC aspects of the essential requirements. It is recognised that there is **still some missing information** which will hopefully be specified in the forthcoming 1st amendment to this standard. In the meanwhile to allow a common approach based on the already existing standards, the following recommendations are made:

I. Emission

Having in mind the increased use of medical electrical equipment the EMC task force group is aware of the need for electromagnetic emission tests in the high frequency range.

1. However, by now it **does not support emission tests in the low frequency range** due to the following reasons:

   a) In general extra low frequency field emitters do not cause safety problems. Requirements for some specific devices should be defined in product standards.

   b) There are no applicable standards available in this field yet.

   c) The majority of the NBA does not agree on the necessity of such tests.

2. Problems with voltage variations of the general power supply in hospitals increase with the increasing use of medical electrical device and might lead to safety-relevant impairment of the device performance. The EMC task force group identified that **there is a need for testing the potential to disturb the local power supply** within a hospital, however, mandatory tests, e.g. according to EN 60555-2, 3 should not be made before a harmonised requirement will be included into EN 60601-1-2. The EMC task force group does not agree with the rational of clause 36.201.2.1 because especially in a local power supply system disturbances caused by power consuming devices can occur more frequently compared with a public system and might affect the performance of live saving equipment.

II. Immunity

In general, the MDD's essential requirements address terms of safety and freedom of unacceptable risks. In particular, clause 9.2 and 12.5 refer to **risks** due to magnetic fields, external electric influences and electrostatic discharges rather than to any degradation of performance.

The EMC task force group feels it necessary to clarify the terms "function" and "safe fail" that are addressed in EN 60601-1-2, clause 36.202 where equipment under test is required either "to **fail** without creating a safety hazard" or "to perform its intended **function** as specified by the manufacturer".

In respect to the general requirements of the MDD which address safety-relevant aspects only to minimise risk to an acceptable level the following clarifications are proposed:

"**Function**" refers to safety-relevant aspects rather than to any kind of device performance. For example, this means that a slight distortion of a display could be accepted whereas changing of any kind of energy release could not be tolerated.

"**Fail safe**" means any kind of change in performance that makes it obvious to the user that the intended function is degraded if this does not pose hazard to the patient. This

may be either an interruption of operation or an audible and/or visible indication of interference.

As a general rule, the risk assessment should **include EMC risks** and the influence of the expected electromagnetic environment. However, it should be kept in mind that even within hospitals the electromagnetic environment can be quite different. Based on this analysis and the intended use, the manufacturer should

a) classify the equipment into class A or B according to EN 55011
b) design the interference properties of the equipment as

- **immune** to the applied test fields or
- **irrelevant changes** of device performance or
- **fail safe** in the sense as defined above

Although it is recommended that manufacturers should design their products in a way as to increase immunity as high as it is reasonably achievable the **necessity for mandatory immunity tests** should be made dependent on the **risk potential** of the medical products as it results from the risk analysis of the product.

As a general rule the EMC task force group recommends to consider immunity **tests** not being **mandatory** for **class I** devices which by definition do not pose inherent hazard to the patient. The manufacturer should be allowed to demonstrate compliance with the essential requirements by other means like drawing conclusions from the operation principle and the chosen design of his equipment.

In special cases risk analysis, however, may make it necessary even for some class I products to provide increased immunity performance as for instance electric wheelchairs that need to be operated safely under high tension lines with fields exceeding the limit values of the immunity requirements of EN 60601-1-2.

III. Application of EN 60601-1-2

Based on the results of the inquiry the EMC task force group recommends to apply the clauses of EN 60601-1-2 related to EMC testing as follows:

36.201.1 **Radio frequency emissions**
Classification according to EN 55011 into class A or B is made by the manufacturer, based on the intended use of the equipment and the fact, that even within hospitals there are areas of quite different electromagnetic environment. In general, equipment will be class A, equipment intended for home use, class B.

36.201.1.6 **High frequency surgical equipment**
Testing according to EN 55011, class A, group 2, operation condition of the device according to EN 60601-2-2.

36.201.2 **Low frequency emission**
No tests required (64 % of the NBs do not agree on the necessity of this test).

36.202.1 **Electrostatic discharge**

Testing as specified according to EN 61000-4-2 with 3 kV and 8 kV respectively. (The task force group is aware of that the standardising committee discusses an increase of the test voltage for contact discharges but has to await the decision.)

36.202.2 **Radiated radio frequency fields**
Testing according to EN 61000-4-3, level 2 (3 V/m)

36.202.3.1 **Bursts**
Testing as specified according to EN 61000-4-4. (There may be a change in test voltage level for plug-connected devices to 2 kV in the future.)

36.202.3.2 **Surges**
Testing as specified according to EN 61000-4-5

36.202.4 **Voltage dips, short interruptions and voltage variations on power supply input lines**
Testing according to EN 61000-4-11

36.202.5 **Conducted disturbances, induced by radio frequency fields**
Testing according to IEC 1000-4-6
(86 % of the NBs agree on the necessity of this test)

36.202.6 **Magnetic fields**
Testing according to EN 61000-4-8
(77 % of the NBs agree on the necessity of this test)

Although EN 60601-1-2 does indicate tests according to 36.202.4, 36.202.5 and 36.202.6 being still under consideration, the EMC task force group recommends to perform this tests due to the following reasons:

a) the overwhelming majority of NBs agreed on the necessity of the tests to demonstrate compliance with the essential requirements

b) there are already standards of the EN 61000 or IEC 1000 series available.