EUROPEAN CO-ORDINATION NB-MED NOTIFIED BODIES	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Recommendation** **NB-MED/2.2/Rec1**

Title:	**EMC requirements**
Chapter:	**2.2 Essential Requirements**

Text:	**„Design dossier“**
Key words:	**EMC, design dossier, essential requirements**

1. Background

EN 60601-1-2:1993 as a harmonised standard for EMC addresses requirements as "under consideration". In view of the essential requirements that medical devices have to account for the generally acknowledged state of the art. The Notified Bodies accepted to define a common position on this state of the art, taking into account already existing applicable standards rather than to develop new requirements even if only intermediate.

This Recommendation represents an updated version that takes into account the meanwhile testing experience and changes in standardisation.

2. Data Collection

According to the essential requirements

- "devices shall be designed in such a way as to remove or minimise as far as possible (MDD, Annex I, paragraph 9.2),

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 1-8	EN 55011, EN 61000-4-3, EN 61000-4-8
MDD	Annex: I-9.2, 12.5	EN 55011, EN 60601-1-2, EN 61000-3-2, EN 61000-3-3, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5, EN 61000-4-6, EN 61000-4-8, EN 61000-4-11
IVD	Annex: I-3-3	see MDD

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
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- "risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electric influences, electrostatic discharges ..." and
- "risks of reciprocal interference with other devices normally used in the investigations of for the treatment given"

and in particular

- "devices must be designed and manufactured in such a way as to minimise the risk of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment" (MDD, Annex I, paragraph 12.5).

It is accepted, that the essential requirement of electromagnetic compatibility comprises protection of other devices against electromagnetic ***emissions*** as well as ***immunity*** of the particular device against electromagnetic fields in the environment of the intended use to continue to perform satisfactorily.

3. Recommendations

As a basic standard EN 60601-1-2 should be used as a harmonised standard for EMC aspects of the essential requirements. It is recognised that there is still some missing information which needs common understanding among the Notified Bodies. Therefore the following recommendations are made:

3.1 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.

A) By now, it does not support emission tests in the low frequency range.

This is due to the following reasons:

a) In general extra low frequency field emitters do not cause safety problems. If needed, 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 Notified Bodies does not agree on the necessity of such tests.

B) There is a need for testing the potential to disturb the local power supply within a hospital, however, **mandatory tests should not be made** before a harmonised requirement will be included into EN 60601-1-2. However, it is **recommended** to perform the following tests:

a) **Harmonic distortions** according to EN 61000-3-2 for devices with rated input currents up to 16A.
b) **Voltage fluctuations according** to EN 61000-3-3.

This is due to the following reasons:

a) Both cited standards refer to equipment used at public supply systems. The use of the majority of medical electrical devices is not restricted to hospitals and may occur in rooms like those of physicians that are not independently supplied.
b) Problems with voltage variations of the general power supply in hospitals increase with the increased use of medical electrical devices and might lead to safety-relevant impairment of the device performance.

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 e. g. life saving equipment.

3.2 Immunity

In general, the MDD's essential requirements address terms of safety and freedom of unacceptable risks and to minimise risks connected with reasonable foreseeable (electromagnetic) environment.

This means on the one hand, that the conventional single fault approach to safety is not appropriate in EMC and that there is a need to define "satisfactory performance" in the light of the essential requirements.

EN 60601-1-2:1993, paragraph 36.2.2 defines electromagnetic immunity as under exposure continuing to perform its intended *function* as specified by the manufacturer or *fail without creating a safety hazard*.

The EMC task force group feels it necessary to clarify the terms "function" and "safe fail".

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. Degradations that shall not be allowed are:
component failures
- changes in programmable parameters
- reset to default settings
- change of operating mode
- false safety relevant alarms
- cessation on any intended medical function with relevance to the patient, even if accompanied by an alarm
- initiation of any unintended function with relevance to the patient, even if accompanied by an alarm
- initiation of unintended mechanical movement
- error of a displayed numerical value sufficiently large to affect diagnosis, therapy or treatment
- degradation of physiological signals that lead to relevant errors in their interpretation or detection.

"**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 a function and/or an audible or visible indication of interference.

For example, this means that an interruption of the operation of a nebulizer or the degradation of a ECG-recording or the indication of an interference situation by monitoring the ambient field level could be accepted. Interactions that shall not be allowed are the unjustified initiation of an alarm of patient monitors.

The Notified Bodies are aware that in the proximity of mobile communication devices such as emergency handsets or mobile telephones medical device performance **might be significantly degraded** even if the existing immunity requirements are met. If this might lead to hazards, **warnings** should be included in the instructions for use demanding that within a safety distance the use of such transmitters shall be prohibited.

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** those **class I** devices where risk analysis shows that they do not pose inherent hazard to the patient neither alone nor in connection with other devices and where compliance with the essential requirements can be demonstrated by other means like drawing conclusions from the operation principle and the chosen design of his equipment.

However, in special cases risk analysis may make it unavoidable even for some class I products to have their immunity performance tested as for instance electric wheelchairs that need to be operated safely within fields exceeding the common electromagnetic environment as for instance below power lines.

3.3 Application of EN 60601-1-2

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

36.201 **Radio frequency emissions**
Classification 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**, like life supporting equipment, equipment intended for home use, class **B**.
Products that use RF energy for internal purpose only are group 1, those that must emit RF energy to perform their intended function are group 2.

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

36.201.2 **Low frequency emission**
No tests required *(according to a vote of 64 % of the Notified Bodies)*.

36.202.1 **Electrostatic discharge**
Testing as specified according to EN 61000-4-2

36.202.2 **Radiated radio frequency fields**
Testing according to EN 61000-4-3

36.202.3.1 **Bursts**
Testing as specified according to EN 61000-4-4

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*) with modifications according to the draft 2nd edition of EN 60601-1-2 (IEC 62A7247/CD).

36.202.5 **Conducted disturbances induced by radio frequency fields**
Testing according to EN 61000-4-6*) with modifications according to the draft 2nd edition of EN 60601-1-2 (IEC 62A7247/CD).

36.202.6 **Magnetic fields**
Testing according to EN 61000-4-8*) with continuous fields and the nominal frequencies only.

*) The overwhelming majority of the Notified Bodies agreed on the necessity of the test to demonstrate compliance with the essential requirements.

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Title:	**EMC requirements**

Rev. 0: The Notified Body group NB-MED recognised the fact that different NB's choose 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.

Notified Body Meeting, Brussels, September 24 & 25, 1996:
The document was approved by the NB-MED plenary.
Confirmed at stage 3.
New revision no: 0

Medical Devices Expert Group Meeting, Brussels, February 9 & 10, 1998:
The stage 3 document was presented to the Medical Devices Experts Group and accepted without changes:
Confirmed at stage 4.

Rev. 1: Notified Body Meeting, Brussels, June 24 & 25, 1887:

It was reported on the rework done on the accepted NB-MED recommendation “EMC requirements“. The new revised Recommendation will reflect also the new draft EN 60101-1-2.

Notified Body Meeting, Brussels, March 3 & 4, 1998:

The task force on EMC reported that the accepted NB-MED recommendation is today still "harmonised" with the current revision of IEC 60601-1-2 (draft of 2nd edition was issued at the end of 1996). The subject on immunity, which was detailed explained and recommended by the NB-MED task force "EMC", will be taken on board now for further revision of the mentioned standard. The new draft standard contains - as a new exception criteria - that the device in presence of electromagnetic influences should maintain clinical utility (as proposed by NB-MED task force: clinical utility as relevant function/performance for the device). Prof. Leitgeb explained also that manufacturers have more freedom in terms that lower immunity levels as proposed by the draft standard could be accepted if there is a reason or justification for that. Prof. Leitgeb assured the NB-MED that the major subjects of the NB-MED recommendation are considered/covered in the new draft standard; in case of a finalised standard the NB-MED task force should ensure this standard is reflected in the NB-MED recommendation.

Notified Body Meeting, Brussels, November 3 & 4, 1998:

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Prof. Leitgeb reported that the existing Recommendation *NB-MED/2.2/Rec1 "EMC requirements"* (stage 4) is going to be revised in terms that e .g. the references to the standards will be updated. Also an enquiry will distributed to NB-MED asking what are the experience with this recommendation to consider these comments for revising. Hopefully on occasion at the next NB-MED meeting the revised document will be presented. The members of NB-MED were asked to send their comments for improving to the Technical Secretariat or directly to Prof. Leitgeb. Comments which were made by BfArM and COCIR will be considered.

Notified Body Meeting, Brussels, March 2 & 3, 1999:

In absence of Prof. Leitgeb Mrs. O'Connell pointed out to the tabled revised draft NB-MED Recommendation NB-MED/2.2/Rec1 on EMC (see NBM/55/99). Mr. Schmidt-Andersen mentioned that this revised document has been circulated among the members of the task force; but it was not so clear whether the made comments were considered or whether comments are still expected. The NB-MED agreed that further development on this particular Recommendation will be made within the task force together NBRG; all comments (especially made by BfArM) should be considered.

Notified Body Meeting, Brussels, June 8 & 9, 1999:

Prof. Leitgeb explained the made changes (new wording underlined in document NBM/55/99) in comparison with the existing Recommendation. Changes are: (i) new existing standards were implemented also with regard to the IVD-directive; (ii) definition of "function" was included, given by the new draft of EN 60601-1-2; (iii) EMC problems in the proximity of mobile communication devices becomes more and more interesting within hospitals; the existing standards do not protect from interference with these devices. Therefore warnings should be included in the instructions for use even if the EMC-standards are met; (iv) the given recommendation to consider immunity tests not being mandatory for class I was clarified by the new wording: "As a general rule the EMC task force group recommends to consider immunity tests not being mandatory those class I devices where risk analysis shows that they do not pose inherent hazard to the patient neither alone nor in connection with other devices and where compliance ..."; Prof. Leitgeb mentioned that the statement in this context given by the German BfArM was not adopted.
The NB-MED adopted the revised document with these presented changes.
Confirmed at stage 3 (although it was fully accepted – as a stage 4 document - at the Medical Devices Experts Group meeting on February '98 but shall be presented once again to this group)
New revision no: 1