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/Rec2**

Title:	**Treatment of computer used to program Active Implantable Medical Devices (AIMD)**
Chapter:	**2.2 Essential Requirements**

Text:	**„Computers used to program active implantable medical devices need special rules in regard to their status as medical device“**
Key words:	**Computers, programmes, AIMD´s**

Purpose of the document

Identify the cases where commercially available computers used to program Active Implantable Medical Devices should not be considered as medical devices.

Background

- **Active Implantable Medical Devices such as** implantable pulse generators (IPG) and implantable Defibrillators (ICD), implantable Neuro pulse generators, implantable drug administration devices and cochlear implants fall into the scope of the AIMD Directive 90/385/EEC.

- Equipment specifically designed to program these implanted AIMD's are accessories of AIMD's and therefore, they also fall into the scope of the above mentioned directive.

Commercially available computers are being used more and more as the programmer for IPG's.

The Guidelines on medical devices classification specify that "multi-application equipment which may be used in combination with medical devices are not a medical

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 2	
MDD		
IVD		

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VdTÜV
Technical Secretariat NB-MED
PO Box 10 38 34
D-45038 Essen

G. Hinrich Schaub (- 178)
Jörg Höppner (- 138)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: vdtuev.hoeppner@t-online.de

device unless its manufacturer places it on the market with specific intended purpose of a medical device".

Definitions

1. **Medical Devices (90/385/EEC)**

   Means any instrument, apparatus, appliance, material or other article, whether used alone or in combinations, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human being in the ..."

2. **Active Medical Device (90/385/EEC)**

   Means any medical device relying for its function on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3. **Active Implantable Medical Device (AIMD) (90/385/EEC)**

   Means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

4. **“Intended purpose" (EC Directive 93/42/EEC):**

   The intended use means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or promotional materials".

5. **Medical Electrical System (EN 60601-1-1)**

   Totality of more than one item of Medical Electrical Equipment or of Medical Electrical Equipment in combination with other non-medical electrical equipment that by coupling behaves as a unit with specified functions.

Title:	**Treatment of computer used to program Active Implantable Medical Devices (AIMD)**

Description of the system

The system allowing communication with the implantable parts of the AIMD is usually constituted as follows:

- a commercially available computer

- a wand or patient applied part (part of the system in contact with the patient from one side and connected to the computer on the other side. This part of the system may also include an interface module which, among other functions, provides electrical isolation between computer and patient applied part).

- Software used to program the implantable parts of the AIMD.

Handling of the system

Manufacturers have the freedom

- either to consider the system as a whole and to affix the CE marking on the whole system

  OR

- to consider each part of the system and to affix the ***relevant*** CE marking on each part of the system.
  Note*: A description or definition of several interfaces between the parts should be given.*

Regulatory Status of the computer

A. The computer is a medical device in the following cases:

- The computer bears the trade name of the AIMD manufacturer
- The original information provided with the computer has been replaced or modified
- Modifications have been made to the software or hardware of the computer, which have not been made according to the instructions provided by the manufacturer of the computer.

***Note**: For the purpose of this document it is understood that the insertion of a circuit board to an available slot is not considered as a modification of the software as long as the insertion is performed in accordance with the computers manufacturer's instructions for use.*

B. The computer ***as part of a Medical Electrical System*** is not a medical device in the following cases:

- The wand/applied part is connected to an existing port located usually on the back of the computer.

- The wand/applied part is connected to a dedicated circuit board to be inserted into an available slot accessible from the outside of the computer or located inside the computer.
  ***Note**: The board is inserted inside into the computer according to the instructions given by the computer manufacturer and/or the board manufacturer.*

Conformity assessment procedures when each part is considered separately

The manufacturer has to demonstrate that the Medical Electrical System satisfies the applicable requirements of the AIMD Directive,

- Wand/applied part: equipment which makes the link between the patient and the computer, dedicated programming software (program module, memory card or diskette) are AIMD's and should satisfy all applicable essential requirements of the AIMD directive and bear the CE marking.

- The computer if not considered as a medical device should comply with applicable national regulations and as of January 1st, 1996 may bear the CE marking of conformity with other directives (e. g. EMC, Low Voltage).

The applicable standards are EN 950 as well as the relevant EMC harmonized standards adopted by CENELEC and published in the Official Journal of the European Communities.

In this case the manual of the software for the wand/applied part dedicated for use with the computer must indicate either the characteristics of the computer required or

some types of equipment (trade name and model) available on the market with which it can be used. The computer in this case shall not bear the CE marking of conformity with the AIMD. The compatibility with other resident software should be ensured.

- In order to avoid possible confusion between the AIMD and the EMC directive, the manual of the computer shall indicate the directive applied.

- Irrespective of the fact the computer is considered as a medical device or not, the manufacturer shall demonstrate that the medical electrical system system (wand/applied part + computer) is safe for the patient and the user.

- The computer if considered as a medical device, falls into the scope of the AIMD directive and therefore shall meet all the applicable essential requirements and be subject to the appropriate conformity assessment procedure. The computer shall bear the CE marking of conformity conform the AIMD directive

NB-MED	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Rationale and history sheet to NB-MED/2.2/Rec2**

Title:	**Treatment of computer used to program Active Implantable Medical Devices (AIMD)**

Rev. 1: Notified Body Meeting, Brussels, January 19, 1995:
The document was approved by the NB-MED plenary.
Confirmed at stage 3.
New revision no: 1

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. 2: Notified Body Meeting, Brussels, November 3 &4, 1998:
BfArM has made some comments (see NBM/154/98) to the current stage 4 document. NB-MED agreed that further development on this particular Recommendation will be made within the **NBRG**; also other comments (e.g. made by COCIR) should be considered.

NBRG Meeting, Copenhagen, May 10 & 11, 1999:
A new draft document was presented by Mr. R.-H. The new draft bases on the results of a meeting with BfArM; the earlier controversial subjects were discussed and finally a common agreed document was drafted. The new document emphasizes the treatment of computers used to program active implantable medical devices; the scope of the document was now reduced with deleting the reference to MDD. Also the definition for “medical electrical system” was taken from IEC 601-1 and some other slight changes were made. NBRG made some further slight changes. The document will be provided to the Technical Secretariat by Mr. R.-H. NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1999.

Notified Body Meeting, Brussels, November 2 &3, 1999:
Mr. R.-H. reported that the current and valid/accepted stage 4 document (see NBM/123/99) has just been worked on but due to technical reasons the finalised text has not yet reached the Technical Secretariat. The draft document should be discussed on occasion of the NBRG meeting on November 3. To the next plenary meeting a revised document will be proposed.

NBRG Meeting, Brussels, November 3, 1999:
The tabled draft document was discussed. Due to the limited time the members of **NBRG** were asked to bring their comments to the Technical Secretariat until end of November. The finalised document should be discussed on the NBRG-meeting in March 2000.

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VdTÜV
Technical Secretariat NB-MED
PO Box 10 38 34
D-45038 Essen

G. Hinrich Schaub (- 178)
Jörg Höppner (- 138)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: vdtuev.hoeppner@t-online.de

Revision no: 2
Confirmed to be at Stage: 2

Rev. 3: NBRG Meeting, Cologne, February 3, 2000:
The tabled draft document (NBRG/153/00) was discussed. NBRG agreed that the document, as discussed and revised, should be presented for adoption at the February/March NB-MED Plenary meeting. Some words for clarification were added and also some editorial changes were made.
Revision no: 3
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, February 29 & March 1, 2000:
The document (NBM/36/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 3