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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

**TREATMENT OF COMPUTERS USED TO PROGRAM
IMPLANTABLE PULSE GENERATORS**

Purpose of the document

Identify the cases where commercially available computers should not be considered as medical devices.

Background

- Implantable pulse generators (IPG) and Defibrillators (ICD) 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. Therefore, they fall also into the scope of the above mentioned directive.

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

The Guidelines on medical classification specify that "multi-application equipment which may be used in combination with medical devices are not a medical device unless its manufacturer places it on the market with specific intended purpose of a medical device".

The definition of a medical device in the AIMD Directive is as follows:

"Medical device 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 ..."

Definition of "intended use" (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".

Definition 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 (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 wand).
- 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 CE marking on each part of the system.

Regulatory Status of the computer

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

- the computer bears the trade name of the IPG 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. These modifications 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 PCMCIA 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 is not a medical device in the following cases:

- The wand is connected to an existing port located usually on the back of the computer.
- The wand is connected to a dedicated circuit board to be inserted into an available PCMCIA slot accessible from the outside of the computer or located inside the computer.

The board is inserted 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.

- Wand, equipment which makes the link between the patient and the computer, dedicated programming software (program module, memory card or diskette) are AIMD's.

Therefore they must 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 must bear the CE marking of conformity with the EMC directive.

The applicable standards are IEC 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 of the wand 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 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 with the AIMD directive.
- Irrespective of the fact the computer is considered as a medical device or not, the manufacturer shall demonstrate that the system (wand + computer) is safe for the patient and the user.
- In order to avoid possible confusion between the AIMD and the EMC directive, the manual of the computer shall indicate the directive applied.

Conclusion

Unless the IPG/ICD manufacturer modifies its original intended purpose or affixes its trade name, commercially available computers shall not be considered as medical device. Therefore the computer shall not be subject to the requirements of the AIMD directive.